

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended: March 31, 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: 001-36278

Alliqua BioMedical, Inc.

(Exact name of registrant as specified in its charter)

Delaware

58-2349413

(State or other jurisdiction of incorporation or organization)

(I.R.S. Employer Identification Number)

1010 Stony Hill Road  
Yardley, PA

19067

(Address of principal executive office)

(Zip Code)

Registrant's telephone number, including area code: (215) 702-8550

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 Website, 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 or a smaller reporting company. See the 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 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 by Rule 12b-2 of the Exchange Act). Yes  No

As of May 2, 2017, the registrant had 45,975,994 shares of common stock outstanding.

ALLIQUA BIOMEDICAL, INC.

TABLE OF CONTENTS

**PART I – FINANCIAL INFORMATION**

ITEM 1.	<u>Financial Statements</u>	
	<u>Condensed Consolidated Balance Sheets as of March 31, 2017 and December 31, 2016</u>	3
	<u>Condensed Consolidated Statements of Operations for the Three Months Ended March 31, 2017 and 2016</u>	4
	<u>Condensed Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2017 and 2016</u>	5
	<u>Notes to Condensed Consolidated Financial Statements</u>	6
ITEM 2.	<u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	13
ITEM 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	18
ITEM 4.	<u>Controls and Procedures</u>	19

**PART II – OTHER INFORMATION**

ITEM 1.	<u>Legal Proceedings</u>	19
ITEM 1A.	<u>Risk Factors</u>	19
ITEM 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	32
ITEM 3.	<u>Defaults Upon Senior Securities</u>	33
ITEM 4.	<u>Mine Safety Disclosures</u>	33
ITEM 5.	<u>Other Information</u>	33
ITEM 6.	<u>Exhibits</u>	33

Signatures

**PART I – FINANCIAL INFORMATION**  
**ITEM 1. FINANCIAL STATEMENTS**

**ALLIQUA BIOMEDICAL, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
*(in thousands, except share and per share data)*

	<u>March 31,</u> <u>2017</u>	<u>December 31,</u> <u>2016</u>
	<u>(Unaudited)</u>	
<b>ASSETS:</b>		
Current Assets:		
Cash and cash equivalents	\$ 2,350	\$ 5,580
Accounts receivable, net	2,861	2,760
Inventory, net	2,631	2,702
Prepaid expenses and other current assets	451	735
Total current assets	<u>8,293</u>	<u>11,777</u>
Improvements and equipment, net	1,956	2,092
Intangible assets, net	27,290	28,498
Goodwill, net	11,959	11,959
Other assets	229	173
Total assets	<u>\$ 49,727</u>	<u>\$ 54,499</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 2,311	\$ 2,612
Accrued expenses and other current liabilities	4,672	5,286
Contingent consideration, current	-	675
Senior secured term loan, net	11,745	11,541
Warrant liability	672	20
Total current liabilities	<u>19,400</u>	<u>20,134</u>
Contingent consideration, long-term	500	1,141
Deferred tax liability	752	749
Other long-term liabilities	338	385
Total liabilities	<u>20,990</u>	<u>22,409</u>
Commitments and Contingencies		
Stockholders' Equity		
Preferred Stock, par value \$0.001 per share, 1,000,000 shares authorized, no shares issued and outstanding	-	-
Common Stock, par value \$0.001 per share, 95,000,000 shares authorized; 36,122,025 and 29,669,036 shares issued and outstanding as of March 31, 2017 and December 31, 2016, respectively	36	30
Additional paid-in capital	160,002	156,363
Accumulated deficit	(131,301)	(124,303)
Total stockholders' equity	<u>28,737</u>	<u>32,090</u>
Total liabilities and stockholders' equity	<u>\$ 49,727</u>	<u>\$ 54,499</u>

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

**ALLIQUA BIOMEDICAL, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(Unaudited)**  
*(in thousands, except share and per share data)*

	<b>Three Months Ended March 31,</b>	
	<b>2017</b>	<b>2016</b>
Revenue, net of returns, allowances and discounts	\$ 4,594	\$ 3,957
Cost of revenues	1,660	1,590
Gross profit	2,934	2,367
Operating expenses		
Selling, general and administrative	7,740	9,740
Royalties	185	217
Research and product development	111	199
Acquisition-related	635	-
Change in fair value of contingent consideration liability	35	362
Total operating expenses	8,706	10,518
Loss from operations	(5,772)	(8,151)
Other (expense) income		
Interest expense	(573)	(619)
Interest income	2	8
Change in fair value of warrant liability	118	737
Warrant modification expense	(770)	-
Total other (expense) income	(1,223)	126
Loss from continuing operations before tax	(6,995)	(8,025)
Income tax expense	(3)	(3)
Loss from continuing operations	(6,998)	(8,028)
Income from discontinued operations, net of tax of \$0 for the three months ended March 31, 2017 and 2016	-	346
Net loss	\$ (6,998)	\$ (7,682)
Net loss per basic and diluted common share:		
Loss from continuing operations	\$ (0.23)	\$ (0.29)
Income from discontinued operations	-	0.01
Net loss per basic and diluted common share	\$ (0.23)	\$ (0.28)
Weighted average shares used in computing basic and diluted net loss per common share	30,713,415	27,293,087

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

**ALLIQUA BIOMEDICAL, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(Unaudited)  
(in thousands)

	<b>Three Months Ended March 31,</b>	
	<b>2017</b>	<b>2016</b>
<b>Operating Activities</b>		
Net loss	\$ (6,998)	\$ (7,682)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,382	1,037
Amortization of deferred lease incentive	(11)	(8)
Deferred income tax expense	3	3
Provision for (recovery of) doubtful accounts	7	(80)
Reserve for note receivable	350	-
Provision for excess and slow moving inventory	23	-
Stock-based compensation expense	491	1,706
Deferred rent	2	-
Amortization of debt issuance and discount costs	204	198
Warrant modification expense	770	-
Change in fair value of warrant liability	(118)	(737)
Fair value adjustment of contingent consideration liability	35	362
Changes in operating assets and liabilities:		
Accounts receivable	(108)	91
Inventory	48	(398)
Prepaid expenses and other assets	227	(129)
Accounts payable	(301)	(285)
Accrued expenses and other current liabilities	(652)	(224)
<b>Net Cash Used in Operating Activities</b>	<b>(4,646)</b>	<b>(6,146)</b>
<b>Investing Activities</b>		
Purchase of improvements and equipment	(39)	(362)
Issuance of note	(350)	-
<b>Net Cash Used in Investing Activities</b>	<b>(389)</b>	<b>(362)</b>
<b>Financing Activities</b>		
Contingent purchase price payments	(675)	(2,573)
Net proceeds from issuance of common stock	2,534	-
Payment of withholding taxes related to stock-based employee compensation	(54)	-
<b>Net Cash Provided by (Used in) Financing Activities</b>	<b>1,805</b>	<b>(2,573)</b>
<b>Net Decrease in Cash and Cash Equivalents</b>	<b>(3,230)</b>	<b>(9,081)</b>
<b>Cash and Cash Equivalents - Beginning of period</b>	<b>5,580</b>	<b>26,080</b>
<b>Cash and Cash Equivalents - End of period</b>	<b>\$ 2,350</b>	<b>\$ 16,999</b>
<b>Supplemental Disclosure of Cash Flows Information</b>		
Cash paid during the period for:		
Interest	\$ 370	\$ 421
Non-cash investing and financing activities:		
2015 Accrued bonus awarded in equity	\$ -	\$ 474
Common stock issued for contingent purchase price payments	675	2,574

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

**ALLIQUA BIOMEDICAL, INC. AND SUBSIDIARIES**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**1. Description of Business and Basis of Presentation**

Alliqua BioMedical, Inc. (the “Company”) is a regenerative technologies company that commercializes differentiated regenerative medical products which assist the body in the repair of human tissue.

***Basis of Presentation***

The condensed consolidated financial statements contained in this report are unaudited. In the opinion of management, the condensed consolidated financial statements include all adjustments, which are of a normal recurring nature, necessary to present fairly the Company’s financial position as of March 31, 2017 and results of operations and cash flows for the three months ended March 31, 2017 and 2016. While management believes that the disclosures presented are adequate to make the information not misleading, these unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the notes thereto in the Company’s latest year-end financial statements, which are included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2016 (the “2016 Annual Report”). The results of the Company’s operations for any interim period are not necessarily indicative of the results of operations for any other interim period or for the full year.

***Principles of Consolidation***

The accompanying condensed consolidated financial statements include the financial statements of the Company and its wholly-owned subsidiary, AquaMed Technologies, Inc. All significant inter-company transactions and accounts have been eliminated in consolidation.

***Reclassifications***

Certain amounts in prior periods have been reclassified to conform to the current year presentation. Such reclassifications did not have a material effect on the Company’s financial condition or results of operations as previously reported.

***Discontinued Operations***

In order to add capital and to focus on future investments on commercializing its own regenerative technologies effective June 30, 2016, the Company entered into a purchase agreement with BSN medical, Inc. (“BSN”) whereby the Company agreed to sell to BSN all of the Company’s rights, including all distribution rights, exclusivity rights, intellectual property rights and marketing rights to the sorbion product line pursuant to its distribution agreement with Sorbion GmbH & Co KG. The results of operations for the three months ended March 31, 2016 reflect the Company’s continuing operations. Summarized operating results of discontinued operations for the three months ended March 31, 2016 are presented in the following table (in thousands):

	<u><u>March 31,</u></u> <u>2016</u>
Revenue, net of returns, allowances and discounts	\$ 686
Cost of revenues	<u>187</u>
Gross profit	499
Selling, general and administrative	<u>153</u>
Income from discontinued operations, net of tax	<u><u>\$ 346</u></u>

Non-cash amortization expense of \$19,000 is included in selling, general and administrative expense for the three months ended March 31, 2016.

There were no assets and liabilities or operating results of discontinued operations as of or for the three months ended March 31, 2017.

## ***Significant Accounting Policies and Estimates***

The Company's significant accounting policies are disclosed in Note 2 — *Summary of Significant Accounting Policies* in the 2016 Annual Report. Since the date of the 2016 Annual Report, there have been no material changes to the Company's significant accounting policies. The preparation of the condensed consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. These estimates and assumptions include valuing equity securities and derivative financial instruments issued in financing transactions, allowance for doubtful accounts, inventory reserves, deferred taxes and related valuation allowances, and the fair values of long lived assets, intangibles, goodwill and contingent consideration. Actual results could differ from the estimates.

## ***Recent Accounting Principles***

In May 2014, the FASB issued ASU 2014-09, "Revenue from Contracts with Customers (Topic 606)" ("ASU 2014-09"). ASU 2014-09 supersedes the revenue recognition requirements in ASC Topic 605, "Revenue Recognition" and some cost guidance included in ASC Subtopic 605-35, "Revenue Recognition - Construction-Type and Production-Type Contracts." The core principle of ASU 2014-09 is that revenue is recognized when the transfer of goods or services to customers occurs in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. ASU 2014-09 requires the disclosure of sufficient information to enable readers of the Company's financial statements to understand the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts. ASU 2014-09 also requires disclosure of information regarding significant judgments and changes in judgments, and assets recognized from costs incurred to obtain or fulfill a contract. ASU 2014-09 provides two methods of retrospective application. The first method would require the Company to apply ASU 2014-09 to each prior reporting period presented. The second method would require the Company to retrospectively apply ASU 2014-09 with the cumulative effect recognized at the date of initial application. ASU 2014-09 will be effective for the Company beginning in fiscal 2019 as a result of ASU 2015-14, "Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date," which was issued by the FASB in August 2015 and extended the original effective date by one year. The Company is currently evaluating the impact of adopting the available methodologies of ASU 2014-09 and 2015-14 upon its financial statements in future reporting periods. The Company has not yet selected a transition method. The Company is in the process of evaluating the new standard against its existing accounting policies, including the timing of revenue recognition, and its contracts with customers to determine the effect the guidance will have on its financial statements and what changes to systems and controls may be warranted.

There have been four new ASUs issued amending certain aspects of ASU 2014-09, ASU 2016-08, "Principal versus Agent Considerations (Reporting Revenue Gross Versus Net)," was issued in March 2016 to clarify certain aspects of the principal versus agent guidance in ASU 2014-09. In addition, ASU 2016-10, "Identifying Performance Obligations and Licensing," issued in April 2016, amends other sections of ASU 2014-09 including clarifying guidance related to identifying performance obligations and licensing implementation. ASU 2016-12, "Revenue from Contracts with Customers - Narrow Scope Improvements and Practical Expedients" provides amendments and practical expedients to the guidance in ASU 2014-09 in the areas of assessing collectability, presentation of sales taxes received from customers, noncash consideration, contract modification and clarification of using the full retrospective approach to adopt ASU 2014-09. Finally, ASU 2016-20, "Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers," was issued in December 2016, and provides elections regarding the disclosures required for remaining performance obligations in certain cases and also makes other technical corrections and improvements to the standard. With its evaluation of the impact of ASU 2014-09, the Company will also consider the impact on its financial statements related to the updated guidance provided by these four new ASUs.

## **2. Going Concern**

The Company's financial statements are prepared using accounting principles generally accepted in the United States of America applicable to a going concern that contemplates the realization of assets and liquidation of liabilities in the normal course of business.

As of March 31, 2017, the Company had a cash balance of approximately \$2.4 million. On April, 3, 2017, the Company closed an underwritten public offering. Total gross proceeds to the Company were approximately \$3.8 million before deducting underwriting and estimated offering expenses. The Company has experienced recurring losses since its inception. The Company incurred a net loss of \$7.0 million and utilized \$4.6 million in cash from operations for the three months ended March 31, 2017, and had an accumulated deficit of \$131.3 million as of March 31, 2017. As of March 31, 2017, the Company was in default of a covenant pertaining to trailing twelve-month revenue under the Credit Agreement (as defined in *Note 7- Debt*) as a result of the Company's failure to achieve \$22,250,000, \$24,600,000 and \$27,200,000 of gross revenue for the twelve-month periods ended September 30, 2016, December 31, 2016 and March 31, 2017, respectively. Under an agreement dated January 26, 2017, as amended on March 7, 2017 and April 27, 2017, the lender agreed to forbear from exercising any rights and remedies related to the default until the earlier of June 30, 2017 or the date when the lender becomes aware of any other default. The lender reserved the rights, commencing with the occurrence of any of these events, to pursue any rights and remedies available to it, including, but not limited to, declaring all or any portion of the outstanding principal amount to be immediately due and payable, imposing a default rate of interest as specified in the Credit Agreement, or pursuing the lender's rights and remedies as a secured party under the UCC as a secured lender. In addition, the lender has a lien on substantially all of the Company's assets and, as a result of the default, may seek to foreclose on some or substantially all of the Company's assets after the expiration of the forbearance. Such action could hinder the Company's ability to recover the remaining carrying value of some or all of its intangible assets including goodwill that aggregated approximately \$39.2 million at March 31, 2017. These factors raise substantial doubt as to the Company's ability to continue as a going concern within one year from the date of this filing. The ability of the Company to continue as a going concern is dependent upon the Company's successful efforts to raise sufficient capital and attain profitable operations.

