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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**Form 10-Q**

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

For the quarterly period ended September 30, 2016

Commission file number: 1-33818

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**ENTEROMEDICS INC.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction  
of incorporation)

**48-1293684**  
(IRS Employer  
Identification No.)

**2800 Patton Road, St. Paul, Minnesota 55113**  
(Address of principal executive offices, including zip code)

**(651) 634-3003**  
(Registrant's telephone number, including area code)

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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 entity)

Smaller Reporting Company

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

As of November 11, 2016, 113,154,501 shares of the registrant's Common Stock were outstanding.

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INDEX

PART I – FINANCIAL INFORMATION

<a href="#">Item 1. Condensed Consolidated Financial Statements (unaudited)</a>	3
<a href="#">Condensed Consolidated Balance Sheets at September 30, 2016 and December 31, 2015</a>	3
<a href="#">Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2016 and 2015</a>	4
<a href="#">Condensed Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2016 and 2015</a>	4
<a href="#">Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2016 and 2015</a>	5
<a href="#">Notes to Condensed Consolidated Financial Statements</a>	6
<a href="#">Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations</a>	20
<a href="#">Item 3. Quantitative and Qualitative Disclosures About Market Risk</a>	31
<a href="#">Item 4. Controls and Procedures</a>	31

PART II – OTHER INFORMATION

<a href="#">Item 1. Legal Proceedings</a>	31
<a href="#">Item 1A. Risk Factors</a>	31
<a href="#">Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</a>	32
<a href="#">Item 3. Defaults Upon Senior Securities</a>	32
<a href="#">Item 4. Mine Safety Disclosures</a>	33
<a href="#">Item 5. Other Information</a>	33
<a href="#">Item 6. Exhibits</a>	33
<a href="#">SIGNATURES</a>	33

**Registered Trademarks and Trademark Applications:** In the United States we have registered trademarks for VBLOC®, ENTEROMEDICS® and MAESTRO®, each registered with the United States Patent and Trademark Office, and trademark applications for VBLOC POWER TO CHOOSE and VBLOC POWER TO CHOOSE AND DESIGN. In addition, some or all of the marks VBLOC, ENTEROMEDICS, MAESTRO, MAESTRO SYSTEM ORCHESTRATING OBESITY SOLUTIONS, VBLOC POWER TO CHOOSE and VBLOC POWER TO CHOOSE AND DESIGN are the subject of either a trademark registration or application for registration in Australia, Brazil, China, the European Community, India, Kuwait, Mexico, Saudi Arabia, Switzerland and the United Arab Emirates. This Quarterly Report on Form 10-Q contains other trade names and trademarks and service marks of EnteroMedics and of other companies.

**PART I – FINANCIAL INFORMATION****ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****ENTEROMEDICS INC.  
Condensed Consolidated Balance Sheets  
(Unaudited)**

	<u>September 30, 2016</u>	<u>December 31, 2015</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 6,841,547	\$ 7,927,240
Accounts receivable	191,680	57,928
Inventory	2,133,861	1,686,324
Prepaid expenses and other current assets	371,386	831,495
Total current assets	9,538,474	10,502,987
Property and equipment, net	228,459	326,296
Other assets	809,390	757,802
Total assets	<u>\$ 10,576,323</u>	<u>\$ 11,587,085</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Current portion of convertible notes payable	\$ 4,439,133	\$ 717,391
Accounts payable	680,819	172,050
Accrued expenses	2,851,383	3,595,415
Accrued interest payable	—	1,172
Total current liabilities	7,971,335	4,486,028
Convertible notes payable, less current portion (net of discounts of \$217,306 and \$149,340 at September 30, 2016 and December 31, 2015, respectively)	1,236,867	549,791
Common stock warrant liability	212,915	2,877,817
Total liabilities	<u>9,421,117</u>	<u>7,913,636</u>
Commitments and contingencies (note 5)		
Stockholders' equity:		
Common stock, \$0.01 par value; 150,000,000 and 13,333,333 shares authorized at September 30, 2016 and December 31, 2015, respectively; 74,414,549 and 7,163,820 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	744,145	71,638
Additional paid-in capital	296,917,990	281,182,349
Accumulated deficit	<u>(296,506,929)</u>	<u>(277,580,538)</u>
Total stockholders' equity	1,155,206	3,673,449
Total liabilities and stockholders' equity	<u>\$ 10,576,323</u>	<u>\$ 11,587,085</u>

See accompanying notes to condensed consolidated financial statements.

**ENTEROMEDICS INC.**  
**Condensed Consolidated Statements of Operations**  
**(Unaudited)**

	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>	
	2016	2015	2016	2015
Sales	\$ 296,760	\$ 64,000	\$ 644,760	\$ 143,000
Cost of goods sold	146,631	23,346	342,070	54,109
Gross profit	<u>150,129</u>	<u>40,654</u>	<u>302,690</u>	<u>88,891</u>
Operating expenses:				
Selling, general and administrative	3,361,572	4,289,017	15,088,297	13,952,899
Research and development	1,253,390	1,762,013	3,879,378	6,451,406
Total operating expenses	<u>4,614,962</u>	<u>6,051,030</u>	<u>18,967,675</u>	<u>20,404,305</u>
Operating loss	<u>(4,464,833)</u>	<u>(6,010,376)</u>	<u>(18,664,985)</u>	<u>(20,315,414)</u>
Other income (expense):				
Interest income	1,493	157	4,991	1,446
Interest expense	(1,391,134)	(565,522)	(3,393,374)	(840,491)
Change in value of warrant liability	241,741	2,416,443	3,330,254	2,416,443
Change in value of convertible notes payable	(909,030)	—	(200,004)	—
Other, net	(700)	8,628	(3,272)	9,561
Net loss	<u>\$ (6,522,463)</u>	<u>\$ (4,150,670)</u>	<u>\$ (18,926,390)</u>	<u>\$ (18,728,455)</u>
Net loss per share—basic and diluted	<u>\$ (0.17)</u>	<u>\$ (0.60)</u>	<u>\$ (0.99)</u>	<u>\$ (3.35)</u>
<b>Shares used to compute basic and diluted net loss per share</b>	<b>38,781,980</b>	<b>6,931,306</b>	<b>19,162,561</b>	<b>5,587,847</b>

See accompanying notes to condensed consolidated financial statements.

**ENTEROMEDICS INC.**  
**Condensed Consolidated Statements of Comprehensive Loss**  
**(Unaudited)**

	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>	
	2016	2015	2016	2015
Net loss	<u>\$ (6,522,463)</u>	<u>\$ (4,150,670)</u>	<u>\$ (18,926,390)</u>	<u>\$ (18,728,455)</u>
Comprehensive loss	<u>\$ (6,522,463)</u>	<u>\$ (4,150,670)</u>	<u>\$ (18,926,390)</u>	<u>\$ (18,728,455)</u>

See accompanying notes to condensed consolidated financial statements.

**ENTEROMEDICS INC.**  
**Condensed Consolidated Statements of Cash Flows**  
**(Unaudited)**

	<u>Nine months ended September 30,</u>	
	<u>2016</u>	<u>2015</u>
<b>Cash flows from operating activities:</b>		
Net loss	\$(18,926,390)	\$(18,728,455)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	109,382	146,292
Loss on sale of equipment	—	885
Stock-based compensation	2,201,949	4,357,742
Amortization of commitment fees, debt issuance costs and original issue discount	1,596,093	754,242
Change in value of convertible notes payable	200,004	—
Change in value of warrant liability	(3,330,254)	(2,416,443)
Change in operating assets and liabilities:		
Accounts receivable	(133,752)	(22,300)
Inventory	(447,537)	(395,504)
Prepaid expenses and other current assets	459,970	189,097
Other assets	(290,480)	(66,643)
Accounts payable	508,769	(198,864)
Accrued expenses	(744,036)	(346,245)
Accrued interest payable	1,673,793	(514,937)
Net cash used in operating activities	<u>(17,122,489)</u>	<u>(17,241,133)</u>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(11,544)	(37,263)
Net cash used in investing activities	<u>(11,544)</u>	<u>(37,263)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from sale of common stock and warrants for purchase of common stock	—	22,651,932
Common stock financing costs	(28,000)	(1,731,714)
Proceeds from convertible notes payable	17,250,000	—
Repayments on convertible notes payable	(446,867)	—
Repayments on notes payable	—	(3,000,000)
Debt issuance costs	(726,793)	—
Net cash provided by financing activities	<u>16,048,340</u>	<u>17,920,218</u>
Net increase (decrease) in cash and cash equivalents	<u>(1,085,693)</u>	<u>641,822</u>
<b>Cash and cash equivalents:</b>		
Beginning of period	7,927,240	11,619,167
End of period	<u>\$ 6,841,547</u>	<u>\$ 12,260,989</u>
<b>Supplemental disclosure:</b>		
Cash paid for interest	\$ 169,259	\$ 601,185
<b>Noncash investing and financing activities:</b>		
Conversion of convertible notes and interest payable	\$ 14,234,201	\$ —

See accompanying notes to condensed consolidated financial statements.