Management is evaluating all options to raise sufficient funds to meet its outstanding debt obligations and to fund the Company's working capital requirements. There can be no assurances, however, that management will be able to obtain sufficient additional funds when needed, or that such funds, if available, will be obtained on terms satisfactory to the Company. There is no assurance that the Company will be successful in achieving profitable operations. The condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded assets and liabilities that might be necessary should the Company be unable to continue as a going concern.

### 3. Net Loss Per Common Share

Basic loss per share data for each period presented is computed using the weighted-average number of shares of common stock outstanding during each such period. Diluted income (loss) per share data is computed using the weighted-average number of common and dilutive common-equivalent shares outstanding during each period. Dilutive common-equivalent shares consist of: (a) shares that would be issued upon the exercise of stock options and warrants, computed using the treasury stock method; and (b) shares of non-vested restricted stock.

The following securities are excluded from the calculation of weighted average dilutive common shares because their inclusion would have been anti-dilutive:

	<u>As of March 31,</u>	
	<u>2017</u>	<u>2016</u>
Stock options	7,073,282	7,198,456
Warrants	4,541,121	3,365,407
Non-vested restricted stock	826,668	816,287
Total	<u>12,441,071</u>	<u>11,380,150</u>

### 4. Termination of Merger Agreement

On October 5, 2016, the Company entered into a merger agreement to acquire the business of Soluble Systems, LLC ("Soluble") through a series of transactions. On February 27, 2017, the Company terminated this agreement, due to its inability to secure the requisite financing to meet the closing conditions of the merger agreement.

In connection with the merger agreement to acquire the business of Soluble, the Company provided Soluble with bridge loans in the form of subordinated promissory notes totaling approximately \$1.4 million. The Company advanced Soluble \$1.0 million during the year ended December 31, 2016 and \$350,000 on January 30, 2017. Pursuant to the terms of the merger agreement, the amount is to be repaid in full upon termination of the agreement. The Company believes that the collectability of the amount due from Soluble is in doubt and, therefore, has fully reserved the amount due as of March 31, 2017. As of December 31, 2016, the Company had provided for a full reserve for the amount that had been advanced to Soluble as of that date. During the three months ended March 31, 2017, the Company recorded bad debt expense of \$350,000. This expense is included in acquisition related expense. The Company also incurred approximately \$285,000 of other acquisition related expenses related to the Soluble transaction during the three months ended March 31, 2017. The net balance of the note receivable is \$0 and is included in prepaid and other current assets as of March 31, 2017 and December 31, 2016.

### 5. Inventory

Inventory consists of the following (dollars in thousands):

	<u>March 31,</u>		<u>December 31,</u>	
	<u>2017</u>		<u>2016</u>	
Raw materials	\$	148	\$	135
Work in process		139		173
Finished goods		2,367		2,394
Less: Inventory reserve for excess and slow moving inventory		(23)		-
Total	<u>\$</u>	<u>2,631</u>	<u>\$</u>	<u>2,702</u>



## 6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following (in thousands):

	<u>March 31,</u> <u>2017</u>	<u>December 31,</u> <u>2016</u>
Salaries, benefits and incentive compensation	\$ 2,534	\$ 3,070
Milestone payment to licensor	1,000	1,000
Professional fees	564	692
Royalty fees	185	197
Deferred revenue	175	181
Other	214	146
Total accrued expenses and other current liabilities	<u>\$ 4,672</u>	<u>\$ 5,286</u>

## 7. Debt

### *Senior Secured Term Loan Facility*

On May 29, 2015, the Company entered into a Credit Agreement and Guaranty (the "Credit Agreement") with Perceptive Credit Opportunities Fund, L.P. ("Perceptive"). The Credit Agreement provided a senior secured term loan in a single borrowing to the Company in the principal amount of \$15.5 million. The Credit Agreement (i) has a four-year term, (ii) accrues interest at an annual rate equal to the greater of (a) one-month LIBOR or 1% plus (b) 9.75%, (iii) is interest only for the first 24 months, followed by monthly amortization payments of \$225,000, with the remaining unpaid balance due on the maturity date and (iv) is secured by a first priority lien on substantially all of the Company's assets. The Company is required to pay an exit fee when the term loan is paid in full equal to the greater of 2% of the outstanding principal balance immediately prior to the final payment or \$200,000, which was amended in conjunction with the extinguishment of debt described below from the greater of 1% of the outstanding principal balance immediately prior to the final payment or \$100,000. The interest rate at March 31, 2017 was 10.75%.

In connection with the Credit Agreement, the Company incurred approximately \$1.3 million of debt issuance costs. The debt issuance costs are being amortized over the term of the loan on a straight-line basis, which approximates the effective interest method. During the three months ended March 31, 2017 and 2016, the Company recorded amortization of debt issuance costs of \$64,000 and \$72,000 respectively, which is included in interest expense for the periods presented.

In connection with the entry into the Credit Agreement, a five-year warrant (the "Warrant") to purchase 750,000 shares of common stock, par value of \$0.001 per share at an exercise price of \$5.5138 per share (the "Exercise Price") was issued to Perceptive. The Company granted Perceptive customary demand and piggy-back registration rights with respect to the shares of common stock issuable upon exercise of the Warrant. The warrant contains a weighted average anti-dilution feature whereby the Exercise Price is subject to reduction if the Company issues shares of common stock (or securities convertible into common stock) in the future at a price below the current Exercise Price. As a result, the warrant was determined to be a derivative liability. The warrant had an issuance date fair value of approximately \$2.7 million which was recorded as a debt discount. During the three months ended March 31, 2017 and 2016, the Company recorded amortization of debt discount of \$140,000 and \$126,000, respectively, which is included in interest expense for the periods presented. See Note 11 – *Fair Value Measurement* for additional details.

As of March 31, 2017, the Company was in default of a covenant pertaining to trailing twelve-month revenue under the Credit Agreement as a result of the Company's failure to achieve \$22,250,000, \$24,600,000 and \$27,200,000 of gross revenue for the twelve-month periods ended September 30, 2016, December 31, 2016 and March 31, 2017, respectively. Under an agreement dated January 26, 2017, as amended March 7, 2017 and April 27, 2017, the lender agreed to forbear from exercising any rights and remedies related to the default until the earlier of June 30, 2017 or the date when the lender becomes aware of any other default. The lender reserved the rights, commencing with the occurrence of any of these events, to pursue any rights and remedies available to it, including, but not limited to, declaring all or any portion of the outstanding principal amount to be immediately due and payable, imposing a default rate of interest as specified in the credit agreement, or pursuing the lender's rights and remedies as a secured party under the UCC as a secured lender. In addition, the lender has a lien on substantially all of the Company's assets and, as a result of the default, may seek to foreclose on some or substantially all of the Company's assets after the expiration of the forbearance. The Company has classified the entire principal balance of approximately \$13.8 million as a current liability in its balance sheet as of March 31, 2017.

In connection with the entry into the January 26, 2017 forbearance agreement, as amended on March 7, 2017, the Company also amended and restated the warrant issued to Perceptive in connection with the closing of the Credit Agreement on May 29, 2015. The amended and restated warrant is exercisable for 2,000,000 shares of the Company's common stock. The amended and restated warrant is exercisable at an exercise price of \$0.50. The amended and restated warrant contains a weighted average anti-dilution feature whereby the exercise price of the amended and restated warrant is subject to reduction if the Company issues shares of common stock (or securities convertible into common stock) in the future at a price below the current exercise price of such warrant. See Note 11 – *Fair Value Measurement* for additional details.

Debt consists of the following (in thousands):

	<u>March 31,</u> <u>2017</u>	<u>December 31,</u> <u>2016</u>
Long-term debt	\$ 13,752	\$ 13,752
Unamortized debt issuance and discount costs	(2,007)	(2,211)
<b>Total</b>	<u>\$ 11,745</u>	<u>\$ 11,541</u>

## 8. Commitments and Contingencies

### *Agreements for Human Placental Based Products*

#### **Human Longevity, Inc.**

In November 2013, the Company entered into a License, Marketing and Development Agreement (the “License Agreement”) and Supply Agreement (the “Biovance Supply Agreement”) with Celgene Cellular Therapeutics (“CCT”), an affiliate of Celgene Corporation (“Celgene”). The agreements grant the Company an exclusive, royalty-bearing license in CCT’s intellectual property for certain placental based products, including ECM and Biovance®, as well as provide the Company with the its requirements of Biovance for distribution. In January 2016, Human Longevity, Inc.’s (“HLI”), a genomics-based, technology-driven company, announced the purchase of LifebankUSA and other select assets from CCT. CCT assigned and HLI assumed the license and supply agreements the Company entered into with CCT, for certain placental based products. The Company is required to pay HLI annual license fees, designated amounts when certain milestone events occur and royalties on all sales of licensed products, with such amounts being variable and contingent on various factors. During the three months ended March 31, 2017 and 2016, the Company incurred royalties of approximately \$185,000 and \$67,000, respectively, in connection with this agreement. Approximately \$185,000 is included in accrued expenses as of March 31, 2017 in connection with this agreement. The initial term of the License Agreement ends on November 14, 2023, unless sooner terminated pursuant to the termination rights under the License Agreement, and will extend for additional two-year terms unless either party gives written notice within a specified period prior to the end of a term.

The License Agreement with HLI is terminable on a product-by-product basis if the Company fails to meet certain minimum sales thresholds in the second year or any subsequent year of commercial sales of each licensed product. Each year of commercial sales are referred to in the License Agreement as “launch years” and the calendar period constituting each launch year for each licensed product is determined in accordance with the terms of the License Agreement. To maintain its license for Biovance, the Company must meet a minimum gross sales amount for Biovance in the second year and third year of commercial sales. If the Company fails to meet the minimum threshold in the second year of commercial sales of product, it would be able to cure such failure by making a cure payment specified in the License Agreement to HLI; provided, however, the Company does not have the option to make a cure payment, should it fail to meet the minimum threshold for such product in the third year of commercial sales and HLI may terminate the License Agreement with respect to such product.

In September 2014, the Company entered into a First Amendment to the License Agreement (the “Amended License Agreement”), pursuant to which the Company received the right to market Biovance for podiatric and orthopedic applications. The Amended License Agreement also amends certain terms and the related schedule for milestone payments to CCT. In May 2015, the Company amended its exclusive licensing agreement with CCT, which granted the Company the right to develop and market CCT’s connective tissue matrix product, also known as Interfyl.

In April 2016, the Company entered into a Supply Agreement with HLI, pursuant to which HLI supplies the Company with the Company’s entire requirement of Interfyl™ Human Connective Tissue Matrix. Additionally, the Company agreed to make certain future milestone payments upon the achievement of certain milestones. The Company initiated sales and marketing efforts of Interfyl™ Human Connective Tissue Matrix in September 2016 and achieved two milestones under the license agreement. The Company is required to pay HLI \$500,000 related to the first commercial sale of Interfyl in the flowable matrix configuration and \$500,000 related to the first commercial sale of Interfyl in the particulate form. Commercial sales of both configurations occurred in September 2016, and as such the recorded \$1.0 million of milestone expense during the year ended December 31, 2016. This milestone payment is payable in November 2017 and is included in accrued expenses and other current liabilities as of March 31, 2017 and December 31, 2016.

## ***Contingent Consideration***

### *Celleration, Inc.*

On May 29, 2015, the Company acquired all outstanding equity interest of Celleration, Inc. (“Celleration”), a medical device company focused on developing and commercializing the MIST Therapy® therapeutic ultrasound platform for the treatment of acute and chronic wounds. The Company agreed to pay contingent consideration of 3.5 times revenue from acquired MIST Therapy products in excess of certain revenue targets for the years ending December 31, 2015 and 2016, payable in equal amounts of cash and the Company’s common stock. This contingent consideration was payable in two installments in March 2016 and March 2017.

The first installment consisted of \$2.6 million of cash and approximately 986,000 shares of the Company’s common stock valued at approximately \$2.6 million and was paid in March 2016. This payment was based on 3.5 times of the excess of 2015 MIST Therapy revenue of approximately \$10.2 million over 2014 MIST Therapy revenue of approximately \$8.7 million.

The second installment consisted of \$675,000 of cash and approximately one million shares of the Company’s common stock valued at approximately \$675,000 and was paid in March 2017. This payment was based on 3.5 times of the excess of 2016 MIST Therapy revenue of approximately \$10.5 million over 2015 MIST Therapy revenue of approximately \$10.2 million. There are no further contingent payments due in connection with the Celleration acquisition.

### *Choice Therapeutics, Inc.*

On May 5, 2014, the Company acquired all outstanding equity interest of Choice Therapeutics, Inc., a provider of innovative wound care products using proprietary TheraBond 3D® Antimicrobial Barrier Systems. The Company agreed to pay contingent consideration based upon the company achieving specific performance metrics over the three twelve month periods, ended April 30, 2017. As of March 31, 2017, the Company estimates this contingent liability to be \$500,000. The contingent liability is payable in the form of the Company’s common stock and will be paid in June 2017.

## ***Litigation, Claims and Assessments***

The Company is subject to periodic lawsuits, investigations and claims that arise in the ordinary course of business. The Company is not party to any material litigation as of March 31, 2017.

## **9. Stockholders’ Equity**

### ***Private Placement***

On February 27, 2017, the Company entered into a securities purchase agreement (the “Securities Purchase Agreement”) with certain accredited investors, pursuant to which the Company agreed to issue and sell to the investors in a private placement (the “Private Placement”) an aggregate of 5,540,000 shares of the Company’s common stock at a purchase price of \$0.50 per share. The Company closed the Private Placement on the same day as it entered into the Securities Purchase Agreement and received aggregate gross proceeds of \$2,770,000. In connection with the Private Placement, the Company paid an aggregate of \$196,000 of financial advisory fees and \$40,000 of administrative fees, which were recorded as a reduction of additional paid-in capital.