**EnteroMedics Inc.**  
**Notes to Condensed Consolidated Financial Statements**  
**(Unaudited)**

**(1) Summary of Significant Accounting Policies**

***Description of Business***

EnteroMedics Inc. (the Company) develops and sells implantable systems to treat obesity, metabolic diseases and other gastrointestinal disorders. The Company was incorporated in the state of Minnesota on December 19, 2002 and was reincorporated in Delaware on July 22, 2004. The Company is headquartered in St. Paul, Minnesota. In January 2006, the Company established EnteroMedics Europe S arl, a wholly-owned subsidiary located in Switzerland.

The Company's board of directors and stockholders approved a 1-for-15 reverse split (the Reverse Stock Split) of the Company's outstanding common stock that became effective after trading on January 6, 2016. The Reverse Stock Split did not change the par value of the Company's stock or the number of preferred shares authorized by the Company's Fifth Amended and Restated Certificate of Incorporation. An amendment to the Certificate of Incorporation was also approved in connection with the Reverse Stock Split to increase the number of shares of the Company's common stock authorized for issuance to 150 million shares, effective immediately after the Reverse Stock Split on January 6, 2016. All share and per share amounts have been retroactively adjusted to reflect the Reverse Stock Split for all periods presented.

***Risks and Uncertainties***

The Company is focused on the design and development of medical devices that use neuroblocking technology to treat obesity, metabolic diseases and other gastrointestinal disorders and currently has approvals to commercially launch the vBloc Rechargeable System in the United States, the European Economic Area and other countries that recognize the European CE Mark. The Company has devoted substantially all of its resources to recruiting personnel, developing its product technology, obtaining patents to protect its intellectual property and raising capital, and has recently commenced commercial operations in the United States deriving revenues from its primary business activity in 2015.

The Company's products require approval from the U.S. Food and Drug Administration (FDA) or corresponding foreign regulatory agencies prior to commercial sales. The Company received FDA approval on January 14, 2015 for vBloc Therapy, delivered via the vBloc Rechargeable System, and has begun a controlled commercial launch at select surgical centers in the United States. The vBloc Rechargeable System has also received CE Mark and was previously listed on the Australian Register of Therapeutic Goods (ARTG).

The medical device industry is characterized by frequent and extensive litigation and administrative proceedings over patent and other intellectual property rights. Whether a product infringes a patent involves complex legal and factual issues, the determination of which is often difficult to predict, and the outcome may be uncertain until the court has entered final judgment and all appeals are exhausted. The Company's competitors may assert that its products or the use of the Company's products are covered by U.S. or foreign patents held by them.

The Company's activities are subject to significant risks and uncertainties, including the ability to obtain additional financing, and there can be no assurance that the Company will be successful in obtaining additional financing on favorable terms, or at all. If adequate funds are not available, the Company may have to further reduce its cost structure until financing is obtained and/or delay development or commercialization of products or license to third parties the rights to commercialize products or technologies that the Company would otherwise seek to commercialize.

***Basis of Presentation***

The Company has prepared the accompanying condensed consolidated financial statements in conformity with accounting principles generally accepted in the United States of America. The Company's fiscal year ends on December 31.

The accompanying condensed consolidated financial statements and notes thereto are unaudited. In the opinion of the Company's management, these statements include all adjustments, which are of a normal recurring nature, necessary to present a fair presentation. Interim results are not necessarily indicative of results for a full year. The condensed consolidated balance sheet as of December 31, 2015 was derived from audited consolidated financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America. The information included in this Form 10-Q should be read in conjunction with the Company's Annual Report on Form 10-K for the year ended December 31, 2015.

## [Table of Contents](#)

### ***Use of Estimates***

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

### ***Principles of Consolidation***

The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary. All intercompany transactions and accounts have been eliminated in consolidation.

### ***Fair Value of Financial Instruments***

Carrying amounts of certain of the Company's financial instruments, including cash and cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued liabilities approximate fair value due to their short maturities. The Company's common stock warrants are required to be reported at fair value and the Company has elected to report its senior amortizing convertible notes at fair value. The fair values of common stock warrants and investments in debt and equity securities, if any, are disclosed in Note 3. The fair value of the Company's senior amortizing convertible notes is disclosed in Notes 3 and 7.

### ***Common Stock Warrant Liability***

Common stock warrants that were issued in connection with the July 8, 2015 public offering and the November 9, 2015, January 11, 2016 and May 2, 2016 senior amortizing convertible notes are classified as a liability in the condensed consolidated balance sheets, as the common stock warrants issued provide for certain anti-dilution protections in the event shares of common stock or securities convertible into shares of common stock are issued below the then-existing exercise price. The fair value of these common stock warrants is re-measured at each financial reporting period and immediately before exercise, with any changes in fair value being recognized as a component of other income (expense) in the condensed consolidated statements of operations.

### ***Cash and Cash Equivalents***

The Company considers highly liquid investments generally with maturities of 90 days or less when purchased to be cash equivalents. Cash equivalents are stated at cost, which approximates market value. The Company's cash equivalents are primarily in money market funds and certificates of deposit. The Company deposits its cash and cash equivalents in high-quality credit institutions.

### ***Short-Term Investments***

The Company considers all investments with maturities greater than three months and less than one year at the time of purchase as short-term investments and classifies them as either available for sale or held to maturity. The Company also considers certain investments with maturities greater than one year but which are also held for liquidity purposes and are available for sale as short-term investments.

Available-for-sale securities are carried at fair value based on quoted market prices, with the unrealized gains and losses included in other comprehensive income within stockholders' equity in the condensed consolidated balance sheets. Realized gains and losses and declines in value judged to be other than temporary on available-for-sale securities are included in interest and other income. Interest and dividends on securities classified as available for sale are included in interest income. The cost of securities sold is based on the specific identification method.

Short-term investments in debt securities which the Company has the positive intent and ability to hold to maturity are reported at cost, adjusted for premiums and discounts that are recognized in interest income, using the interest method, over the period to maturity. Unrealized losses on held-to-maturity securities reflecting a decline in value determined to be other than temporary are charged to income.

### ***Inventory***

The Company accounts for inventory at the lower of cost or market and records any long-term inventory as other assets in the condensed consolidated balance sheets.

## [Table of Contents](#)

### ***Property and Equipment, Net***

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation of property and equipment is computed using the straight-line method over their estimated useful lives of five to seven years for furniture and equipment and three to five years for computer hardware and software. Leasehold improvements are amortized on a straight-line basis over the lesser of their useful life or the term of the lease. Upon retirement or sale, the cost and related accumulated depreciation or amortization are removed from the condensed consolidated balance sheets and the resulting gain or loss is reflected in the condensed consolidated statements of operations. Repairs and maintenance are expensed as incurred.

### ***Impairment of Long-Lived Assets***

The Company evaluates its long-lived assets for impairment by comparison of the carrying amounts to future net undiscounted cash flows expected to be generated by such assets when events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. Should an impairment exist, the impairment loss would be measured based on the excess carrying value of the asset over the asset's fair value or estimates of future discounted cash flows. The Company has not identified any such impairment losses to date.

### ***Income Taxes***

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carry-forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance for deferred income tax assets is recorded when it is more likely than not that some portion or all of the deferred income tax assets will not be realized. The Company has provided a full valuation allowance against the gross deferred tax assets. The Company's policy is to classify interest and penalties related to income taxes as income tax expense in the condensed consolidated statements of operations.

### ***Medical Device Excise Tax***

On January 14, 2015, the Company received FDA approval for vBloc Therapy, delivered via the vBloc Rechargeable System, and starting in the second quarter of 2015 revenues were generated from sales in the United States. As a result, the Company is now required to pay a quarterly Medical Device Tax which is a part of the Affordable Care Act, which imposes a 2.3% excise tax on the sale of certain medical devices by device manufactures, producers or importers. The excise tax was effective on sales of devices made after December 31, 2012. The Company records the Medical Device Tax as an operating expense in the condensed consolidated statements of operations. A moratorium was placed on the Medical Device Tax for 2016 and 2017.

### ***Comprehensive Loss***

Comprehensive loss is defined as the change in equity of a company during a period from transactions and other events and circumstances excluding transactions resulting from investment owners and distributions to owners. There was no difference from reported net loss for the three and nine months ended September 30, 2016 and 2015.

### ***Revenue Recognition***

Revenue is recognized when persuasive evidence of an arrangement exists, title or risk of loss has passed, the selling price is fixed or determinable and collection is reasonably assured. Products are sold through direct sales or medical device distributors and revenue is recognized upon sale to a bariatric center of excellence or a medical device distributor when no right of return or price protection exists. Terms of sales to international distributors are generally EXW, reflecting that goods are shipped "ex works," in which risk of loss is assumed by the distributor at the shipping point. A provision for returns is recorded only if product sales provide for a right of return. No provision for returns was recorded for the three and nine months ended September 30, 2016 and 2015, as the product sales recorded did not provide for rights of return.

### ***Research and Development Expenses***

Research and development expenses are charged to expense as incurred. Research and development expenses include, but are not limited to, product development, clinical trial expenses, including supplies, devices, explants and revisions, quality assurance, regulatory expenses, payroll and other personnel expenses, materials and consulting costs.



## [Table of Contents](#)

### **Net Loss Per Share**

Basic net loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is based on the weighted-average common shares outstanding during the period plus dilutive potential common shares calculated using the treasury stock method. Such potentially dilutive shares are excluded when the effect would be to reduce a net loss per share. The Company's potential dilutive shares, which include outstanding common stock options and warrants, have not been included in the computation of diluted net loss per share for all periods as the result would be anti-dilutive.

The following table sets forth the computation of basic and diluted net loss per share for the three and nine months ended September 30, 2016 and 2015:

	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
<b>Numerator:</b>				
Net loss	<u>\$ (6,522,463)</u>	<u>\$ (4,150,670)</u>	<u>\$ (18,926,390)</u>	<u>\$ (18,728,455)</u>
<b>Denominator for basic and diluted net loss per share:</b>				
Weighted-average common shares outstanding	<u>38,781,980</u>	<u>6,931,306</u>	<u>19,162,561</u>	<u>5,587,847</u>
Net loss per share—basic and diluted	<u>\$ (0.17)</u>	<u>\$ (0.60)</u>	<u>\$ (0.99)</u>	<u>\$ (3.35)</u>

The following table sets forth the potential shares of common stock that are not included in the calculation of diluted net loss per share because to do so would be anti-dilutive as of the end of each period presented:

	September 30,	
	2016	2015
Stock options outstanding	1,414,918	1,030,033
Warrants to purchase common stock	3,953,413	3,746,647

### **Recently Issued or Adopted Accounting Standards**

In March 2016, the Financial Accounting Standards Board (FASB) issued *Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting (Accounting Standards Update No. 2016-09 (ASU 2016-09))*. ASU 2016-09 modifies several aspects of the accounting for share-based payment awards, including income tax consequences, and classification on the statement of cash flows. This guidance will be effective for interim and annual reporting periods beginning after December 15, 2016. The Company is currently evaluating the impact of adopting ASU 2016-09 on its consolidated financial statements.

In May 2014, FASB issued *Revenue from Contracts with Customers, Topic 606 (Accounting Standards Update No. 2014-09 (ASU 2014-09))*, which provides a framework for the recognition of revenue, with the objective that recognized revenues properly reflect amounts an entity is entitled to receive in exchange for goods and services. This guidance will be effective for interim and annual reporting periods beginning after December 15, 2017. The Company is currently evaluating the impact of adopting ASU 2014-09 on its consolidated financial statements.

There have been no other significant changes in recent accounting pronouncements during the nine months ended September 30, 2016 as compared to the recent accounting pronouncements described in the Company's Annual Report on Form 10-K for the year ended December 31, 2015.

### **(2) Liquidity and Management's Plans**

The accompanying condensed consolidated financial statements have been prepared assuming the Company will continue as a going concern. The Company has financed its operations to date principally through the sale of equity securities, debt financing and interest earned on investments. As of September 30, 2016, the Company had \$6.8 million of cash and cash equivalents to fund its operations through 2016 and early 2017.

## Table of Contents

The Company's operations include plans that consider the controlled commercial launch of vBloc Therapy, delivered via the vBloc Rechargeable System, which was approved by the FDA on January 14, 2015. The Company believes that it has the ability to manage the growth of its expenditures and operations depending on the amount of available cash flows. However, the Company will ultimately need to achieve sufficient revenues from product sales and/or obtain additional debt or equity financing to support its operations.

On November 4, 2015, the Company entered into a securities purchase agreement (the Purchase Agreement) with institutional investors to issue \$25.0 million of senior amortizing convertible notes (the Notes) along with the accompanying warrants. \$1.5 million of the Notes was funded at the first closing on November 9, 2015 (the First Closing). An additional \$11.0 million of the Notes was funded at the second closing on January 11, 2016 (the Second Closing). Pursuant to two amendments to the Purchase Agreement entered into on May 2, 2016 (the First Amendment), and July 14, 2016 (the Second Amendment), \$6.25 million was funded at the third closing on May 2, 2016 (The Third Closing). The remaining amount, up to \$6.25 million, may be funded at the fourth closing, which can occur no later than December 1, 2016 (the Fourth Closing). In order for the Fourth Closing to occur, the holders of the Notes must waive certain conditions which are not currently satisfied due to recent declines in the Company's stock price. Such waivers have not yet been either requested or provided. These conditions include (i) the requirement that the average VWAP of the Company's stock price over the prior fifteen days be at least \$0.20 per share, (ii) that the Company's stock have an aggregate average daily dollar trading volume of more than \$100,000 over prior fifteen days, and (iii) that the Company have an adequate number of common shares available for conversions of principal and interest related to the Fourth Closing on the date of the Fourth Closing (collectively, the Closing Conditions) (see also Note 6).

In May 2016, the Company received written notices from the Nasdaq Stock Market Nasdaq stating that the Company was not in compliance with the following two Nasdaq listing requirements: (1) the requirement that the Company have a minimum of \$2.5 million stockholders' equity (the Stockholders' Equity Requirement) and (2) the \$1.00 minimum bid price stock price requirement (the Minimum Bid Requirement).

On July 19, 2016, the Company received a letter from Nasdaq granting the Company an extension until November 14, 2016 to regain compliance with the Stockholders' Equity Requirement. The extension was granted based on the plan the Company submitted to Nasdaq to regain compliance with the Stockholders' Equity Requirement through a combination of note conversions and accelerated principal amortizations and infusions of equity capital prior to the deadline. We received a notice of delisting on November 9, 2016, and intend to appeal to Nasdaq for a hearing before the Listing Qualification Panel prior to being delisted. The basis for the Company's appeal of the Nasdaq delisting notices is expected to consist of:

- Fourth quarter 2016 reductions in the Company's operating expense levels
- On November 7, 2016, the Company filed a preliminary proxy statement for a special meeting of our stockholders in order to obtain approval for, among other things, an increase in the number of common shares authorized to be issued and the authorization to effect a reverse-split of its common stock. While obtaining shareholder approval of each of these proposals is not certain, the Company believes it will be able to obtain stockholder approval for the authorized share increase and reverse stock split in December 2016.
- After stockholder approval is obtained, the Company intends to declare a reverse-split of its outstanding shares of common stock in such a ratio to increase its minimum bid stock price above the \$1.00 minimum required by Nasdaq while maintaining its current authorized share count,
- After stockholder approval is obtained to increase the number of authorized shares and the reverse stock split is implemented, the Company intends to conduct a firm commitment underwritten public offering consisting of common stock and warrants to purchase common stock in amounts sufficient to increase the Company's shareholder equity above the \$2.5 million Nasdaq minimum and to provide funding for the Company's operations for the foreseeable future. The Company has not yet obtained any commitments to participate in the offering and does not expect to obtain any commitments until after the stockholder meeting has occurred.