### ***Stock-Based Compensation***

During the three months ended March 31, 2017 and 2016, the Company recognized \$491,000 and \$1.7 million of stock-based compensation expense, of which, \$11,000 and \$82,000 is included in cost of revenues and \$480,000 and \$1.6 million is included in selling, general and administrative expenses in the condensed consolidated statements of operations, respectively. As of March 31, 2017, there was \$1.9 million of unrecognized stock-based compensation expense which will be amortized over a weighted average period of 1.2 years.

## **10. Related Party**

In November 2015, the Company entered into a manufacturing supply agreement with a company where a Company director was then member of the Board of Directors. During the three months ended March 31, 2017 and 2016, the Company incurred costs of approximately \$127,000 and \$163,000, respectively, from this vendor. Approximately \$82,000 and \$102,000 is included in accounts payable related to this related party as of March 31, 2017 and December 31, 2016, respectively.

## **11. Fair Value Measurement**

Fair value is defined as the price that would be received upon selling an asset or the price paid to transfer a liability on the measurement date. It focuses on the exit price in the principal or most advantageous market for the asset or liability in an orderly transaction between willing market participants. A three-tier fair value hierarchy is established as a basis for considering such assumptions and for inputs used in the valuation methodologies in measuring fair value. This hierarchy requires entities to maximize the use of observable inputs and minimize the use of unobservable inputs. The three levels of inputs used to measure fair values are as follows:

Level 1: Observable prices in active markets for identical assets and liabilities.

Level 2: Observable inputs other than quoted prices in active markets for identical assets and 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 and liabilities.

#### *Warrant Liabilities*

In connection with the entry into the January 26, 2017 forbearance agreement, as amended on March 7, 2017, the Company also amended and restated the warrant issued to Perceptive in connection with the closing of the Credit Agreement on May 29, 2015. The amended and restated warrant is exercisable for 2,000,000 shares of the Company's common stock. The amended and restated warrant is exercisable at an exercise price of \$0.50. See Note 7 – *Debt* for additional details. In connection with this amendment, the Company recomputed the fair value of the original warrant and modified warrant as \$789,000 and \$19,000, respectively, using the Binomial option pricing model (Level 3 inputs) using the following assumptions: expected volatility of 65.33%-78.98%, risk-free rate of 1.49%-1.95%, expected term of 3.34-5.00 years, and expected dividends of 0.00%. As a result, the Company recorded warrant modification expense of \$770,000 during the three months ended March 31, 2017, which represents the incremental value of the modified warrant as compared to the original warrant, both valued as of the January 26, 2017 modification date. The modification expense was recognized from the date of modification through March 31, 2017, which was the period under which the forbearance was in effect.

On March 31, 2017, the Company recomputed the fair value of its warrant liability of outstanding warrants to purchase an aggregate of 2,290,338 shares of common stock as \$672,000 using the Binomial option pricing model (Level 3 inputs) using the following assumptions: expected volatility of 79.19%-94.41%, risk-free rate of 0.91%-1.93%, expected term of 0.61-4.83 years, and expected dividends of 0.00%. The Company recorded a gain on the change in fair value of these warrant liabilities of \$118,000 during the three months ended March 31, 2017. The issuance of common stock in connection with the February 27, 2017 Private Placement triggered an adjustment to the exercise price of certain warrants originally issued in November 2012 from \$5.51 per share to \$0.50 per share with a corresponding adjustment to the number of shares underlying such warrants from 66,287 shares to 290,338 shares. The impact of such adjustment is included in the change in fair value of the warrant liabilities during the three months ended March 31, 2017.

Warrants that contain exercise reset provisions and contingent consideration liabilities are Level 3 derivative liabilities measured at fair value on a recurring basis using pricing models for which at least one significant assumption is unobservable as defined in ASC 820. The fair value of contingent consideration liabilities that are classified as Level 3 were estimated using a discounted cash flow technique with significant inputs that are not observable in the market and thus represents a Level 3 fair value measurement as defined in ASC 820. The significant inputs in the Level 3 measurement not supported by market activity include the probability assessments of expected future cash flows related to the acquisitions, appropriately discounted considering the uncertainties associated with the obligation, and as calculated in accordance with the terms of the acquisition agreements. The development and determination of the unobservable inputs for Level 3 fair value measurements and the fair value calculations are the responsibility of the Company's Chief Financial Officer and are approved by the Chief Executive Officer.

The following table sets forth a summary of the changes in the fair value of Level 3 warrant liabilities that are measured at fair value on a recurring basis (in thousands):

	<b>March 31,</b>	
	<b>2017</b>	<b>2016</b>
<b><u>Warrant Liabilities</u></b>		
Beginning balance as of January 1,	\$ 20	\$ 861
Change in fair value of warrant liability	(118)	(737)
Warrant modification expense	770	-
Ending balance as of March 31,	<u>\$ 672</u>	<u>\$ 124</u>
	<b>March 31,</b>	
	<b>2017</b>	<b>2016</b>
<b><u>Contingent Consideration</u></b>		
Beginning balance as of January 1,	\$ 1,816	\$ 17,028
Payments of contingent consideration	(1,350)	(5,147)
Change in fair value of contingent consideration	34	362
Ending balance as of March 31,	<u>\$ 500</u>	<u>\$ 12,243</u>

Assets and liabilities measured at fair value on a recurring basis are as follows (in thousands):

	<b>March 31, 2017</b>		
	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
<b>Liabilities:</b>			
Warrant liabilities	\$ -	\$ -	\$ 672
Contingent consideration	-	-	500
<b>Total liabilities</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ 1,172</b>
	<b>December 31, 2016</b>		
	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
<b>Liabilities:</b>			
Warrant liabilities	\$ -	\$ -	\$ 20
Contingent consideration	-	-	1,816
<b>Total liabilities</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ 1,836</b>

## 12. Subsequent Events

### *Underwritten Public Offering*

On April 3, 2017, the Company closed an underwritten public offering of 9,473,250 shares of its common stock at a price to the public of \$0.40 per share. Proceeds from this offering were approximately \$3.8 million before deducting underwriting and estimated offering expenses. The Company intends to use the net proceeds from this offering primarily for working capital, general corporate purposes, and to pay the Company's monthly obligations under its credit agreement. The shares of common stock were issued pursuant to the Company's shelf registration statement on Form S-3 previously filed with the Securities and Exchange Commission and declared effective on September 25, 2014.

On April 3, 2017, the Company issued warrants to purchase an aggregate of 236,831 of the Company's common stock to the underwriter of this offering. These warrants are immediately exercisable, have an exercise price of \$0.44, and expire on March 29, 2022. Pursuant to an anti-dilution provision provided in the warrants dated November 8, 2012 to purchase common stock at an initial exercise price of \$2.19, the exercise price of these warrants was adjusted to the public offering price of \$0.40. As of April 3, 2017, November 2012 warrants to purchase 362,293 shares of the Company's common stock were outstanding. These warrants expire in November 2017.

### *Issuance of Additional Shares under the Securities Purchase Agreement*

Under the Securities Purchase Agreement entered into in the Private Placement, the Company sold and issued to private investors 5,540,000 shares of its common stock at a purchase price of \$0.50 per share. The Securities Purchase Agreement contains a "most-favored nation provision" that provides that if the Company, during 120 days from February 27, 2017, issues or sells any common stock or common stock equivalents reasonably believed to be more favorable in terms or conditions than those in the Private Placement, then the Company must amend the terms of the Securities Purchase Agreement to give these private investors the benefit of such favorable terms or conditions. In accordance with this provision, on April 11, 2017, the Company issued an aggregate of 380,717 shares of its common stock to these investors. The Company will issue 1,004,283 additional shares of its common stock if it obtains stockholder approval as required by the applicable rules and regulations of the NASDAQ Capital Market.

### *Amendment and Adjustments of the Perceptive Warrant*

On April 6, 2017, the Company and Perceptive entered into an amendment and restatement of a warrant to reduce the exercise price from \$0.50 to \$0.47. The warrant is exercisable for 2,000,000 shares of the Company's stock. Perceptive will not have the right to exercise the warrant to the extent that after giving effect to such exercise, Perceptive would beneficially own in excess of 9.99% of the common stock outstanding immediately after giving effect to such exercise.

## **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 in conjunction with the condensed consolidated financial statements and related notes above.

## Forward-Looking Statements

This Quarterly Report on Form 10-Q contains “forward-looking statements,” which include information relating to future events, future financial performance, strategies, expectations, competitive environment and regulation. Words such as “may,” “should,” “could,” “would,” “predict,” “potential,” “continue,” “expect,” “anticipate,” “future,” “intend,” “plan,” “believe,” “estimate,” and similar expressions, as well as statements in future tense, identify forward-looking statements. Forward-looking statements should not be read as a guarantee of future performance or results and may not be accurate indications of when such performance or results will actually be achieved. Forward-looking statements are based on information we have when those statements are made or our management’s good faith belief as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Important factors that could cause such differences include, but are not limited to:

- our ability to continue as a going concern;
- inadequate capital;
- the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives;
- our ability to recover the carrying value of some or all of our intangible assets including goodwill;
- our ability to obtain reimbursement from third party payers for our products;
- our ability to achieve and maintain minimum sales requirements under our license agreements;
- our ability to obtain and maintain regulatory approval of our existing products and any future products we may develop;
- our ability to cure or obtain forbearance or waivers for existing covenant defaults under our outstanding indebtedness and to remain in compliance with our debt covenants;
- market acceptance of our existing and future products;
- loss or retirement of key executives;
- our plans to make significant additional outlays of working capital before we expect to generate significant revenues and the uncertainty regarding when we will begin to generate significant revenues, if we are able to do so;
- an unfavorable decision on product reimbursement;
- adverse economic conditions and/or intense competition;
- loss of a key customer or supplier;
- entry of new competitors and products;
- adverse federal, state and local government regulation;
- technological obsolescence of our products;
- technical problems with our research and products;
- risks of mergers and acquisitions including the time and cost of implementing transactions and the potential failure to achieve expected gains, revenue growth or expense savings;
- price increases for supplies and components; and
- the inability to carry out research, development and commercialization plans.

For a discussion of these and other risks that relate to our business and investing in shares of our common stock, you should carefully review the risks and uncertainties described under the heading “Part II – Item 1A. Risk Factors” and elsewhere in this Quarterly Report on Form 10-Q and in our Annual Report on form 10-K for the year ended December 31, 2016. The forward-looking statements contained in this Quarterly Report on Form 10-Q are expressly qualified in their entirety by this cautionary statement. We do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.

## **Overview**

We are a regenerative technologies company that commercializes differentiated regenerative medical products which assist the body in the repair or replacement of soft tissue. Through our sales and distribution network, together with our proprietary products, we believe we offer solutions that allow clinicians to utilize the latest advances in regenerative technologies to bring improved patient outcomes to their practices. Our contract manufacturing business provides custom hydrogels to the OEM market.

## **Recent Events**

### ***Termination of Merger Agreement***

On October 5, 2016, we entered into a merger agreement to acquire the business of Soluble Systems, LLC (“Soluble”) through a series of transactions. On February 27, 2017, we terminated this agreement, due to the inability to secure the requisite financing to meet the closing conditions of the merger agreement.

### ***Private Placement***

On February 27, 2017, we issued and sold an aggregate of 5,540,000 shares of our common stock at a purchase price of \$0.50 per share issued to certain accredited investors in a private placement (the “Private Placement”), pursuant to a Securities Purchase Agreement (the “Securities Purchase Agreement”). We received aggregate gross proceeds of \$2,770,000.

### ***Underwritten Public Offering***

On April 3, 2017, we closed an underwritten public offering of 9,473,250 shares of our common stock at a price to the public of \$0.40 per share. Proceeds from this offering, net of underwriter fees were \$3,524,049. We intend to use the net proceeds from this offering primarily for working capital and general corporate purposes, and to pay our monthly obligations under the Credit Agreement. The shares of common stock were issued pursuant to our shelf registration statement on Form S-3 previously filed with the Securities and Exchange Commission and declared effective on September 25, 2014.

On April 3, 2017, we issued warrants to purchase an aggregate of 236,831 of our common stock to the underwriter of this offering. These warrants are immediately exercisable, have an exercise price of \$0.44, and expire on March 29, 2022.

### ***Amendment and Adjustments of the Perceptive Warrant***

On April 6, 2017, we and Perceptive Credit Opportunities Fund, L.P. (“Perceptive”) entered into an amendment and restatement of a warrant to reduce the exercise price from \$0.50 to \$0.47. The warrant is exercisable for 2,000,000 shares of our common stock. Perceptive will not have the right to exercise the warrant to the extent that after giving effect to such exercise, Perceptive would beneficially own in excess of 9.99% of the common stock outstanding immediately after giving effect to such exercise.

### ***Senior Secured Term Loan Facility***

As of March 31, 2017, we are in default of a covenant pertaining to trailing twelve-month revenue under the Credit Agreement as a result of our failure to achieve \$22,250,000, \$24,600,000 and \$27,200,000 of gross revenue for the twelve-month periods ended September 30, 2016, December 31, 2016 and March 31, 2017, respectively. Under an agreement dated January 26, 2017, as amended on March 7, 2017 and April 27, 2017, the lender agreed to forbear from exercising any rights and remedies related to the default until the earlier of June 30, 2017 or the date when the lender becomes aware of any other default. The lender has the rights to pursue any rights and remedies available to it, including, but not limited to, declaring all or any portion of the outstanding principal amount to be immediately due and payable, imposing a default rate of interest as specified in the credit agreement, or pursuing the lender’s rights and remedies as a secured party under the UCC as a secured lender. In addition, the lender has a lien on substantially all of our assets and, as a result of the default, may seek to foreclose on some or substantially all of our assets after the expiration of the forbearance. We are in negotiations with other financing parties to refinance this debt. However, no assurance can be given that we will be able to obtain additional debt to refinance our existing obligations on commercially reasonable terms or at all.

## Results of Operations

### Three Months Ended March 31, 2017 Compared to the Three Months Ended March 31, 2016

**Overview.** For the three months ended March 31, 2017 and 2016, we had a net loss of \$7.0 million and \$7.7 million, respectively. Included in the operating loss for the three months ended March 31, 2017 and 2016 was non-cash stock-based compensation of \$491,000 and \$1.7 million, respectively, and non-cash warrant modification expense of \$770,000 during the three months ending March 31, 2017. Also, included in the operating loss for the three months ended March 31, 2017 was \$635,000 of expenses related to the terminated acquisition of Soluble Systems, LLC (“Soluble”).

**Revenues, net.** For the three months ended March 31, 2017 revenues increased by \$637,000, or 16%, to \$4.6 million from \$4.0 million for the three months ended March 31, 2016. The increase in our overall revenue was due to a 28% increase in product sales, primarily attributable to growth in our biologic products.

The components of revenue were as follows for the three months ended March 31, 2017 and 2016 (in thousands):

	Three Months Ended March 31,	
	2017	2016
<b>Revenues</b>		
Product	\$ 4,365	\$ 3,404
Contract manufacturing	229	553
Total revenues, net	<u>\$ 4,594</u>	<u>\$ 3,957</u>

**Gross profit.** Our gross profit was \$2.9 million for the three months ended March 31, 2017 compared to gross profit of \$2.4 million for the three months ended March 31, 2016. The improved results for the three months ended March 31, 2017, as compared to the three months ended March 31, 2016 was primarily due to the greater volume of product sales as product revenue typically commands higher gross profit margins. Gross margin on our product sales was approximately 75%, while our overall gross margin was approximately 64% for the three months ended March 31, 2017. Gross margin on our product sales was approximately 75%, while our overall gross margin was approximately 60% for the three months ended March 31, 2016.

The components of cost of revenues are as follows for the three months ended March 31, 2017 and 2016 (in thousands):

	Three Months Ended March 31,	
	2017	2016
<b>Cost of revenues</b>		
Materials and finished products	\$ 1,005	\$ 846
Stock-based compensation	11	82
Compensation and benefits	230	250
Depreciation and amortization	206	182
Equipment, production and other expenses	208	230
Total cost of revenues	<u>\$ 1,660</u>	<u>\$ 1,590</u>

**Selling, general and administrative expenses.** The following table highlights selling, general and administrative expenses by type for the three months ended March 31, 2017 and 2016 (in thousands):

	Three Months Ended March 31,	
	2017	2016
<b>Selling, general and administrative expenses</b>		
Compensation and benefits	\$ 3,848	\$ 4,161
Stock-based compensation	480	1,624
Professional fees	733	1,139
Marketing	359	373
Depreciation and amortization	1,176	836
Other expenses	1,144	1,607
Total selling, general and administrative expenses	<u>\$ 7,740</u>	<u>\$ 9,740</u>

Selling, general and administrative expenses decreased by \$2.0 million to \$7.7 million for the three months ended March 31, 2017, as compared to \$9.7 million for the three months ended March 31, 2016. The decrease in selling, general and administrative expenses is consistent with our goal of decreasing our operating expenditures.



Compensation and benefits decreased by \$313,000 to \$3.8 million for the three months ended March 31, 2017, as compared to \$4.2 million for the three months ended March 31, 2016. The decrease in compensation and benefits was primarily due to the decrease in the average number of full-time employees in 2017 compared to 2016. We expect our average headcount for the full year of 2017 to be lower than the full year of 2016. Stock-based compensation decreased by \$1.1 million, to \$480,000 for the three months ended March 31, 2017, as compared to \$1.6 million for the three months ended March 31, 2016. The decrease in stock-based compensation is due to the decrease in equity awards granted during the three months ended March 31, 2017 compared to the three months ended March 31, 2016.

Professional fees decreased by \$406,000 to \$733,000 for the three months ended March 31, 2017, as compared to \$1.1 million for the three months ended March 31, 2016. The decrease in professional fees was primarily due to a decrease in legal and consulting expenses.

Other selling, general and administrative expenses consist of costs associated with our selling efforts and general management, including recruiting, information technology, travel, training and third party logistics. Other expenses decreased by \$463,000 to \$1.1 million for the three months ended March 31, 2017 from \$1.6 million for the three months ended March 31, 2016. The decrease in other expenses is primarily due to a decrease in the average number of full-time employees in 2017 compared to 2016.

**Acquisition-related expenses.** During the three months ended March 31, 2017, we incurred \$635,000 in acquisition-related costs related to acquisition of Soluble, which we terminated in February 2017. The incurred costs during the three months ended March 31, 2017 include bad debt expense of \$350,000 related to a subordinated promissory note receivable made to Soluble in connection with the terminated acquisition, as well as professional costs associated with terminating the acquisition.

**Warrant modification expense.** During the three months ended March 31, 2017, we recorded \$770,000 of warrant modification expense in connection with the amendment of the warrant issued to Perceptive. In connection with entry into the January 2017 forbearance agreement, as amended March 2017, we also amended and restated the warrant issued to Perceptive in connection with the closing of the Credit Agreement in May 2015. The amended and restated warrant is exercisable for 2,000,000 shares of our common stock. The expense recorded during the three months ended March 31, 2017 represents the incremental value of the modified warrant as compared to the original warrant, both valued as of the January 26, 2017 modification date.

#### **Liquidity and Capital Resources**

As of March 31, 2017, we had cash and cash equivalents totaling approximately \$2.4 million compared to \$5.6 million at December 31, 2016. The decrease was largely attributable to cash used in operating activities of approximately \$4.6 million, \$675,000 to pay a portion of the contingent consideration related to the Celleration acquisition, and \$350,000 issued as a bridge loan to Soluble in connection with the terminated acquisition. This decrease was offset by \$2.5 million received from net proceeds from the issuance of common stock.

Net cash used in operating activities was \$4.6 million and \$6.1 million for the three months ended March 31, 2017 and 2016, respectively. Net cash used in operating activities for both periods was principally to fund our net cash loss. The net cash flow used in operating activities for the three months ended March 31, 2017 and 2016 included \$1.6 million of compensation and royalty payments that were accrued at both December 31, 2016 and 2015, respectively.

Net cash used in investing activities was \$389,000 and \$362,000 for the three months ended March 31, 2017 and 2016, respectively. Cash used in investing activities during the three months ended March 31, 2017 included \$350,000 provided to Soluble as a bridge loan in connection with the terminated acquisition and \$39,000 related to the purchase of improvements and equipment. Cash used in investing activities during the three months ended March 31, 2016 related to the purchase of improvements and equipment.

Net cash provided by financing activities for the three months ended March 31, 2017 consisted of \$2.5 million of net proceeds received from the issuance of our common stock offset by \$675,000 utilized to pay the cash portion of the contingent consideration related to the Celleration acquisition. Net cash used in financing activities for the three months ended March 31, 2016 consisted of \$2.6 million utilized to pay the cash portion of the contingent consideration related to the Celleration acquisition.

At March 31, 2017, current assets totaled \$8.3 million and current liabilities totaled \$19.4 million, as compared to current assets totaling \$11.8 million and current liabilities totaling \$20.1 million at December 31, 2016. As a result, we had negative working capital of \$11.1 million at March 31, 2017 compared to negative working capital of \$8.4 million at December 31, 2016.

Our cash requirements have historically been for mergers and acquisitions, post-market clinical trials, marketing and sales activities, finance and administrative costs, capital expenditures and overall working capital. We have experienced negative operating cash flows since inception and have funded our operations primarily from sales of common stock and other securities.

## Liquidity Outlook

Our financial statements have been prepared assuming we will continue as a going concern. We have experienced recurring losses since our inception. We incurred a net loss of \$7.0 million and used \$4.6 million in cash from operations for the three months ended March 31, 2017, and had an accumulated deficit of \$131.3 million as of March 31, 2017. At March 31, 2017, we had approximately \$2.4 million of cash and cash equivalents. On February 27, 2017, we closed a private placement of 5,540,000 shares of common stock at a purchase price of \$0.50 per share, pursuant to a securities purchase agreement with certain accredited investors. We received net proceeds of approximately \$2.5 million. On April, 3, 2017, we closed an underwritten public offering. Total gross proceeds were approximately \$3.8 million before deducting underwriting and estimated offering expenses.

On May 29, 2015, simultaneously with and related to the closing of the Celleration acquisition, we entered into our Credit Agreement. The Credit Agreement provided a senior secured term loan in a single borrowing in the principal amount of \$15.5 million, with a current balance of \$13.8 million. The Credit Agreement (i) has a four-year term, (ii) accrues interest at an annual rate equal to the greater of (a) one-month LIBOR or 1% plus (b) 9.75%, payable monthly (iii) monthly principal payments of \$225,000 commencing in May 2017, with the remaining unpaid balance due on the maturity date and (iv) is secured by a first priority lien on substantially all our assets. The Credit agreement requires us to meet certain financial covenants. We are currently in default of a covenant pertaining to trailing twelve-month revenue under the Credit Agreement as a result of our failure to achieve \$22,250,000, \$24,600,000 and \$27,200,000 of gross revenue for the twelve-month periods ended September 30, 2016, December 31, 2016 and March 31, 2017, respectively. Under an agreement dated January 26, 2017, as amended on March 7, 2017 and April 27, 2017, the lender agreed to forbear from exercising any rights and remedies related to the default until the earlier of June 30, 2017 or the date when the lender becomes aware of any other default. The lender has the rights to pursue any rights and remedies available to it, including, but not limited to, declaring all or any portion of the outstanding principal amount to be immediately due and payable, imposing a default rate of interest as specified in the Credit Agreement, or pursuing the lender's rights and remedies as a secured party under the UCC as a secured lender. In addition, the lender has a lien on substantially all of our assets and, as a result of the default, may seek to foreclose on some or substantially all of our assets after the expiration of the forbearance.

During the three months ended March 31, 2017, we made a bridge loan of \$350,000 in cash to Soluble in connection with the terminated acquisition. In 2016, we advanced Soluble \$1.0 million. We believe the collectability of the \$1.4 million due from Soluble is in doubt and, therefore, have fully reserved the amount due as of March 31, 2017.

Even though we have taken steps to reduce our operating expenditures, we expect to continue incurring losses and negative cash flows from operations until our products reach commercial profitability. As a result of these expected losses and negative cash flows from operations, along with our current cash position, and our current outstanding principal balance of approximately \$13.8 million, which the lender may declare due and payable in full following the termination of a forbearance agreement. We do not have sufficient resources to fund operations beyond the next twelve months from the date of filing this quarterly report and we will need to raise additional capital to finance our losses and negative cash flows from operations. If our lender declares the amounts owed under the Credit Agreement due and payable in full, it would hinder our ability to recover the carrying value of some or all of our intangible assets including goodwill that aggregated approximately \$39.2 million at March 31, 2017. Therefore, due to our history of recurring losses and our negative working capital, there is substantial doubt about our ability to continue operating as a going concern within one year from the date of this filing. Our plans include the continued commercialization of our products, raising capital through the sale of additional equity and/or debt securities, and exploring other strategic alternatives. There can be no assurances, however, that we will be successful in obtaining the level of financing needed for our operations. If we are unsuccessful in raising additional capital, we may need to reduce activities, curtail or cease operations.

## Off Balance Sheet Arrangements

As of March 31, 2017, we had no off-balance sheet arrangements in the nature of guarantee contracts, retained or contingent interests in assets transferred to unconsolidated entities (or similar arrangements serving as credit, liquidity or market risk support to unconsolidated entities for any such assets), or obligations (including contingent obligations) arising out of variable interests in unconsolidated entities providing financing, liquidity, market risk or credit risk support to us, or that engage in leasing, hedging or research and development services with us.

## Critical Accounting Policies

There have been no significant changes to our critical accounting policies and estimates from the information provided in Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations," included in the Annual Report on Form 10-K for the year ended December 31, 2016.

## Recent Accounting Pronouncements

Recently issued accounting pronouncements are addressed in Note 1 in the Notes to Condensed Consolidated Financial Statements.

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

Not required.

## ITEM 4. CONTROLS AND PROCEDURES

### *Disclosure Controls and Procedures.*

As of March 31, 2017, we conducted an evaluation of the effectiveness of our “disclosure controls and procedures” (“Disclosure Controls”), as defined by Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). The Disclosure Controls evaluation was done under the supervision and with the participation of management, including our chief executive officer and chief financial officer. There are inherent limitations to the effectiveness of any system of disclosure controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives. Based upon this evaluation, our chief executive officer and chief financial officer have concluded that our Disclosure Controls were effective at the reasonable assurance level as of March 31, 2017.

### *Changes in Internal Control over Financial Reporting*

There have been no changes in our internal control over financial reporting during the fiscal quarter ended March 31, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

From time to time, we may become involved in lawsuits, investigations and claims that arise in the ordinary course of business. As of the date of this filing, we are not party to any material litigation nor are we aware of any such threatened or pending legal proceedings that we believe could have a material adverse effect on our business, financial condition or operating results.

There are no material proceedings in which any of our directors, officers or affiliates or any registered or beneficial shareholder of more than 5% of our common stock is an adverse party or has a material interest adverse to our interest.

### ITEM 1A. RISK FACTORS

There are numerous and varied risks, known and unknown, that may prevent us from achieving our goals. You should carefully consider the risks factors previously discussed in Part I, Item 1A “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2016, including the consolidated financial statements and related notes. If any of the following risks, or any other risks not described below, actually occur, it is likely that our business, financial condition, and/or operating results could be materially adversely affected. The risks and uncertainties described below include forward-looking statements and our actual results may differ from those discussed in these forward-looking statements.

#### **Risks Related to Our Company**

*The report of our independent auditors contains an explanatory paragraph as to our ability to continue as a going concern, which could prevent us from obtaining new financing on reasonable terms or at all.*

Because we have had recurring losses, negative cash flows from operating activities, limited cash on hand in light of expected expenditures and are in default of our Credit Agreement with Perceptive Credit Opportunities Fund, L.P., the report of Marcum LLP, our independent auditors, with respect to our financial statements at December 31, 2016, and for the year ended December 31, 2016, contains an explanatory paragraph as to our potential inability to continue as a going concern. This opinion indicates that substantial doubt exists regarding our ability to remain in business. Such an opinion may adversely affect our ability to obtain new financing on reasonable terms or at all.

*We have experienced significant losses and expect losses to continue for the foreseeable future.*

We have incurred annual net losses of \$28.2 million and \$26.0 million, respectively, during the years ended December 31, 2016 and 2015. As of December 31, 2016, we had an accumulated deficit of \$124.3 million. We expect to incur additional operating losses for the foreseeable future. Although we expect sales to continue to increase in 2017 and beyond from our existing product offerings, there can be no assurance our sales will increase or that we will ever be profitable in the future.