Failure of the Company to receive shareholder approval in December 2016 on the proposals to increase the number of authorized shares and the authorization of a reverse stock split will likely result in Nasdaq delisting and will significantly impair the Company's ability to raise the additional capital necessary to continue operations beyond the first quarter of 2017.

**(3) Short-term Investments and Fair Value Measurements**

Fair value of financial assets and liabilities is defined as the price that would be received to sell an asset or transfer a liability in an orderly transaction between market participants at the measurement date. A fair value hierarchy has been established that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy are described below:

- Level 1—Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.
- Level 2—Quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active or model-derived valuations for which all significant inputs are observable, either directly or indirectly.
- Level 3—Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable.

The Company's assets that are measured at fair value on a recurring basis are classified within Level 1 or Level 2 of the fair value hierarchy. The Company does not hold any assets that are measured at fair value using Level 3 inputs. The types of instruments the Company invests in that are valued based on quoted market prices in active markets may include U.S. treasury securities and money market funds. Such instruments are classified by the company within Level 1 of the fair value hierarchy. U.S. treasuries are valued using unadjusted quoted prices for identical assets in active markets that the Company can access.

The types of instruments the Company invests in that are valued based on quoted prices in less active markets, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency include the Company's U.S. agency securities, commercial paper, U.S. corporate bonds and municipal obligations. Such instruments are classified by the Company within Level 2 of the fair value hierarchy. The Company values these types of assets using consensus pricing or a weighted average price, which is based on multiple pricing sources received from a variety of industry standard data providers (e.g. Bloomberg), security master files from large financial institutions, and other third-party sources. The multiple prices obtained are then used as inputs into a distribution-curve-based algorithm to determine the daily market price.

The Company did not hold any short-term investments classified as available for sale or held to maturity as of September 30, 2016 and December 31, 2015.

The fair value of the Company's common stock warrant liability is calculated using a Black-Scholes valuation model and is classified as Level 2 in the fair value hierarchy. The common stock warrants issued July 8, 2015 had a fair value of \$172,981 and \$2,759,583 on September 30, 2016 and December 31, 2015, respectively. The common stock warrants issued November 9, 2015 had a fair value of \$14,488 and \$118,234 on September 30, 2016 and December 31, 2015, respectively. The common stock warrants issued January 11, 2016 had a fair value of \$15,610 and \$515,157 on September 30, 2016 and January 11, 2016, respectively. The common stock warrants issued May 2, 2016 had a fair value of \$9,836 and \$150,195 on September 30, 2016 and May 2, 2016, respectively. The fair value was calculated using the following assumptions:

	July 2015 Warrants		November 2015 Warrants	
	September 30, 2016	December 31, 2015	September 30, 2015	December 31, 2015
Risk-free interest rates	0.88%	1.31%	1.14%	1.76%
Expected life	27 months	36 months	49 months	58 months
Expected dividends	0%	0%	0%	0%
Expected volatility	97.89%	97.94%	96.40%	86.27%

  

	January 2016 Warrants		May 2016 Warrants	
	September 30, 2016	January 11, 2016	September 30, 2016	May 2, 2016
Risk-free interest rates	1.14%	1.58%	1.14%	1.32%
Expected life	51 months	60 months	55 months	60 months
Expected dividends	0%	0%	0%	0%
Expected volatility	96.12%	85.90%	94.95%	89.28%

## [Table of Contents](#)

The following table summarizes fair value measurements of the Notes and the common stock warrants issued in 2015 and during the nine months ended September 30, 2016 by level at September 30, 2016:

	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
Senior amortizing convertible notes			\$5,676,000	\$5,676,000
Common stock warrants		\$212,915		212,915
Total		<u>\$212,915</u>	<u>\$5,676,000</u>	<u>\$5,888,915</u>

Through September 30, 2016, the Company had converted \$3.2 million of the Notes' principal and interest into shares of common stock. For the three month and nine month periods ended September 30, 2016, respectively, there were losses of \$909,000 and \$200,000 recognized in the condensed consolidated statements of operations from changes in fair value of the Notes.

During the three months ended September 30, 2016, all remaining amounts outstanding from the First Closing were paid off via conversions into shares of common stock. As of December 31, 2015, the fair value of the outstanding Notes from the First Closing was determined to be \$1.3 million. On September 30, 2016 and January 11, 2016, the fair value of the outstanding Notes from the Second Closing was determined to be \$2.4 million and \$9.9 million, respectively. On September 30, 2016 and May 2, 2016, the fair value of the outstanding Notes from the Third Closing was determined to be \$3.2 million and \$6.0 million, respectively. The fair values were calculated using a Binomial Lattice model and the following assumptions:

	<u>November 2015 Notes</u>		<u>January 2016 Notes</u>	
	<u>September 30, 2016</u>	<u>December 31, 2015</u>	<u>September 30, 2016</u>	<u>January 11, 2016</u>
Risk-free interest rates	N/A	1.11%	0.65%	1.01%
Expected life	N/A	1.86 years	1.11 years	1.83 years
Expected dividends	N/A	0%	0%	0%
Expected volatility	N/A	57.5%	70.0%	60.0%
Fair value per share of common stock	N/A	\$ 1.95	\$ 0.14	\$ 1.33

	<u>May 2016 Notes</u>	
	<u>September 30, 2016</u>	<u>May 2, 2016</u>
Risk-free interest rates	0.65%	0.69%
Expected life	1.11 years	1.52 years
Expected dividends	0%	0%
Expected volatility	70.0%	65.0%
Fair value per share of common stock	\$ 0.14	\$ 0.80

#### **(4) Inventory**

From the Company's inception, inventory related purchases had been used for research and development related activities and had accordingly been expensed as incurred. In December 2011, the Company began receiving ARTG listings for components of the Maestro Rechargeable System from the Australian Therapeutic Goods Administration, with the final components being listed on the ARTG in January 2012. As a result, the Company determined certain assets were recoverable as inventory beginning in December 2011. The Company accounts for inventory at the lower of cost or market and records any long-term inventory as other assets in the condensed consolidated balance sheets. There was approximately \$686,000 and \$519,000 of long-term inventory, primarily consisting of raw materials, as of September 30, 2016 and December 31, 2015, respectively.

## [Table of Contents](#)

Current inventory consists of the following as of:

	September 30, 2016	December 31, 2015
Raw materials	\$ 686,629	\$ 576,898
Work-in-process	1,431,056	1,066,345
Finished goods	16,176	43,081
Inventory	<u>\$ 2,133,861</u>	<u>\$ 1,686,324</u>

### (5) Commitments and Contingencies

#### *Operating Lease*

The Company rents its office, warehouse and laboratory facilities under an operating lease, which was originally set to expire on September 30, 2015. On August 25, 2015, the Company entered into an amendment extending the term of the operating lease for three years until September 30, 2018, with monthly base rent ranging from \$18,925 to \$20,345. Total rent expense recognized for each of the three month periods ended September 30, 2016 and 2015 was \$58,905 and \$67,718, and for each of the nine month periods ended September 30, 2016 and 2015 was \$176,175 and \$203,154. At September 30, 2016, future minimum payments under the lease are as follows:

<u>Year ending December 31:</u>	
Remaining three months in 2016	\$ 58,905
2017	235,620
2018	176,715
	<u>\$471,240</u>

#### *Product Liability Claims*

The Company is exposed to product liability claims that are inherent in the testing, production, marketing and sale of medical devices. Management believes any losses that may occur from these matters are adequately covered by insurance, and the ultimate outcome of these matters will not have a material effect on the Company's financial position or results of operations. The Company is not currently a party to any litigation and is not aware of any pending or threatened litigation that could have a material adverse effect on the Company's business, operating results or financial condition.

#### *Clinical Trials*

The Company is evaluating the vBloc System in human clinical trials, including the EMPOWER trial and ReCharge trial. Both of these clinical trials require patients to be followed out to 60 months. The Company is required to pay for patient follow up visits only to the extent they occur. In the event a patient does not attend a follow up visit, the Company has no financial obligation. The Company is also required to pay for explants or revisions, including potential conversions of ReCharge control devices to active devices, should a patient request or be required to have one during the course of the clinical trials. The Company has no financial obligation unless an explant, revision or conversion is requested or required. Clinical trial costs are expensed as incurred.

### (6) Senior Amortizing Convertible Notes

On November 4, 2015, the Company entered into the Purchase Agreement to issue and sell to four institutional investors 7% senior amortizing convertible notes due 2017 in three separate closings. The Notes were initially convertible into shares of the Company's common stock at a price equal to \$4.35 per share with an aggregate principal amount of \$25.0 million. Each Note was sold with a warrant to purchase a share of common stock (the Warrants) with an exercise price of \$4.65 per share. The Company issued and sold Notes and Warrants for aggregate total proceeds of \$12.5 million in two separate closings through March 31, 2016, and after entering into the First Amendment, which provided that the scheduled third closing would be split into two separate closings, issued and sold Notes and Warrants for aggregate total proceeds of \$6.25 million in the Third Closing. The Company may issue and sell Notes and Warrants for aggregate total proceeds of up to \$6.25 million in the Fourth Closing, which pursuant to the Second Amendment, is scheduled to occur no later than December 1, 2016. The Second Amendment provided the holders' consent to the

## [Table of Contents](#)

Company reducing the conversion price of the Notes from time to time in order to incentivize the holders of the Notes to convert their Notes into shares of the Company's common stock. Since entering into the Second Amendment, we have experienced a significant increase in accelerated principal and interest conversions at the election of the holders and we have continued to offer incentives to the holders of the Notes to facilitate conversions of the outstanding Notes into equity. In addition, at the Fourth Closing, the holders of the Notes will be obligated to purchase at least 50% of the aggregate principal of the Notes they convert, either on a voluntary or installment conversion basis, on and after July 1, 2016, up to an aggregate principal amount of \$6.25 million, although no holder will be obligated to purchase more Notes than originally scheduled in the First Amendment. During the third quarter of 2016, \$9.8 million of aggregate principal amount of Notes were converted by holders of the Notes into approximately 60.2 million shares. Between October 1, 2016 and November 11, 2016, \$3.2 million of aggregate principal amount of Notes were converted by holders of the Notes into approximately 39.7 million shares of the Company's common stock.

### ***Description of the Notes***

The Notes are payable in monthly installments, accrue interest at a rate of 7.0% per annum from the date of issuance and will mature 24 months after the First Closing, unless converted or redeemed earlier. The Notes may be repaid, at the Company's election, in either cash or shares of the Company's common stock at a discount to the then-current market price. The Notes are also convertible from time to time, at the election of the holders, into shares of the Company's common stock at an initial conversion price of \$4.35 per share. The conversion price was adjusted to \$1.09 per share on January 29, 2016, the 16<sup>th</sup> trading day following the Reverse Stock Split, per the terms of the Notes.

The holder of each Note has the right to convert any portion of such Note unless the holder, together with its affiliates, beneficially owns in excess of 4.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to the conversion, as such percentage ownership is determined in accordance with the terms of the Notes. However, any holder may increase or decrease such percentage to any other percentage, but in no event above 9.99%, provided that any increase of such percentage will not be effective until 61 days after providing notice to the Company.

The Company has determined that the conversion feature in the Notes requires bifurcation and liability classification and measurement, at fair value, and requires evaluation at each reporting period. Under Accounting Standards Codification (ASC) 825, Financial Instruments, the FASB provides an alternative to bifurcation and companies may instead elect fair value measurement for the entire instrument, including the debt and conversion feature. The Company has elected the fair value alternative in order to simplify its accounting and reporting of the Notes upon issuance. The fair value of the Warrants is recorded as a discount to the Notes and amortized to interest expense following the effective interest rate method over the term of the Notes.

The First Closing occurred on November 9, 2015. At the First Closing, the Company issued and sold Notes with an aggregate principal amount of \$1.5 million, along with Warrants exercisable for 117,520 shares. During the quarter ended September 30, 2016, all remaining principal and interest amounts outstanding under Notes issued at the First Closing were paid off via conversions to common shares.

The Second Closing occurred on January 11, 2016 after the Company received approval of the offering by the Company's stockholders and the satisfaction of certain customary closing conditions. At the Second Closing, the Company issued and sold Notes with an aggregate principal amount of \$11.0 million, along with Warrants exercisable for 861,842 shares. The fair value of the Warrants issued on January 11, 2016 was determined to be \$515,000 using a Black-Scholes valuation model and the following assumptions: (1) dividend yield of 0%; (2) expected volatility of 85.90%; (3) weighted average risk-free interest rate of 1.58%; and (4) expected life of 5.0 years.

The Third Closing occurred on May 2, 2016 after the Company entered into the First Amendment and satisfied certain closing conditions. At the Third Closing, the Company issued and sold Notes with an aggregate principal amount of \$6.25 million, along with Warrants exercisable for 489,684 shares.

At the Fourth Closing, the Company may be required to issue and sell Notes with an aggregate principal amount of up to \$6.25 million, along with Warrants exercisable for 489,682 shares, but only if the holders of the Notes waive the requirement that the Company be in compliance with the Closing Conditions at the Fourth Closing.

## [Table of Contents](#)

The following table summarizes the installment amounts and additional conversions by the holders of the Notes issued at the First Closing through September 30, 2016:

	Principal	Interest	Total	Common Shares
Installment amount at December 31, 2015	\$ 65,217	\$ 23,651	\$ 88,868	56,967
Holder conversions during the quarter ended December 31, 2015	18,261	2,375	20,636	13,228
<b>Balance, December 31, 2015</b>	<b>83,478</b>	<b>26,026</b>	<b>109,504</b>	<b>70,195</b>
Installment amount at February 29, 2016	65,217	23,681	88,898	91,953
Installment amount at March 31, 2016	65,217	14,827	80,044	88,960
Holder conversions during the quarter ended March 31, 2016	104,784	12,762	117,546	106,684
<b>Balance, March 31, 2016</b>	<b>318,696</b>	<b>77,296</b>	<b>395,992</b>	<b>357,792</b>
Installment amount at April 30, 2016	65,217	13,853	79,070	101,764
Installment amount at May 31, 2016	65,217	13,082	78,299	148,467
Installment amount at June 30, 2016	54,217	11,275	65,492	251,320
Holder conversions during the quarter ended June 30, 2016	1,627	174	1,801	2,000
<b>Balance, June 30, 2016</b>	<b>504,974</b>	<b>115,680</b>	<b>620,654</b>	<b>861,343</b>
Installment amount at July 31, 2016	65,217	10,148	75,365	386,492
Installment amount at August 31, 2016	46,957	5,830	52,787	321,505
Holder conversions during the quarter ended September 30, 2016	882,852	78,634	961,486	5,076,930
<b>Balance, September 30, 2016</b>	<b>\$1,500,000</b>	<b>\$210,292</b>	<b>\$1,710,292</b>	<b>6,646,270</b>

The following table summarizes the installment amounts and additional conversions by the holders of the Notes issued at the Second Closing through September 30, 2016:

	Principal	Interest	Total	Common Shares
Installment amount at March 2, 2016	\$ 404,762	\$ 149,300	\$ 554,062	*
Holder conversions during the quarter ended March 31, 2016	987,000	124,050	1,111,050	1,048,167
<b>Balance, March 31, 2016</b>	<b>1,391,762</b>	<b>273,350</b>	<b>1,665,112</b>	<b>1,048,167</b>
Installment amount at April 29, 2016	404,762	149,497	554,259	713,334
Installment amount at May 31, 2016	291,428	86,518	377,946	716,625
Installment amount at June 30, 2016	404,762	82,913	487,675	1,598,908
Holder conversions during the quarter ended June 30, 2016	25,373	2,995	28,368	29,000
<b>Balance, June 30, 2016</b>	<b>2,518,087</b>	<b>595,273</b>	<b>3,113,360</b>	<b>4,106,034</b>
Installment amount at July 31, 2016	213,429	47,457	260,886	1,337,879
Installment amount at August 31, 2016	631,429	116,511	747,940	4,536,725
Installment amount at September 30, 2016	404,762	45,846	450,608	3,618,881
Holder conversions during the quarter ended September 30, 2016	4,868,679	418,847	5,287,526	29,277,719
<b>Balance, September 30, 2016</b>	<b>\$8,636,386</b>	<b>\$1,223,934</b>	<b>\$9,860,320</b>	<b>42,877,238</b>