*We will require additional capital in order to execute the longer term aspects of our business plan.*

The implementation of our growth strategy will continue to result in an increase in our fixed cost structure. Due to the time delay between outlays for working capital expenditures, such as costs to acquire rights to additional products, the hiring and training of sales agents and personnel, marketing costs, the purchasing of inventory, the billing and collection of revenue, debt service costs, and diligence costs related to merger and acquisition activities, we expect to have a net cash outflow from operating activities as a result of these expenditures. Future results of operations involve significant risks and uncertainties. Factors that could affect our future operating results and cause actual results to vary materially from expectations include, but are not limited to, potential demand for our products, risks from competitors, regulatory approval of our new products, technological change, and dependence on key personnel.

In order to complete our future growth strategy, additional equity and/or debt financing will be required. If we are unable to raise additional capital or if we encounter circumstances that place unforeseen constraints on capital resources, we will be required to take even stronger measures to conserve liquidity, which may include, but are not limited to, eliminating all non-essential positions and ceasing all marketing efforts. We would have to curtail business development activities and suspend the pursuit of our business plan. There can be no assurance that we will be successful in improving revenues, reducing expenses and/or securing additional capital in sufficient amounts and on favorable terms.

***We have a substantial amount of indebtedness under our \$13.8 million principal term loan and are in default under the Credit Agreement, which may adversely affect our cash flow and our ability to operate our business.***

In order to finance our acquisition of Celleration, on May 29, 2015, we and each of our subsidiaries entered into the Credit Agreement with Perceptive Credit Opportunities Fund, L.P., which provided for a senior, secured term loan with a current principal amount of approximately \$13.8 million. The full unpaid principal amount of the term loan will mature on May 29, 2019. Prior to maturity, on the last business day of each calendar month following May 29, 2017, we will be required to make monthly principal payments of \$225,000, with any remaining unpaid balance of the term loan being payable in cash on the maturity date. The repayment of the term loan and our obligations under the Credit Agreement are secured by a first priority lien on all of our existing and after acquired tangible and intangible assets, including intellectual property. The Credit Agreement also contains certain restrictions that prohibit us and our subsidiaries from engaging in certain transactions and activities, including but not limited to the following:

- entering into, creating, incurring or assuming any indebtedness of any kind, subject to limited exceptions;
- creating or incurring new liens, subject to certain exceptions;
- entering into new acquisitions or investments in other entities, subject to certain exceptions;
- winding up, liquidating or dissolving;
- merging or consolidating with another person or disposing of assets, subject to certain exceptions;
- entering into inbound or outbound licenses, subject to certain exceptions;
- changing the nature of our core business;
- paying cash dividends; and
- repaying, repurchasing or otherwise acquiring shares of our common stock or other equity securities.

Our ability to meet our expenses, debt obligations and other financial covenants under the Credit Agreement will depend on our future performance, which will be affected by financial, business, economic, regulatory and other factors. We will be unable to control many of these factors. We cannot be certain that our earnings will be sufficient to allow us to pay the principal and interest on our debt and meet any other obligations. If we do not have enough money to service our debt, we will be required, but may be unable to refinance or restructure all or part of our existing debt, sell assets, borrow money or raise equity on terms acceptable to us, if at all, and the lender could foreclose on its security interest and liquidate some or all of our assets, which would harm our business, financial condition and results of operations.

The Credit Agreement also requires us to meet certain financial covenants. Our ability to meet these financial covenants may be affected by events beyond our control. If, as or when required, we are unable to repay, refinance or restructure our indebtedness under, or amend the covenants contained in, the Credit Agreement, the lender could institute foreclosure proceedings against our assets, which would harm our business, financial condition and results of operations. We are currently in default under the Credit Agreement.

In addition, as a result of our increased level of indebtedness, demands on our cash resources will continue to increase in the future and could, among other things:

- require us to dedicate a large portion of our cash flow from operations to the servicing and repayment of our debt, thereby reducing funds available for working capital, capital expenditures, research and development expenditures and other general corporate requirements;
- limit our ability to obtain additional financing to fund future working capital, capital expenditures, research and development expenditures and other general corporate requirements;
- limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate;

- restrict our ability to make strategic acquisitions or dispositions or to exploit business opportunities;
- place us at a competitive disadvantage compared to our competitors that have less debt;
- adversely affect our credit rating, with the result that the cost of servicing our indebtedness might increase and our ability to obtain surety bonds could be impaired;
- adversely affect the market price of our common stock; and
- limit our ability to apply proceeds from an offering or asset sale to purposes other than the servicing and repayment of debt.

***We are currently in default under the Credit Agreement, which allows the lender to exercise certain rights and remedies, including, without limitation, declaring the entire outstanding indebtedness under the Credit Agreement of approximately \$13.8 million immediately due and payable, imposing a default rate of interest and/or foreclosing on some or substantially all of our assets.***

We are currently in default of the Credit Agreement, as a result of our failure to achieve \$22,250,000, \$24,600,000, and \$27,000,000 of gross revenue for the twelve-month periods ended September 30, 2016, December 31, 2016, and March 31, 2017, respectively. Under an agreement dated January 26, 2017, as amended on March 7, 2017 and April 27, 2017, Perceptive Credit Opportunities Fund, L.P., the lender, agreed to forbear from exercising any rights and remedies related to the default until the earlier of April 30, 2017, or the date when the lender becomes aware of any other default. The remedies available for the lender include, among others, the ability to accelerate and immediately demand payment of the outstanding debt of approximately \$13.8 million under the Credit Agreement, to impose a default rate of interest, to foreclose on some or all of our assets, and/or to take possession of or sell some or all of our assets. Were the lender to demand payment of the outstanding debt after expiration of the forbearance period, we would currently have insufficient funds to satisfy that obligation, and the lender's exercise of its other remedies would have a material adverse effect on our operations and financial condition.

We are exploring initiatives to address solutions to our credit issues, which include a restructuring of the Credit Agreement with the lender and the evaluation and pursuit of various sources of financing including a refinancing. However, no assurance can be given that we can restructure our Credit Agreement or that additional financing will be available on commercially reasonable terms or at all.

***Occurrence of an event of default under the Credit Agreement could result in a material adverse effect on our business, operating results and financial condition, or the loss of our assets as the lender holds a first priority security interest in all of our assets and the assets of our subsidiaries.***

Events of default under the Credit Agreement include, but are not limited to, the following:

- failure to pay principal, interest or other amounts, if any, when due;
- any form of bankruptcy or insolvency proceeding instituted by or against us or any of our subsidiaries that is not dismissed in 60 days;
- a default occurring under any debenture, mortgage, credit agreement, indenture or other instrument representing or securing indebtedness in an amount exceeding \$250,000;
- we or any of our subsidiaries is party to a change of control;
- the FDA or other governmental authority (i) issues a letter or other communication asserting any of our products lacks a required product authorization, including in respect of CE marks or 510(k)s or 361 HCT/P qualification, or (ii) initiates enforcement action or warning against us, any of our products or manufacturing facilities resulting in the discontinuance of marketing, withdrawal of any material products, or delay in the manufacture of any material products, each lasting for more than 90 days;
- a recall of any product that has generated or is expected to generate at least \$1.0 million in revenue in the aggregate over any consecutive twelve (12) month period;
- we or any of our subsidiaries enters into a settlement agreement with the FDA or any other governmental authority that results in aggregate liability as to any single or related series of transactions, incidents or conditions, in excess of \$500,000;
- we are in default under our license agreement with HLI or the license agreement is terminated, amended, waived or otherwise modified in a manner materially adverse to the lender's interests; and
- failure to observe or perform any other covenant contained in the Credit Agreement.

Upon occurrence of an event of default under the Credit Agreement, payment of the entire principal amount could be accelerated and become immediately due and payable. The cash that we may be required to pay would most likely come out of our working capital, which may be insufficient to repay the obligation or leave us with insufficient cash to finance our operations. In such event, we may lose some or all of our assets as the lender could foreclose on its security interests and liquidate some or all of these assets, which would harm our business, financial condition and results of operations. We may also be required to file for bankruptcy, sell assets, or cease operations, any of which would put our company, our investors and the value of our common stock, at significant risk.

The pledge of these assets and other restrictions may limit our flexibility in raising capital for other purposes. Because substantially all of our assets are pledged under the Credit Agreement, our ability to incur additional secured indebtedness or to sell or dispose of assets to raise capital may be impaired, which could have an adverse effect on our financial flexibility.

***Our goodwill and long-lived assets are subject to potential further impairment, and if those become further impaired, it could materially further the reduction in the value of our assets and increase our net loss for the year in which the write-off occurs.***

Our intangible and fixed assets have finite useful lives and are amortized or depreciated over their useful lives on either a straight-line basis or over the expected period of benefit or as revenues are earned from the sales of the related products. The underlying assumptions regarding the estimated useful lives of these intangible assets are reviewed annually and more often if an event or circumstance occurs making it likely that the carrying value of the assets may not be recoverable and are adjusted through accelerated amortization if necessary. Whenever events or changes in circumstances indicate that the carrying value of the assets is not recoverable we test intangible assets for impairment based on estimates of future cash flows. If an intangible asset is considered to be impaired, the amount of the impairment will equal the excess of the carrying value over the fair value of the asset.

As of December 31, 2016, we had \$12.0 million in goodwill related to acquisitions, which represents the purchase price we paid in excess of the fair value of the net tangible assets and identifiable intangible assets we acquired. We assess the recoverability of goodwill annually, at the beginning of the fourth quarter of each fiscal year, and between annual tests if an event occurs or circumstances change that would indicate the carrying amount may be impaired. Under Financial Accounting Standards Board guidance for goodwill and other intangible assets, a reporting unit is defined as an operating segment or one level below the operating segment, called a component. However, two or more components of an operating segment will be aggregated and deemed a single reporting unit if the components have similar economic characteristics. We adopted authoritative accounting guidance that allows us to first assess qualitative factors to determine whether it is necessary to perform the more detailed two-step quantitative goodwill impairment test. We perform the quantitative test if the qualitative assessment determined it is more likely than not that a reporting unit's fair value is less than its carrying amount. We may elect to bypass the qualitative assessment and proceed directly to the quantitative test for any reporting unit. When performing the quantitative test, an impairment loss is recognized if the carrying amount of the reporting unit's net assets exceeds the estimated fair value of the reporting unit and the carrying amount of reporting unit goodwill is determined to exceed the implied fair value of that goodwill. The estimated fair value of a reporting unit is calculated using a discounted cash flow model. During the year ended December 31, 2016, we recorded an impairment charge of approximately \$1.7 million related to our MIST tradename and approximately \$9.2 million related to our goodwill.

If actual results differ from the assumptions and estimates used in the goodwill and intangible asset calculations, we could incur further impairment or amortization charges. Any finding that the value of our goodwill and long-lived assets has been further impaired would require us to write off the impaired portion, which could materially reduce the value of our assets and reduce our net income or increase our net loss for the year in which the write off occurs and increase our accumulated deficit, which could contribute to difficulty in raising additional funds.

***If we fail to meet certain minimum sales thresholds for products licensed pursuant to our agreement with HLI, we could lose our right to license such products.***

Our license agreement with HLI is terminable on a product-by-product basis if we fail to meet certain minimum sales thresholds in the second year or any subsequent year of commercial sales of the licensed products. Each year of commercial sales is referred to in the license agreement as "launch years" and the calendar period constituting each launch year for the licensed product is determined in accordance with the terms of the license agreement, and for the purpose of determining whether the license can be terminated for failure to meet the minimum sales threshold, Biovance and Interfyl are treated on an aggregate basis as if a single licensed product. To maintain our license for Biovance and Interfyl, we must meet a minimum gross sales amount for Biovance and Interfyl in the second year and third year of commercial sales. If we fail to meet the minimum threshold in the second year of commercial sales of a licensed product, we would be able to cure such failure by making a cure payment specified in the license agreement to HLI; provided, however, we do not have the option to make a cure payment, should we fail to meet the minimum threshold for such product in the third year of commercial sales, and HLI may terminate the license agreement with respect to such product. If we do not meet the minimum sales threshold, HLI may terminate the license with respect to Biovance and Interfyl. Even though we are implementing sales and marketing strategies to meet this minimum gross sales amount, no assurance can be given that we will be able to meet the minimum sales threshold for Biovance and Interfyl in the second or third year of commercial sales as required by the license agreement. If we were to lose or otherwise become unable to maintain our right to license Biovance, Interfyl or other products from HLI, it could have a material adverse effect on our business, financial condition and results of operations. In addition, any termination of our right to license Biovance, Interfyl or other products under the license agreement with HLI could trigger an event of default under our Credit Agreement.

***Decisions in reimbursement levels by governmental or other third-party payers for our products and procedures using our products may have an adverse impact on acceptance and use of our products.***

We believe that our products will be purchased principally by hospitals, physicians and other healthcare providers, which typically bill various third-party payers, such as state and federal healthcare programs (e.g., Medicare and Medicaid), private insurance plans and managed care plans, for the products and services provided to their patients. The ability of our customers to obtain appropriate reimbursement for products and services from third-party payers is critical to the success of our business because reimbursement status affects which products customers purchase and the prices they are willing to pay. In addition, our ability to obtain reimbursement approval in foreign jurisdictions will affect our ability to expand our product offerings internationally.

Third-party payers have adopted, and are continuing to adopt, a number of policies intended to curb rising healthcare costs. These policies include:

- imposition of conditions of payment by foreign, state and federal healthcare programs as well as private insurance plans;
- rules related to how products and services may be marketed; and
- reduction in reimbursement amounts applicable to specific products and services.

Adverse decisions relating to coverage or reimbursement of our products would have an adverse impact on the acceptance of our products and the prices that our customers are willing to pay for them.

We are unable to predict whether foreign, federal, state or local healthcare reform legislation or regulation affecting our business may be proposed or enacted in the future, or what effect any such legislation or regulation would have on our business. Changes in healthcare systems in the United States or internationally in a manner that significantly reduces reimbursement for procedures using our products or denies coverage for these procedures would also have an adverse impact on the acceptance of our products and the prices which our customers are willing to pay for them.

***Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.***

We believe that our success will depend, in part, upon our ability to retain our executive officers, including David Johnson, our Chief Executive Officer, Brian M. Posner, our Chief Financial Officer, Nino Pionati our Chief Strategy and Marketing Officer and Bradford C. Barton, our Chief Operating Officer, and other key personnel, and attract additional skilled personnel, which may require substantial additional funds. There can be no assurance that we will be able to find and attract additional qualified employees or retain any such executive officers and other key personnel. Our inability to hire qualified personnel, the loss of services of our executive officers or key personnel, or the loss of services of executive officers or key personnel who may be hired in the future may have a material and adverse effect on our business.

***Our strategic business plan may not produce the intended growth in revenue and operating income.***

Our strategies include making significant investments in sales and marketing programs to achieve revenue growth and margin improvement targets. If we do not achieve the expected benefit from these investments or otherwise fail to execute on our strategic initiatives, we may not achieve the growth improvement we are targeting and our results of operations may be adversely affected.

***Our acquisition strategy may not produce the intended growth in revenue and operating income.***

As part of our strategy for growth, we may make acquisitions and enter into strategic alliances such as joint ventures and joint development agreements. However, we may not be able to identify suitable acquisition candidates, complete acquisitions or integrate acquisitions successfully, and our strategic alliances may not prove to be successful. Such acquisitions could reduce shareholders' ownership, require us to incur debt, expose us to liabilities and result in amortization expenses related to intangible assets with definite lives. In addition, acquisitions involve other risks, including diversion of management resources otherwise available for ongoing development of our business and risks associated with entering new markets with which we have limited experience or where distribution alliances with experienced distributors are not available. Our future profitability may depend in part upon our ability to further develop our resources to adapt to these new products or business areas and to identify and enter into satisfactory distribution networks. Moreover, we may fail to realize the anticipated benefit of any acquisition as rapidly as expected or at all, or the acquired business may not perform in accordance with our expectations. We may also incur significant expenditures in anticipation of an acquisition that is never realized. There can be no assurance that difficulties encountered in connection with acquisitions will not have a material adverse effect on our business, financial condition and results of operations.

***Our future success depends upon market acceptance of our existing and future products.***

We believe that our success will depend in part upon the acceptance of our existing and future products by the medical community, hospitals and physicians and other health care providers, third-party payers, and end-users. Such acceptance may depend upon the extent to which the medical community and end-users perceive our products as safer, more effective or cost-competitive than other similar products. Ultimately, for our new products to gain general market acceptance, it may also be necessary for us to develop marketing partners for the distribution of our products. There can be no assurance that our new products will achieve significant market acceptance on a timely basis, or at all. Failure of some or all of our future products to achieve significant market acceptance could have a material adverse effect on our business, financial condition, and results of operations.

***We operate in a highly competitive industry and face competition from large, well-established medical device manufacturers as well as new market entrants.***

Competition from other medical device companies and from research and academic institutions is intense, expected to increase, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. In addition to competing with universities and other research institutions in the development of products, technologies and processes, we compete with other companies in acquiring rights to products or technologies from those institutions. A number of factors may limit the market acceptance of our products, including the timing of regulatory approvals and market entry relative to competitive products, the availability of alternative products, and the price of our products relative to alternative products, the availability of third party reimbursement and the extent of marketing efforts by third party distributors or agents that we retain. There can be no assurance that our products will receive market acceptance in a commercially viable period of time, if at all. Furthermore, there can be no assurance that we can develop products that are more effective or achieve greater market acceptance than competitive products, or that our competitors will not succeed in developing or acquiring products and technologies that are more effective than those being developed by us, that would render our products and technologies less competitive or obsolete.

Our competitors enjoy several competitive advantages over us, including some or all of the following:

- large and established distribution networks in the United States and/or in international markets;
- greater financial, managerial and other resources for products research and development, sales and marketing efforts and protecting and enforcing intellectual property rights;
- significantly greater name recognition;
- more expansive portfolios of intellectual property rights;
- established relations with physicians, hospitals, other healthcare providers and third party payers;
- products which have been approved by regulatory authorities for use in the United States and/or Europe and which are supported by long-term clinical data; and
- greater experience in obtaining and maintaining regulatory approvals and/or clearances from the FDA and other regulatory agencies.

Our competitors' products will compete directly with our products. In addition, our competitors as well as new market entrants may develop or acquire new treatments, products or procedures that will compete directly or indirectly with our products. The presence of this competition in our market may lead to pricing pressure which would make it more difficult to sell our products at a price that will make us profitable or prevent us from selling our products at all. Our failure to compete effectively would have a material and adverse effect on our business, results of operations and financial condition.

***Changes to the FDA approval process or ongoing regulatory requirements could make it more difficult for us to obtain FDA approval of our products or comply with ongoing requirements.***

Our products are subject to rigorous pre- and post-approval regulation by the FDA as well as other federal and state authorities. Based on scientific developments, post-market experience, or other legislative or regulatory changes, the current FDA standards of review for approving new medical device and other FDA regulated products are sometimes more stringent than those that were applied in the past. For example, with passage of the Food and Drug Administration Safety and Innovation Act in 2012 (FDASIA), the FDA was required to revisit some of its policies regarding 510(k) devices which resulted in the FDA drafting new guidance for the 510(k) process. The FDA continues to revisit and clarify its guidance regarding 510(k) devices, and such revisions could impact the process for clearing medical devices, determining which devices are eligible for 510(k) clearance, the ability to rescind previously granted 510(k) clearances and additional requirements that may significantly impact the process.

Additionally, we believe that some of our products are regulated under Section 361 of the PHS Act and that as a result no premarket review or approval is required. If the FDA does not agree that one or more of our HCT/P products meet its regulatory criteria for regulation solely as 361 HCT/Ps, our HCT/Ps will be regulated as drugs, devices, and/or biological products, and we could be required to withdraw those products from the market until the applicable approvals are obtained.



We cannot determine what effect changes in regulations or legal interpretations by the FDA or the courts, when and if promulgated or issued, may have on our business in the future. Changes could, among other things, require additional product approvals, different labeling, monitoring of patients, interaction with physicians, education programs for patients or physicians, curtailment of necessary supplies, or limitations on product distribution. These changes, or others required by the FDA could have an adverse effect on the sales of these products, up to and including our inability to sell such products until we may be able to address such requirements. The evolving and complex nature of regulatory science and regulatory requirements, the broad authority and discretion of the FDA and the generally high level of regulatory oversight results in a continuing possibility that from time to time, we will be adversely affected by regulatory actions despite ongoing efforts and commitment to achieve and maintain full compliance with all regulatory requirements.

***Should the FDA determine that Biovance and/or Interfyl do not meet regulatory requirements that permit qualifying HCT/Ps to be processed, stored, labeled and distributed without pre-marketing approval, our supplier may be required by the FDA to stop processing and we may be required to stop distributing Biovance and/or Interfyl, or to narrow the indications for which Biovance and/or Interfyl is marketed, which, in turn, could also result in a default under our Credit Agreement.***

Each of Biovance and Interfyl is a product derived from human tissue. The FDA has specific regulations governing HCT/Ps. An HCT/P is a product containing or consisting of human cells and/or tissue intended for transplantation into humans. HCT/Ps that meet the criteria for regulation solely under Section 361 of the PHS Act and 21 CFR 1271 are not subject to pre-market clearance or approval requirements, but are subject to post-market regulatory requirements. To be a 361 HCT/P, a product must meet all four of the following criteria:

- it must be minimally manipulated;
- it must be intended for homologous use only;
- it must not be combined with another article; and
- it must not have a systemic effect and not be dependent upon the metabolic activity of living cells for its primary function.

We and HLI believe that each of Biovance and Interfyl qualifies as a 361 HCT/P. The FDA has published several draft guidance documents relating to the regulation of HCT/Ps, including the determination of what constitutes minimal manipulation, and held a public hearing on the subject in September 2016. We cannot predict whether or when the FDA will publish any final guidance documents. Moreover, guidance documents, even in final form, are not binding and are merely a reflection of the FDA's thinking on a particular issue at the time that the final guidance document is published. Should the FDA finalize these drafts and include a significant change in its policy with respect to 361 HCT/P qualifications, or determine that our marketing claims exceed what would be permitted for a 361 HCT/P product, and either Biovance and/or Interfyl is determined to not qualify as a 361 HCT/P product, we may have to obtain approval or clearance from the FDA before we can continue to market Biovance or Interfyl in the United States. Furthermore, a communication from the FDA asserting that either Biovance or Interfyl does not qualify as a 361 HCT/P product could also trigger an event of default under our Credit Agreement.

***Modifications to our current products may require new marketing clearances or approvals or require us to cease marketing or recall the modified products until such clearances or approvals are obtained.***

Any modification to an FDA-cleared or approved product that could significantly affect safety or effectiveness, or that would constitute a major change or modification in the product's intended use, requires a new FDA 510(k) clearance or, possibly, a premarket approval. The FDA requires every manufacturer to make its own determination as to whether a modification requires a new 510(k) clearance or premarket approval, but the FDA may review and disagree with any decision reached by the manufacturer. In the future, we may make additional modifications to our products after they have received FDA clearance or approval and, in appropriate circumstances, determine that new clearance or approval is unnecessary. Regulatory authorities may disagree with our past or future decisions not to seek new clearance or approval and may require us to obtain clearance or approval for modifications to our products. If that were to occur for a previously cleared or approved product, we may be required to cease marketing or recall the modified device until we obtain the necessary clearance or approval. Under these circumstances, we may also be subject to significant regulatory fines or other penalties. If any of the foregoing were to occur, our financial condition and results of operations could be negatively impacted.

***We and our manufacturers are required to comply with current good manufacturing practices (“cGMPs”) and current good tissue practices (“cGTPs”) and could be subject to suspensions or product withdrawals if found non-compliant.***

We rely on collaborative relationships with third-party contractors to manufacture various aspects of our products. Reliance on third-party contractors subjects us to a number of risks, including regulatory compliance issues. We may be responsible for the failures of our third-party contractors. The FDA regulates the facilities, processes and procedures used to manufacture and market medical products in the United States. Manufacturing facilities must be registered with the FDA and all products made in such facilities must be manufactured in accordance with cGMP, regulations enforced by the FDA. Compliance with cGMP regulations require the dedication of substantial resources and requires significant expenditures. The FDA periodically inspects our manufacturing facilities and those of our contractors. The inspections are generally random, however, and we cannot predict with certainty when the FDA will inspect our facilities or those of our contractors. Any failure of regulatory standards of compliance by us or on the part of our third-party contractors may compel the FDA to take actions to recall products or to suspend, or withdraw one or more of our product approvals. We or our third-party contractors may also be subject to additional FDA actions as identified in the subsequent section. Further, in the event that we need to use an additional contractor or transfer our processes or methods to manufacture our products to an alternative contractor; or if the FDA decides to curtail or cease our operations or cease or curtail our contractor due to manufacturing problems, the FDA’s actions could result in product delays which could adversely affect our business, results of operations, and financial condition and cash flow.

***We will be subject to ongoing federal and state regulations, and if we fail to comply, our business could be seriously harmed.***

Following regulatory marketing clearance or approval of any products that we may develop, we will be subject to continued regulatory review, including review of adverse (drug or device) events or reactions and clinical results that are reported after our products become commercially available. This would include results from any post-marketing tests or continued actions required by a condition of approval. The manufacturing facilities we may use to make any of our products may become subject to periodic review and inspection by the FDA. If a previously unknown problem or problems with a product or a manufacturing and laboratory facility used by us is discovered, the FDA may impose restrictions on that product or on the manufacturing facility, including requiring us to withdraw the product from the market. Any changes to an approved product, including the way it is manufactured or promoted, often requires FDA approval before the product, as modified, can be marketed. In addition, for products we develop in the future, we and our contract manufacturers may be subject to ongoing FDA requirements for submission of safety and other post-market information. If we or any of our contract manufacturers fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw our regulatory approval;
- suspend or terminate any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us;
- impose restrictions on our operations;
- close the facilities of our contract manufacturers; and/or
- seize or detain products or require a product recall.

Additionally, regulatory review covers our activities in the promotion of our medical products, with significant potential penalties and restrictions for promotion of drugs, devices or tissues for an unapproved use. Sales and marketing programs, such as illegal promotions to health care professionals, are under scrutiny for compliance with various mandated requirements. We are also required to submit information on open and completed clinical trials to public registries and databases. Failure to comply with these requirements could expose us to negative publicity, fines and penalties that could harm our business.

If we violate regulatory requirements at any stage, whether before or after marketing approval is obtained, we may be fined, be forced to remove a product from the market or experience other adverse consequences, including delay, which would materially harm our financial results. Additionally, we may not be able to obtain the labeling claims necessary or desirable for product promotion.

***We and our sales personnel, whether employed by us or by others, must comply with various federal and state anti-kickback, self-referral, false claims and reporting and similar laws, any breach of which could cause a material adverse effect on our business, financial condition and results of operations.***

Our relationships with physicians, hospitals, other healthcare providers and the marketers of our products are subject to scrutiny under various U.S. federal anti-kickback, self-referral, false claims, physician sunshine and other reporting laws and regulations and similar laws, often referred to collectively as healthcare fraud and abuse laws. Healthcare fraud and abuse laws are complex, and even minor, inadvertent violations can give rise to liability, or claims of alleged violations. Possible sanctions for violation of these fraud and abuse laws include monetary fines; civil and criminal penalties; exclusion from federal and state healthcare programs, including Medicare, Medicaid, Veterans Administration health programs, workers' compensation programs and TRICARE, the healthcare system administered by or on behalf of the U.S. Department of Defense for uniformed services beneficiaries, including active duty and their dependents, retirees and their dependents; and forfeiture of amounts collected in violation of such prohibitions. Many states have similar, or sometimes broader, fraud and abuse laws that also authorize substantial civil and criminal penalties for violations. Any government investigation or a finding of a violation of these laws would likely result in a material adverse effect on the market price of our common stock, as well as our business, financial condition and results of operations.

The federal Anti-Kickback Statute prohibits any knowing and willful offer, payment, solicitation or receipt of any form of remuneration in return for the referral of an individual or the ordering or recommending of the use of a product or service for which payment may be made by any federal healthcare program, including Medicare. The definition of "remuneration" has been broadly interpreted to include anything of value, including gifts, discounts, the furnishing of supplies or equipment, payments of cash and waivers of payments. States also often have anti-kickback laws which may be broader in scope and apply to referrals and items or services reimbursed by both governmental and non-governmental third-party payers, including private insurers.

The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or Children's Health Insurance Program to report annually to Centers for Medicare and Medicaid Services information related to payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members. States also often have analogous laws and regulations, such as state anti-kickback and false claims laws, which may be broader in scope and apply to referrals and items or services reimbursed by both governmental and non-governmental third-party payers, including private insurers; and state transparency and reporting laws, which may require drug, device, and biologics manufacturers to report information to the state related to payments and other transfers of value to physicians and other healthcare providers, price disclosures, or marketing expenditures.