## [Table of Contents](#)

The following table summarizes the installment amounts and additional conversions by the holders of the Notes issued at the Third Closing through September 30, 2016:

	<u>Principal</u>	<u>Interest</u>	<u>Total</u>	<u>Common Shares</u>
Installment amount at June 30, 2016	\$ 212,158	\$ 90,659	\$ 302,817	1,162,000
Holder conversions during the quarter ended June 30, 2016	—	—	—	—
<b>Balance, June 30, 2016</b>	<b>\$ 212,158</b>	<b>\$ 90,659</b>	<b>\$ 302,817</b>	<b>1,162,000</b>
Installment amount at July 31, 2016	147,368	32,374	179,742	921,757
Cash Payment – July 31, 2016 installment	42,105	6,107	48,212	*
Installment amount at August 31, 2016	336,842	62,059	398,901	2,427,886
Installment amount at September, 2016	263,158	41,822	304,980	2,416,643
Holder conversions during the quarter ended September 30, 2016	1,915,698	175,092	2,090,790	10,869,063
<b>Balance September 30, 2016</b>	<b>\$2,917,329</b>	<b>\$408,113</b>	<b>\$3,325,442</b>	<b>17,797,349</b>

\* Cash payments

### *Description of the Warrants*

Each Warrant is exercisable immediately and for a period of 60 months from the date of the issuance of the Warrant. Upon the completion of the Fourth Closing, the Warrants will entitle the holders of the Warrants to purchase, in aggregate, 1,958,728 shares of the Company's common stock, subject to certain adjustments. The Warrants were initially exercisable at an exercise price equal to \$4.65, subject to adjustment on the eighteen month anniversary of issuance, and certain other adjustments. The exercise price and number of shares of common stock issuable on the exercise of the Warrants is subject to adjustment upon the issuance of any shares of common stock or securities convertible into shares of common stock below the then-existing exercise price, with certain exceptions, and in the event of any stock split, reverse stock split, recapitalization, reorganization or similar transaction. The holder of each Warrant does not have the right to exercise any portion of such Warrant if the holder, together with its affiliates, beneficially owns in excess of 4.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Warrants. However, any holder may increase or decrease such percentage to any other percentage, but in no event above 9.99%, provided that any increase of such percentage will not be effective until 61 days after providing notice to the Company.

The exercise price of the Warrants issued November 9, 2015 was reduced to \$1.09 per share on January 29, 2016, the 16<sup>th</sup> trading day following the Reverse Stock Split, per the terms of the Warrants. The exercise price of the Warrants issued January 11, 2016 and May 2, 2016 remains \$4.65 per share per the terms of the Warrants. All of the Warrants issued with the Notes remain subject to adjustment on the eighteen month anniversary of issuance.

### **(7) Stock-based Compensation**

The fair value method of accounting for share-based payments is applied to all share-based payment awards issued to employees and where appropriate, nonemployees, unless another source of literature applies. When determining the measurement date of a nonemployee's share-based payment award, the Company measures the stock options at fair value and re-measures such stock options to the current fair value until the performance date has been reached.



## Table of Contents

Based on the application of these standards, stock-based compensation expense for stock-based awards under the Company's Amended and Restated 2003 Stock Incentive Plan (the Plan) and inducement grants for the three and nine months ended September 30, 2016 and 2015 was allocated to operating expenses and employees and nonemployees as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
Selling, general and administrative	\$310,133	\$1,107,526	\$1,731,768	\$3,349,417
Research and development	45,203	329,431	470,181	1,008,325
<b>Total</b>	<b>\$355,336</b>	<b>\$1,436,957</b>	<b>\$2,201,949</b>	<b>\$4,357,742</b>

  

	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
Employees	\$355,225	\$1,452,709	\$2,198,414	\$4,392,741
Nonemployees	\$ 111	(15,752)	3,535	(34,999)
<b>Total</b>	<b>\$355,336</b>	<b>\$1,436,957</b>	<b>\$2,201,949</b>	<b>\$4,357,742</b>

On June 27, 2016 the Company completed an option exchange offer to its employees whereby certain outstanding options to purchase shares of the Company's common stock were tendered by employees in exchange for new options with the exercise price to be set at the then current market price of the Company's common stock. Options to purchase 449,706 shares of the Company's common stock, which included all the options eligible for exchange, were tendered by employees and cancelled by the Company. On the same date, options to purchase 75,819 shares of the Company's common stock were issued with an exercise price of \$0.3325 per share, which was the Company's closing stock price on June 27, 2016. Because the fair value of the tendered options immediately before the exchange approximated the fair value of the new options granted, no additional compensation expense was recognized.

As of September 30, 2016 there was approximately \$3.5 million of total unrecognized compensation costs, net of estimated forfeitures, related to employee unvested stock option awards, which are expected to be recognized over a weighted-average period of 2.37 years.

The estimated grant-date fair values of the stock options were calculated using the Black-Scholes valuation model, based on the following assumptions for the three and nine months ended September 30, 2016 and 2015:

	Employees		Employees	
	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
Risk-free interest rates	N/A	1.65%-1.67%	0.87%-1.64%	1.49%-1.80%
Expected life	N/A	6.00-6.25 years	4.00-6.25 years	5.50-6.25 years
Expected dividends	N/A	0%	0%	0%
Expected volatility	N/A	110.72%-111.61%	88.43%-96.10%	83.36%-111.77%

  

	Nonemployees		Nonemployees	
	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
Risk-free interest rates	1.03%	1.34%-1.79%	0.89%-1.11%	0.02%-2.10%
Expected life	4.00 years	4.89-8.01 years	4.00-4.39 years	0.08-8.51 years
Expected dividends	0%	0%	0%	0%
Expected volatility	96.64%	83.98%-114.89%	92.41%-96.64%	22.42%-132.01%

## [Table of Contents](#)

Option activity under the Plan for the nine months ended September 30, 2016 was as follows:

	Shares Available For Grant	Outstanding Options	
		Number of Shares	Weighted- Average Exercise Price
<b>Balance, December 31, 2015</b>	296,579	1,018,752	\$ 32.83
Shares reserved	—	—	—
Options granted	(152,152)	152,152	0.65
Options exercised	—	—	—
Options cancelled	652,653	(652,653)	31.40
<b>Balance, September 30, 2016</b>	<u>797,080</u>	<u>518,251</u>	<u>25.55</u>

In addition to the stock options granted pursuant to the Plan, the Company has also granted inducement stock options in connection with the appointments of (i) Dan Gladney to the position of President and Chief Executive Officer on October 28, 2015, (ii) Nick Ansari to the position of Senior Vice President (SVP) of Sales on January 6, 2016, (iii) Peter DeLange to the position of SVP of Operations and Business Development on January 18, 2016 and (iv) Paul Hickey to the position of SVP of Marketing and Reimbursement on January 18, 2016. Mr. Gladney was granted an option to purchase 516,666 shares of the Company's common stock as an inducement grant, with an exercise price of \$3.75 per share, the closing price of the Company's common stock on October 28, 2015. Mr. Delange was granted an option to purchase 166,667 shares of the Company's common stock as an inducement grant, with an exercise price of \$1.38 per share, the closing price of the Company's common stock on January 18, 2016. Mr. Ansari was granted an option to purchase 106,667 shares of the Company's common stock as an inducement grant, with an exercise price of \$1.31 per share, the closing price of the Company's common stock on January 19, 2016. Mr. Hickey was granted an option to purchase 106,667 shares of the Company's common stock as an inducement grant, with an exercise price of \$1.32 per share, the closing price of the Company's common stock on January 22, 2016. Each of the inducement grants will vest as follows: 25% of the shares will vest as of one year from the date of the officer's employment agreement, and the remaining 75% of the shares will then vest in equal 2.0833% installments each month thereafter for 36 months. The inducement options were not eligible for the option exchange program.

## **(8) Stock Sales**

### ***Sales Agreement—July 2015***

On July 8, 2015, the Company closed a public offering, where it sold 2,133,333 units at an aggregate price of \$7.50 per unit, for gross proceeds of \$16.0 million before deducting estimated offering expenses of approximately \$1.4 million, of which \$532,000 was assigned to the warrants issued with each unit sold and was recognized immediately as interest expense in the condensed consolidated statements of operations as the warrants are exercisable upon issuance. Each unit consisted of: (A)(i) one share of common stock or (ii) one pre-funded Series C warrant to purchase one share of common stock at an exercise price equal to \$7.50 per share (Series C Warrant); and (B) one Series A warrant to purchase one share of common stock at an exercise price initially equal to \$9.00 per share (Series A Warrant). Each purchaser of a unit could elect to receive a Series C Warrant in lieu of a share of common stock. No Series C Warrants were issued.