The scope and enforcement of the healthcare fraud and abuse laws is uncertain and subject to rapid change. There can be no assurance that federal or state regulatory or enforcement agencies will not investigate our current or future activities under these laws. Any investigation or challenge could have a material adverse effect on our business, financial condition and results of operations. Any state or federal investigation, regardless of the outcome, could be costly and time-consuming. Additionally, we cannot predict the impact of any changes in these laws, whether these changes are retroactive or will have effect on a going-forward basis only.

Because our business involves arrangements with physicians, hospitals, and healthcare providers, including physicians who consult with us on the design of our products, we could be materially impacted if regulatory or enforcement agencies or courts interpret our financial relationships with healthcare providers who refer, order, or use our products to be in violation of health care fraud and abuse laws. Such governmental action could harm our reputation and the reputations of the healthcare providers that we do business with. In addition, the cost of noncompliance with these laws could be substantial because we could be subject to monetary fines and civil or criminal penalties, and we could also be excluded from state and federal healthcare programs, including Medicare and Medicaid, for non-compliance.

***If we are unable to protect our intellectual property rights adequately, we may not be able to compete effectively.***

Our success depends in part on our ability to protect the proprietary rights to the technologies used in our products. We rely on patent protection, as well as a combination of trademark laws and confidentiality, noncompetition and other contractual arrangements to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep a competitive advantage. Our patents and patent applications, if issued, may not be broad enough to prevent competitors from introducing similar products into the market. Our patents, if challenged or if it attempts to enforce them, may not necessarily be upheld by the courts. In addition, patent protection in foreign countries may be different from patent protection under U.S. laws and may not be favorable to us. Efforts to enforce any of our proprietary rights could be time-consuming and expensive, which could adversely affect our business and prospects and divert management's attention.

***We are dependent on proprietary know-how, and a failure to protect our proprietary know-how would harm our business and operation.***

We rely on trade secret protection to protect our interests in proprietary know-how and for processes for which patents are difficult to obtain or enforce. We may not be able to protect our trade secrets adequately. In addition, we rely on non-disclosure and confidentiality agreements with employees, consultants and other parties to protect, in part, trade secrets and other proprietary technology. These agreements may be breached and we may not have adequate remedies for any breach. Moreover, others may independently develop equivalent proprietary information, and third parties may otherwise gain access to our trade secrets and proprietary knowledge. Any disclosure of confidential data into the public domain or to third parties could allow competitors to learn our trade secrets and use the information in competition against us.

Despite our efforts to protect our proprietary rights, there is no assurance that such protections will preclude our competitors from developing and/or marketing similar products. While we are not aware of any third party intellectual property that would materially affect our business, our failure or inability to obtain patents and protect our proprietary information could result in our business being adversely

affected.

***If we are not able to establish and maintain successful arrangements with third parties or successfully build our own sales and marketing infrastructure, we may not be able to commercialize our products, which would adversely affect our business and financial condition.***

To commercialize our products, we must continue to develop our own sales, marketing and distribution capabilities, which will be expensive and time consuming, or make arrangements with third parties to perform these services for us. The third parties may not be capable of successfully selling any of our products. We will have to commit significant resources to developing a marketing and sales force and supporting distribution capabilities. If we decide to enter into arrangements with third parties for performance of these services, we may find that they are not available on terms acceptable to us, or at all.

***We may face intellectual property infringement claims that could be time-consuming, costly to defend and could result in our loss of significant rights and, in the case of patent infringement claims, the assessment of treble damages.***

On occasion, we may receive notices of claims of our infringement, misappropriation or misuse of other parties' proprietary rights. We may have disputes regarding intellectual property rights with the parties that have licensed those rights to us. We may also initiate claims to defend our intellectual property. Intellectual property litigation, regardless of its outcome, is expensive and time-consuming, could divert management's attention from our business and have a material negative effect on our business, operating results or financial condition. In addition, the outcome of such litigation may be unpredictable. If there is a successful claim of infringement against us, we may be required to pay substantial damages—including treble damages if we were to be found to have willfully infringed a third party's patent—to the party claiming infringement, and to develop non-infringing technology, stop selling our products or using technology that contains the allegedly infringing intellectual property or enter into royalty or license agreements that may not be available on acceptable or commercially practical terms, if at all. Our failure to develop non-infringing technologies or license the proprietary rights on a timely basis could harm our business. In addition, modifying our products to exclude infringing technologies could require us to seek re-approval or clearance from various regulatory bodies for our products, which would be costly and time consuming. Also, we may be unaware of pending patent applications that relate to our technology. Parties making infringement claims on future issued patents may be able to obtain an injunction that would prevent us from selling our products or using technology that contains the allegedly infringing intellectual property, which could harm our business.

***We face the risk of exposure to product liability claims.***

We are and, if successful in developing, testing and commercializing our products, will increasingly be, exposed to potential product liability risks, which are inherent in the testing, manufacturing and marketing of such products. It is likely we will be contractually obligated, under any distribution agreements that we enter into with respect to products our manufactures, to indemnify the individuals and/or entities that distribute our products against claims relating to the manufacture and sale of products distributed by such distribution partners. This indemnification liability, as well as direct liability to consumers for any defects in the products sold, could expose us to substantial risks and losses. While we have obtained product liability insurance, there can be no assurance that we will be able to maintain such insurance on acceptable terms or that such insurance will provide adequate coverage against potential liabilities. As we begin to sell and distribute our new line of proprietary products, we intend to increase the amount of our product liability insurance. A successful product liability claim or series of claims brought against us could result in judgments, fines, damages and liabilities that could have a material adverse effect on our business, financial condition and results of operations. We may incur significant expense investigating and defending these claims, even if they do not result in liability. Moreover, even if no judgments, fines, damages or liabilities are imposed on us, our reputation could suffer, which could have a material adverse effect on our business, financial condition and results of operations.

***Healthcare policy changes, including reforms to the U.S. healthcare system, may have a material adverse effect on us.***

Healthcare costs in the United States have risen significantly over the past decade. There have been, and continue to be, proposals by legislators, regulators, and third-party payers to keep these costs down. The efforts of governments and third-party payers to contain or reduce the cost of healthcare and legislative and regulatory proposals to broaden the availability of healthcare will likely affect the business and financial condition of biomedical companies. A number of legislative and regulatory changes in the healthcare system in the United States and other major healthcare markets have occurred in recent years, and interpretation and application of such changes continue to evolve. These developments have included healthcare reform legislation enacted by certain states and implementation of the Patient Protection and Affordable Care Act (the "Affordable Care Act") enacted in 2010 which resulted in significant changes to the health care industry. These developments could, directly or indirectly, impose limitations on the prices we will be able to charge for our products, or the amounts of reimbursement available for our products from governmental agencies or third-party payers. These limitations could have a material adverse effect on our financial position and results of operations.

The Affordable Care Act includes significant provisions that encourage state and federal law enforcement agencies to increase activities related to preventing, detecting and prosecuting those who commit health care fraud and abuse. The Affordable Care Act continues to be implemented through regulation and government activity but is subject to possible amendment, additional implementing regulations and interpretive guidelines. The manner in which the Affordable Care Act continues to evolve could materially affect the extent to which and the amount at which medical devices and products are reimbursed by government programs such as Medicare, Medicaid and TRICARE. We cannot predict all impacts the Affordable Care Act may have on our products, but it may result in our products being chosen less frequently or the pricing being substantially lowered. Further, the Affordable Care Act has been subject to judicial and Congressional challenges, and legislative initiatives to modify, limit, or repeal the Affordable Care Act continue. For example, members of the current Congress have proposed additional legislative changes, including complete repeal and replacement of certain provisions of the Affordable Care Act. It remains to be seen, however, precisely what new healthcare reform legislation will be enacted, and what impact it will have on the availability of healthcare and containing or lowering the cost of healthcare. Such reforms could have an adverse effect on anticipated revenue from our products and may affect our overall financial condition and ability to develop future products.



Other healthcare reform proposals have emerged at the federal and state levels. We cannot predict the exact effect newly enacted laws or any future legislation or regulation will have on us. However, the implementation of new legislation and regulation may lower reimbursements for our products, reduce medical procedure volumes and adversely affect our business, possibly materially.

***If we cannot maintain relationships with certain of our suppliers, it may be difficult to replace those suppliers and our business may suffer.***

In general, raw materials essential to our business are readily available from multiple sources. However, for reasons of quality assurance, availability, or cost effectiveness, certain components and raw materials are available only from a sole supplier. Noble Biomaterials, Inc. is the principal manufacturer utilized in production of our TheraBond dressings. Noble Biomaterials, Inc. utilizes a proprietary and patented manufacturing process.

We believe that, due to the size and scale of production of our suppliers, there should be adequate supply of these raw materials from these manufacturers. In addition, our policy is to maintain sufficient inventory of components so that our production will not be significantly disrupted even if a particular component or material is not available for a period of time. However, there is no guarantee that our inventory will be sufficient to carry us through any disruption in supply. Because we have no direct control over our third-party suppliers, interruptions or delays in the products and services provided by these third parties may be difficult to remedy in a timely fashion. In addition, if such suppliers are unable or unwilling to deliver the necessary raw materials or products, we may be unable to redesign or adapt our technology to work without such raw materials or products or find alternative suppliers or manufacturers. In such events, we could experience interruptions, delays, increased costs or quality control problems.

Under our supply agreements with HLI, we receive finished goods from HLI. Because we have no direct control over HLI's suppliers, interruptions or delays in the products and services provided by these parties may be difficult to remedy in a timely fashion. In addition, if such suppliers are unable or unwilling to deliver the necessary products, we would be unable to sell any products that we expect from HLI, and, therefore, could experience a significant adverse impact on our revenue.

We purchase the MIST Therapy system from a single source and UltraMIST from a single source. Reliance on outside suppliers makes us vulnerable to a number of risks that could impact our ability to manufacture the MIST Therapy system and UltraMIST and/or disposable applicators, resulting in harm to our business, including:

- inability to obtain an adequate supply in a timely manner or on commercially reasonable terms;
- uncorrected defects that impact the performance, efficacy and safety of our products;
- difficulty identifying and qualifying alternative suppliers for components in a timely manner;
- production delays related to the evaluation and testing of products from alternative suppliers and corresponding regulatory qualifications;
- delays in delivery by our suppliers due to changes in demand from us or other customers; and
- delays in delivery or production stoppage by our supplier due to a shortage of one or more of the components comprising our product.

If the supply of the MIST Therapy system or UltraMIST or the disposable applicators or saline bottles is interrupted or significantly delayed and we are unable to acquire product from alternate sources in a timely manner and at a commercially reasonable price, our ability to meet our customers' demand would be impaired and our business could be harmed. Identifying and qualifying additional or replacement suppliers for the MIST Therapy system and/or UltraMIST or disposable applicators may not be accomplished quickly or at all and could involve significant additional costs. Interruption of supply from our suppliers or failure to obtain additional suppliers would limit our ability to distribute our products and could therefore have an adverse effect on our business.

***Contractual and other disagreements with or involving our licensors, distribution partners and other commercial partners could harm our business, make us liable to them or result in litigation costs or other expenses.***

Our agreements with licensors, distribution partners and other commercial partners require us to comply with performance conditions that are subject to interpretation and could result in disagreements. At any given time, we may be in disputes with one or more licensors, distribution partners or other commercial partners. Any such dispute could be very expensive for us, even if the outcome is ultimately in our favor. We cannot predict the outcome of any arbitration or litigation, the effect of any negative judgment against us or the amount of any settlement that we may enter into with such licensors, distribution partners or any other third-party. A contractual dispute may result in a licensor or other commercial partners seeking to terminate our agreements, which could harm our business, even if such termination would be wrongful.

***We are dependent upon third-party local distributors to market and distribute our products in key markets.***

We rely on third-party distributors for marketing and distribution of our products in certain markets, both domestically and internationally. Our success in generating sales in markets where we have engaged local distributors depends in part on the efforts of others whom we do not employ. Many of these distributors have only limited personnel, which could impair their ability to successfully market, sell and service our products. Because of limited resources or for other reasons, they may not comply with applicable local regulations or respond promptly to adverse event reporting requirements under FDA regulations. As a result of such failures to comply with regulatory requirements, we may experience significant loss of revenue, increased costs and damage to our reputation, and our business, financial condition and results of operations could be materially adversely affected. In addition, if a distributor is terminated by us or goes out of business, it may take us a period of time to locate an alternative distributor, to transfer or obtain appropriate regulatory approvals and to train our personnel to market our products, and our ability to sell and service our products in the region formerly serviced by such terminated distributor could be materially adversely affected. Any of these factors could materially adversely affect our revenue in markets served by distributors, increase our costs in those markets or damage our reputation.

***Security breaches and other disruptions could compromise our information and expose it to liability, which would cause our business and reputation to suffer.***

In the ordinary course of our business, we use networks to collect and store sensitive data, including intellectual property, proprietary business information and that of our customers, suppliers and business partners, personally identifiable information of our customers and employees, and data relating to patients who use our products. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, and regulatory penalties, disrupt our operations and the services we provide to customers, damage our reputation, and cause a loss of confidence in our products and services, which could adversely affect our operating margins, revenues and competitive position.

#### **Risks Related to Our Common Stock**

***Our stock price has been and may continue to be volatile, which could result in substantial losses for investors.***

The market price of our common stock has been and is likely to continue to be highly volatile and could fluctuate widely in response to various factors, many of which are beyond our control, including the following:

- technological innovations or new products and services by or our competitors;
- additions or departures of key personnel;
- sales of our common stock, particularly under any registration statement for the purposes of selling any other securities, including management shares;
- our ability to execute our business plan;
- operating results that fall below expectations;
- loss of any strategic relationship;
- industry developments;
- economic, political and other external factors; and
- period-to-period fluctuations in our financial results.

In addition, the securities markets have from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also significantly affect the market price of our common stock.





***Our common stock could be delisted from The Nasdaq Capital Market if we fail to regain compliance with the minimum bid price requirement of \$1.00 per share for continued listing within the time period required by the Nasdaq Listing Rules.***

On October 12, 2016, we received written notice from the Listing Qualifications Department of the Nasdaq Stock Market (“Nasdaq”) indicating that, based upon the closing bid price of our common stock for the last 30 consecutive business days, we did not meet the minimum bid price of \$1.00 per share required for continued listing on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we had 180 calendar days, or until April 10, 2017, to cure the deficiency and regain compliance with the minimum bid price requirement. If we do not regain compliance by April 10, 2017, an additional 180 days may be granted to regain compliance if we (i) meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market (except for the bid price requirement) and (ii) provide written notice to Nasdaq of our intention to cure the deficiency during the second 180-day compliance period, by effecting a reverse stock split, if necessary.