The Series A Warrants are exercisable for a period of 42 months from the closing date of the public offering. The exercise price and number of shares of common stock issuable on the exercise of the Series A Warrants are subject to adjustment upon the issuance of any shares of common stock or securities convertible into shares of common stock below the then-existing exercise price, with certain exceptions, and in the event of any stock split, reverse stock split, recapitalization, reorganization or similar transaction. The holder of the Series A Warrant does not have the right to exercise any portion of the Series A Warrant if the holder, together with its affiliates, would, subject to certain limited exceptions, beneficially own in excess of 9.99% of the Company's common stock outstanding immediately after the exercise or 4.99% as may be elected by the purchaser.

The exercise price of the Series A Warrants issued July 8, 2015 was reduced to \$2.40 per share on November 9, 2015 as a result of the issuance of the Notes and was further reduced to \$1.50 per share on December 31, 2015, \$0.97 per share on January 29, 2016, and \$0.88 on March 30, 2016, \$0.26 on June 30, 2016, \$0.19 on August 1, 2016, \$0.13 on September 30, 2016 and \$0.08 on October 31, 2016 as a result of conversions of principal and interest amounts outstanding under the Notes into shares of our common stock.

***Sales Agreement—June 2014***

On June 13, 2014, the Company entered into a sales agreement with Cowen and Company, LLC (Cowen) to sell shares of the Company’s common stock having aggregate gross sales proceeds of up to \$25.0 million, from time to time, through an “at-the-market” equity offering program under which Cowen will act as the Company’s sales agent (the Cowen ATM). The Company will determine, at its sole discretion, the timing and number of shares to be sold under the Cowen ATM. The Company will pay Cowen a commission for its services in acting as agent in the sale of common stock equal to 3.0% of the gross sales price per share of all shares sold through it as agent under the sales agreement. As of December 31, 2015, the Company had sold 367,903 shares under the Cowen ATM at a weighted-average selling price of \$20.60 per share for gross proceeds of \$7.6 million before deducting offering expenses. There have been no shares sold under the Cowen ATM subsequent to December 31, 2015 through November 11, 2016. The Company was restricted from issuing shares under the Cowen ATM until November 9, 2016 per the terms of the Purchase Agreement.

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

*The following discussion should be read in conjunction with the condensed consolidated financial statements and notes thereto appearing elsewhere in this Quarterly Report on Form 10-Q.*

*Except for the historical information contained herein, the matters discussed in this "Management's Discussion and Analysis of Financial Condition and Results of Operations," are forward-looking statements that involve risks and uncertainties. In some cases, these statements may be identified by terminology such as "may," "will," "should," "expects," "could," "intends," "might," "plans," "anticipates," "believes," "estimates," "predicts," "potential," or "continue," or the negative of such terms and other comparable terminology. These statements involve known and unknown risks and uncertainties that may cause our results, level of activity, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. Factors that may cause or contribute to such differences include, among others, those discussed in Part I, Item 1A, "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2015. Except as may be required by law, we undertake no obligation to update any forward-looking statement to reflect events after the date of this report.*

### Overview

We are a medical device company with approvals to commercially launch our product, the vBloc Rechargeable System, in the United States, the European Economic Area and other countries that recognize the European CE Mark. We are focused on the design and development of devices that use neuroblocking technology to treat obesity, metabolic diseases and other gastrointestinal disorders. Our proprietary neuroblocking technology, which we refer to as vBloc Therapy, is designed to intermittently block the vagus nerve using high frequency, low energy, electrical impulses. We have a limited operating history and only recently received U.S. Food and Drug Administration (FDA) approval to sell our product in the United States. In addition, we have regulatory approval to sell our product in the European Economic Area and other countries that recognize the European CE Mark and do not have any other source of revenue. We were incorporated in Minnesota on December 19, 2002 and later reincorporated in Delaware on July 22, 2004. We have devoted substantially all of our resources to the development and commercialization of the vBloc Rechargeable System.

The vBloc Rechargeable System, our initial product, uses vBloc Therapy to limit the expansion of the stomach, help control hunger sensations between meals, reduce the frequency and intensity of stomach contractions and produce a feeling of early and prolonged fullness. We believe the vBloc Rechargeable System offers obese patients a minimally-invasive treatment that can result in significant, durable and sustained weight loss. We believe that our vBloc Rechargeable System allows bariatric surgeons to offer a new option to obese patients who are concerned about the risks and complications associated with currently available anatomy-altering, restrictive or malabsorptive surgical procedures.

We received FDA approval on January 14, 2015 for vBloc Therapy, delivered via the vBloc Rechargeable System, for the treatment of adult patients with obesity who have a Body Mass Index (BMI) of at least 40 to 45 kg/m<sup>2</sup>, or a BMI of at least 35 to 39.9 kg/m<sup>2</sup> with a related health condition such as high blood pressure or high cholesterol levels, and who have tried to lose weight in a supervised weight management program and failed within the past five years. We have begun a controlled commercial launch at select surgical centers in the United States and had our first commercial sales in 2015. During 2015, we began a controlled expansion of our commercial operations and started the process of building a sales force. In January 2016, we hired three new executives to oversee this expansion. The direct sales force is supported by field technical managers who provide training, technical and other support services to our customers. Throughout 2015, our sales force called directly on key opinion leaders and bariatric surgeons at commercially-driven surgical centers that met our certification criteria, which led to the training and certification of over 50 surgical centers and 75 surgeons in implanting and administering vBloc Therapy.

We have continued these efforts in the first nine months of 2016 and plan to build on these efforts during the remainder of 2016 through geography and self-pay patient focused direct-to-patient marketing, key opinion leader and center specific partnering, and a multi-faceted reimbursement strategy.

Our direct sales force is targeting outcome-focused, aftercare-based surgical centers in key self-pay markets and is promoting the vBloc Rechargeable System to physicians and patients who have concerns with current bariatric surgical procedures. We are calling on physicians, weight-management specialists, nurses and others involved in the obesity management process who influence patient adoption. Additionally, account management and patient registration processes used during the clinical trial are being transitioned to a commercial registration structure. Centers responsible for implanting our product will be expanded and trained to perform patient selection, implant the vBloc Rechargeable System and manage appropriate follow-up procedures.

Our sales representatives are supported by field clinical experts who are responsible for training, technical support, and other support services at various surgical centers. Our sales representatives implement consumer marketing programs and provide surgical centers and implanting surgeons with educational patient materials.

## [Table of Contents](#)

We market directly to patients but sell our product to select surgical centers throughout the United States that have patients that would like to use the vBloc Rechargeable System to treat obesity and its comorbidities. The surgical centers then sell our product to the patients and implant and administer vBloc Therapy. In 2015 and 2016, the patients that purchased the vBloc Rechargeable System paid for the therapy themselves and did not receive reimbursement from an insurance provider, and we expect that most of our sales will come from self-pay patients in the remainder of 2016 and 2017. Through our agreement with Academy Medical, LLC, the vBloc Rechargeable System was added to Academy Medical's five-year sole source agreement with the U.S. Department of Veterans Affairs (VA) that allows any VA surgeon in the U.S. to purchase the vBloc System from Academy Medical. Additionally, we are working to obtain coverage for our product from the U.S. Centers for Medicare and Medicaid Service, major insurance carriers, local coverage entities and self-insured plans, including Integrated Delivery Networks ("IDNs"). We received coverage from one significant IDN in the northeast in 2016 and are in active discussions with other IDNs throughout the country. To date, we have relied on, and anticipate that we will continue to rely on, third-party manufacturers and suppliers for the production of the vBloc Rechargeable System.