On April 6, 2017, we provided such notice to Nasdaq requesting an additional 180 calendar day period to regain compliance with the minimum bid price requirement, and announcing our intention to regain compliance during this period by effecting a reverse stock split, if necessary.

On April 11, 2017, we received a letter from Nasdaq notifying us that we have been granted an additional 180 calendar days, or until October 9, 2017, to regain compliance with the minimum bid price of \$1.00 per share required for continued listing on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2).

If at any time before October 9, 2017, the bid price of our common stock closes at or above \$1.00 per share for a minimum of 10 consecutive business days, Nasdaq will provide written notification that we have achieved compliance with Nasdaq Listing Rule 5550(a)(2).

If compliance with Nasdaq Listing Rule 5550(a)(2) cannot be demonstrated by October 9, 2017, Nasdaq will provide written notification that our common stock will be delisted. At that time, we may appeal Nasdaq’s determination to a Hearings Panel. There can be no assurance that we will be able to regain compliance with the minimum bid price requirement.

If our common stock is delisted from The Nasdaq Capital Market, our ability to raise capital in the future may be limited. Delisting could also result in less liquidity for our stockholders and a lower stock price. Such a delisting would likely have a negative effect on the price of our common stock and would impair the ability to readily sell or purchase our common stock. Although we expect to take actions to restore our compliance with Nasdaq’s listing requirements, we can provide no assurance that any action taken by us would be successful, or that any such action would stabilize the market price or improve the liquidity of our common stock.

***Our stock price, and the stock price of many other life science companies, have suffered significant declines over the past 12 months.***

Market prices for securities of life sciences companies, particularly companies like ours with limited product revenues, have been highly volatile and have suffered sharp losses over the past 12 months. As a result of these declines, it has become much harder for life sciences companies, like us, to raise money, as needed, in the capital markets. As such, should we desire to sell equity in the future to raise capital, such capital may not be available on favorable terms, or at all. In addition, any such capital raises could be highly dilutive to current stockholders. Depressed valuations of our stock will also make it harder for us to consummate strategic transactions or acquisitions, which have historically been a significant part of our growth strategy, absent significant dilution to our current investors.

***We do not expect to pay dividends in the future. As a result, any return on investment may be limited to the value of our common stock.***

We do not anticipate paying any dividends in the foreseeable future. Our Credit Agreement prohibits us from paying cash dividends or distributions on our capital stock. Even if we are permitted to pay cash dividends in the future, we currently intend to retain any future earnings for funding growth. As a result, an investor should not rely on an investment in our securities if such investor requires dividend income. Capital appreciation, if any, of our shares may be the only source of gain on our securities for the foreseeable future. Moreover, an investor may not be able to re-sell such investor’s shares at or above the price paid for them.

***We are subject to financial reporting and other requirements that place significant demands on our resources.***

We are subject to reporting and other obligations under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), including the requirements of Section 404 of the Sarbanes-Oxley Act of 2002. Section 404 requires us to conduct an annual management assessment of the effectiveness of our internal controls over financial reporting. These reporting and other obligations place significant demands on our management, administrative, operational, internal audit and accounting resources. Any failure to maintain effective internal controls could have a material adverse effect on our business, operating results and stock price. Moreover, effective internal control is necessary for us to provide reliable financial reports and prevent fraud. If we cannot provide reliable financial reports or prevent fraud, we may not be able to manage our business as effectively as we would if an effective control environment existed, and our business and reputation with investors may be harmed.

***There are inherent limitations in all control systems, and misstatements due to error or fraud may occur and not be detected.***

The ongoing internal control provisions of Section 404 of the Sarbanes-Oxley Act of 2002 require us to identify material weaknesses in internal control over financial reporting, which is a process to provide reasonable assurance regarding the reliability of financial reporting for external purposes in accordance with accounting principles generally accepted in the United States. Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our internal controls and disclosure controls will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. In addition, the design of a control system must reflect the fact that there are resource constraints and the benefit of controls must be relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, in our company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple errors or mistakes. Further, controls can be circumvented by individual acts of some persons, by collusion of two or more persons, or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving our stated goals under all potential future conditions. Over time, a control may be inadequate because of changes in conditions, such as growth of the company or increased transaction volume, or the degree of compliance with the policies or procedures may deteriorate. Because of inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

In addition, discovery and disclosure of a material weakness, by definition, could have a material adverse impact on our financial statements. Such an occurrence could discourage certain customers or suppliers from doing business with us, cause downgrades in our future debt ratings leading to higher borrowing costs and affect how our stock trades. This could, in turn, negatively affect our ability to access public debt or equity markets for capital.

***Our board of directors can authorize the issuance of preferred stock, which could diminish the rights of holders of our common stock, and make a change of control of it more difficult even if it might benefit our stockholders.***

Our board of directors is authorized to issue shares of preferred stock in one or more series and to fix the voting powers, preferences and other rights and limitations of the preferred stock. Accordingly, we may issue shares of preferred stock with a preference over our common stock with respect to dividends or distributions on liquidation or dissolution, or that may otherwise adversely affect the voting or other rights of the holders of common stock. Issuances of preferred stock, depending upon the rights, preferences and designations of the preferred stock, may have the effect of delaying, deterring or preventing a change of control, even if that change of control might benefit our stockholders.

***Offers or availability for sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.***

Sales of a significant number of shares of our common stock in the public market could harm the market price of our common stock and make it more difficult for us to raise funds through future offerings of common stock. As additional shares of our common stock become available for resale in the public market, the supply of our common stock will increase, which could decrease the price of our common stock.

In addition, if our stockholders sell substantial amounts of our common stock in the public market, upon the expiration of any statutory holding period under Rule 144, upon the expiration of lock-up periods applicable to outstanding shares, or upon the exercise of outstanding options or warrants, it could create a circumstance commonly referred to as an “overhang,” in anticipation of which the market price of our common stock could fall. The existence of an overhang, whether or not sales have occurred or are occurring, could also make it more difficult for us to raise additional financing through the sale of equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate.

***If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.***

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about it or our business. Although we currently have research coverage by securities and industry analysts, you should not invest in our common stock in anticipation that we will increase such coverage. If one or more of the analysts who covers us at any given time downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analyst’s ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

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

### **(a) Unregistered Sales of Equity Securities**

None

## (b) Issuer Purchases of Equity Securities

The following table sets forth information with respect to purchases by us of our equity securities during the three months ended March 31, 2017:

### Issuer's Purchases of Equity Securities

<u>Period</u>	<u>Total number of shares (or units) purchased</u>	<u>Average price paid per share (or unit)(1)</u>	<u>Total number of shares (or units) purchased as part of publicly announced plans or programs</u>	<u>Maximum number (or approximate dollar value) of shares (or units) that may yet be purchased under the plans or programs</u>
1/1/2017 to 1/31/2017	-	\$ -	-	-
2/1/2017 to 2/28/2017	99,437	0.54	-	-
3/1/2017 to 3/31/2017	-	-	-	-
<b>Total</b>	<b>99,437</b>	<b>\$ 0.54</b>	<b>-</b>	<b>-</b>

(1) For purposes of determining the number of shares to be surrendered to meet tax withholding obligations, the price per share deemed to be paid was the closing price of our common stock on the NASDAQ Capital Market on the applicable vesting date.

(2) Includes 11,763 shares of our common stock surrendered by an employee to pay tax withholding obligations incurred in connection with the vesting of restricted stock on February 6, 2017, 39,270 shares of our common stock surrendered by employees to pay tax withholding obligations incurred in connection with the vesting of restricted stock on February 9, 2017, and 48,404 shares of our common stock surrendered by an employee to pay tax withholding obligations incurred in connection with the vesting of restricted stock on February 21, 2017.

### ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

### ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

### ITEM 5. OTHER INFORMATION

#### *Adjustment to November 2012 Warrants*

On April 3, 2017, we closed an underwritten public offering of 9,473,250 shares of our common stock at a price to the public of \$0.40 per share. Pursuant to an anti-dilution provision provided in the warrants dated November 8, 2012 to purchase common stock at an initial exercise price of \$2.19, the exercise price of these warrants was adjusted to the public offering price of \$0.40. As of April 3, 2017, November 2012 warrants to purchase 362,293 shares of our common stock were outstanding. These warrants expire in November 2017.

#### *Issuance of Additional Shares under the Securities Purchase Agreement*

The Securities Purchase Agreement entered into in the Private Placement contains a “most-favored nation provision” that provides that if we, during 120 days from February 27, 2017, issue or sell any common stock or common stock equivalents reasonably believed to be more favorable in terms or conditions than those in the Private Placement, then we must amend the terms of the Securities Purchase Agreement to give these private investors the benefit of such favorable terms or conditions. Following the Public Offering, in accordance with this provision, on April 11, 2017, we issued an aggregate of 380,717 shares of our common stock to these investors. We will issue 1,004,283 additional shares of common stock if we obtain stockholder approval as required by the applicable rules and regulations of the NASDAQ Capital Market.

### ITEM 6. EXHIBITS

See “Index to Exhibits” for a description of our exhibits.

**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.

**ALLIQUA BIOMEDICAL, INC.**

Date: May 9, 2017

By: /s/ David Johnson  
Name: David Johnson  
Title: Chief Executive Officer  
(Principal Executive Officer)

By: /s/ Brian M. Posner  
Name: Brian M. Posner  
Title: Chief Financial Officer  
(Principal Financial Officer)

## Index to Exhibits

<b>Exhibit No.</b>	<b>Description</b>
3.1	Certificate of Incorporation of Alliqua BioMedical, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on June 11, 2014).
3.2	Bylaws of Alliqua BioMedical, Inc. (incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K filed on June 11, 2014).
3.3	Certificate of Amendment to Certificate of Incorporation of Alliqua BioMedical, Inc. (incorporated by reference to Exhibit 3.3 to the Current Report on Form 8-K filed on June 11, 2014).
3.4	Certificate of Amendment to Certificate of Incorporation of Alliqua BioMedical, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on May 6, 2016).
4.1	Form of Underwriter Warrant, dated April 3, 2017, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on April 4, 2017.
10.1	Forbearance and Amendment Agreement, dated January 26, 2017, by and among Alliqua BioMedical, Inc., AquaMed Technologies, Inc. and Perceptive Credit Holdings, LP., incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on January 30, 2017.
10.2	Amended Warrant, dated January 26, 2017, by and between Alliqua BioMedical, Inc. and Perceptive Credit Holdings, LP., incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on January 30, 2017.
10.3	Form of Securities Purchase Agreement, dated February 27, 2017, by and between Alliqua BioMedical, Inc. and certain accredited investors, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on February 28, 2017.
10.4	Amendment No. 1 to Forbearance and Amendment Agreement, dated March 7, 2017, by and among Alliqua BioMedical, Inc., AquaMed Technologies, Inc. and Perceptive Credit Holdings, LP., incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on March 13, 2017.
10.5	Amended Warrant, dated March 7, 2017, by and between Alliqua BioMedical, Inc. and Perceptive Credit Holdings, LP., incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on March 13, 2017.
10.6	Side Letter, dated March 13, 2017, between Alliqua BioMedical Inc., and Celgene Corporation, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on March 15, 2017.
10.7	Side Letter, dated March 13, 2017, between Alliqua BioMedical Inc., and Jerome Zeldis, M.D., Ph.D., incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on March 15, 2017.
10.8	Amended Warrant, dated April 6, 2017, by and between Alliqua BioMedical, Inc. and Perceptive Credit Holdings, LP., incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on April 12, 2017.
31.1*	Certification of Chief Executive Officer Pursuant to Section 302 of Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer Pursuant to Section 302 of Sarbanes-Oxley Act of 2002.
32.1*	Certification of Chief Executive Officer Pursuant to Section 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Chief Financial Officer Pursuant to Section 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	The following materials from the Company's Quarterly Report on Form 10-Q for the fiscal quarter March 31, 2017, formatted in XBRL (eXtensible Business Reporting Language), (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Stockholders' Equity, (iv) Consolidated Statements of Cash Flows, and (v) Notes to the Consolidated Financial Statements.

\* Filed herewith.

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER  
PURSUANT TO RULES 13a-14(A) AND 15d-14(A)  
OF THE SECURITIES EXCHANGE ACT OF 1934**

I, David Johnson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Alliqua BioMedical, Inc. (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
  - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: May 9, 2017

By: /s/ David Johnson  
David Johnson  
Chief Executive Officer  
(Principal Executive Officer)

---

**CERTIFICATION OF CHIEF FINANCIAL OFFICER  
PURSUANT TO RULES 13a-14(A) AND 15d-14(A)  
OF THE SECURITIES EXCHANGE ACT OF 1934**

I, Brian M. Posner, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Alliqua BioMedical, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 9, 2017

By: /s/ Brian M. Posner  
Brian M. Posner  
Chief Financial Officer  
(Principal Financial Officer)

---



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

This certification is furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350) and accompanies the Quarterly Report on Form 10-Q (the "Form 10-Q") for the three months ended March 31, 2017, of Alliqua BioMedical, Inc. (the "Company"). I, David Johnson, the Chief Executive Officer and Principal Executive Officer of the Company, certify that, based on my knowledge:

- (1) The Form 10-Q fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company as of and for the periods covered in this report.

Date: May 9, 2017

By: /s/ David Johnson

Name: David Johnson

Title: Chief Executive Officer  
(Principal Executive Officer)

The foregoing certification is being furnished as an exhibit to the Form 10-Q pursuant to Item 601(b)(32) of Regulation S-K and Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code) and, accordingly, is not being filed as part of the Form 10-Q for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

---

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

This certification is furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350) and accompanies the Quarterly Report on Form 10-Q (the "Form 10-Q") for the three months ended March 31, 2017 of Alliqua BioMedical, Inc. (the "Company"). I, Brian M. Posner, the Chief Financial Officer and Principal Financial Officer of the Company, certify that, based on my knowledge:

- (1) The Form 10-Q fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company as of and for the periods covered in this report.

Date: May 9, 2017

By: /s/ Brian M. Posner

Name: Brian M. Posner

Title: Chief Financial Officer

(Principal Financial Officer)

The foregoing certification is being furnished as an exhibit to the Form 10-Q pursuant to Item 601(b)(32) of Regulation S-K and Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code) and, accordingly, is not being filed as part of the Form 10-Q for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

---