Data from our ReCharge trial was used to support the premarket approval (PMA) application for the vBloc Rechargeable System, submitted to the FDA in June 2013. The ReCharge trial is a randomized, double-blind, sham-controlled, multicenter pivotal clinical trial testing the effectiveness and safety of vBloc Therapy utilizing our vBloc Rechargeable System. All patients in the trial received an implanted device and were randomized in a 2:1 allocation to treatment or sham control groups. The sham control group received a non-functional device during the trial period. All patients were expected to participate in a standard weight management counseling program. The primary endpoints of efficacy and safety were evaluated at 12 months. As announced, the ReCharge trial met its primary safety endpoint with a 3.7% serious adverse event rate. The safety profile at 12 months was further supported by positive cardiovascular signals including a 5.5 mmHg drop in systolic blood pressure, a 2.8 mmHg drop in diastolic blood pressure and a 3.6 bpm drop in average heart rate.

Although the trial did not meet its predefined co-primary efficacy endpoints, it did demonstrate in the intent to treat (ITT) population (n=239) a clinically meaningful and statistically significant excess weight loss (EWL) of 24.4% (approximately 10% total body weight loss (TBL)) for vBloc Therapy-treated patients, with 52.5% of patients achieving at least 20% EWL. In the per protocol population, the trial demonstrated an EWL of 26.3% for vBloc Therapy-treated patients, with 56.8% of patients achieving at least 20% EWL.

In the ReCharge trial, two-thirds of vBloc Therapy-treated patients achieved at least 5% TBL at 12 months. According to the Centers for Disease Control and Prevention (CDC), 5% TBL can have significant health benefits on obesity related risk factors, or comorbidities, including reduction in blood pressure, improvements in Type 2 diabetes and reductions in triglycerides and cholesterol. Further analysis of our data at 12 months showed a meaningful impact on these comorbidities as noted in the below table showing the improvements seen at 10% TBL, the average weight loss in vBloc Therapy-treated patients.

<b>Risk Factor</b>	<b>10% TBL</b>
Systolic BP (mmHg)	-9
Diastolic BP (mmHg)	-6
Heart Rate (bpm)	-6
Total Cholesterol (mg/dL)	-15
LDL (mg/dL)	-9
Triglycerides (mg/dL)	-41
HDL (mg/dL)	3
Waist Circumference (inches)	-7
HbA1c (%)	-0.5

We subsequently announced that vBloc Therapy-treated patients were maintaining their weight loss at 18 months and 24 months with an EWL of 23.5% and 21.1%, respectively. The trial's positive safety profile also continued throughout this reported time period.

We obtained European CE Mark approval for our vBloc Rechargeable System in 2011 for the treatment of obesity. The CE Mark approval for our vBloc Rechargeable System was expanded in 2014 to also include use for the management of Type 2 diabetes in obese patients. The costs and resources required to successfully commercialize the vBloc Rechargeable System internationally are currently beyond our capability. Accordingly, we intend to devote our near-term efforts toward mounting a successful system launch in the United States. We intend to explore select international markets to commercialize the vBloc Rechargeable System as our resources permit, using direct, dealer and distributor sales models as the targeted market best dictates.

## [Table of Contents](#)

To date, we have not observed any mortality related to our device or any unanticipated adverse device effects in our human clinical trials. We have also not observed any long-term problematic clinical side effects in any patients. In addition, data from our VBLOC-DM2 ENABLE trial outside the United States demonstrate that vBloc Therapy may hold promise in improving obesity-related comorbidities such as diabetes and hypertension. We are conducting, or plan to conduct, further studies in each of these comorbidities to assess vBloc Therapy's potential in addressing multiple indications.

We recently commenced commercial operations in the United States, deriving revenues from our primary business activity in 2015. We expect to incur significant sales and marketing expenses prior to recording sufficient revenue to offset these expenses. We expect our selling, general and administrative expenses to increase as we continue to add the infrastructure necessary to support our initial commercial sales, operate as a public company and develop our intellectual property portfolio. For these reasons, we expect to continue to incur operating losses for the next several years. We have financed our operations to date principally through the sale of equity securities, debt financing and interest earned on investments.

Our board of directors and stockholders approved a 1-for-15 reverse split of the Company's outstanding common stock that became effective after trading on January 6, 2016 (the Reverse Stock Split). The Reverse Stock Split did not change the par value of our stock or the number of preferred shares authorized by our Fifth Amended and Restated Certificate of Incorporation. An amendment to the Certificate of Incorporation was also approved in connection with the Reverse Stock Split to increase the number of shares of our common stock authorized for issuance to 150 million shares, effective immediately after the Reverse Stock Split on January 6, 2016. All share and per share amounts have been retroactively adjusted to reflect the Reverse Stock Split for all periods presented.

## **Financial Overview**

### ***Revenue***

We received FDA approval on January 14, 2015 for vBloc Therapy, delivered via the vBloc Rechargeable System, and began a controlled commercial launch at select surgical centers in the United States. In 2015 we trained and certified over 50 surgical centers and 75 surgeons in implanting and administering vBloc Therapy. We had our first commercial sales within the United States in 2015 and for the year ended December 31, 2015 we recognized \$292,000 in revenue. We have not generated revenue from commercial sales outside of the United States since 2012.

Any revenue from initial sales of a new product in the United States or internationally is difficult to predict and in any event will only modestly reduce our continued losses resulting from our research and development and other activities.

### ***Selling, General and Administrative Expenses***

Our selling, general and administrative expenses consist primarily of compensation for executive, finance, market development and administrative personnel, including stock-based compensation. Other significant expenses include professional services and consulting fees, costs associated with attending medical conferences, other professional fees for legal services, including legal services associated with our efforts to obtain and maintain broad protection for the intellectual property related to our products, and accounting services, cash management fees and travel expenses.

### ***Research and Development Expenses***

Our research and development expenses primarily consist of engineering, product development, quality assurance and clinical and regulatory expenses, incurred in the development of our vBloc Rechargeable System. Research and development expenses also include employee compensation, including stock-based compensation, consulting services, outside services, materials, clinical trial expenses, including supplies, devices, explants and revisions, depreciation and travel. We expense research and development costs as they are incurred.

## **Results of Operations**

### ***Comparison of the Three Months Ended September 30, 2016 and 2015***

*Sales.* Sales were \$297,000 for the three months ended September 30, 2016, compared to \$64,000 sales for the three months ended September 30, 2015. The increase of \$233,000 is the result of continued execution of the controlled commercial launch of the vBloc Rechargeable System at select surgical centers in the United States which resulted in sales of 22 units during the third quarter of 2016 versus six units during the third quarter of 2015.

## [Table of Contents](#)

*Cost of Goods Sold.* Cost of goods sold were \$147,000 for the three months ended September 30, 2016, compared to \$23,000 cost of goods sold for the three months ended September 30, 2015. The expense increase was driven primarily by the 267% increase in unit sales over the prior year period. The Company's gross margin percentage declined to 50.6% for the three months ended September 30, 2016 from 63.5% in the prior year period due primarily to an increase in overhead costs applied to inventory.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses were \$3.4 million for the three months ended September 30, 2016, compared to \$4.3 million for the three months ended September 30, 2015. The decrease of \$0.9 million, or 21.6%, from the prior year period was primarily due to declines of \$1.2 million of payroll-related expenses, and \$171,000 in professional services partially offset by increases of \$366,000 in severance and \$110,000 of supplies expenses.

*Research and Development Expenses.* Research and development expenses declined to \$1.3 million for the three months ended September 30, 2016 from \$1.8 million for the three months ended September 30, 2015. The decrease of \$0.5 million, or 28.9%, from the prior year period was primarily due to decreases of \$597,000 and \$160,000 in payroll-related expenses, and supplies expenses, respectively, partially offset by a \$256,000 increase in professional services expenses. The overall decrease in expense levels are the result of the Company's continued shift away from a research and development focus toward commercialization following FDA approval on January 14, 2015.

*Interest Expense.* Interest expense was \$1.4 million for the three months ended September 30, 2016, compared to \$566,000 for the three months ended September 30, 2015. The increase of \$826,000 was driven by interest costs from the three closings of the senior amortizing convertible notes (the Notes), that occurred on November 9, 2015, January 11, 2016 and May 2, 2016, and increased interest costs due to significant conversions of amounts due under the Notes into common shares by holders of the Notes during the three months ended September 30, 2016 and, as a result, accelerations of "make-whole" interest amounts due under the Notes. Additionally, \$277,000 in debt issuance costs expensed as interest during the second quarter of 2016.

*Change in Value of Convertible Notes Payable.* The value of the Notes payable increased \$909,000 during the three months ended September 30, 2016. During the third quarter of 2016, the principal amount outstanding under the Notes declined from \$15.6 million to \$5.6 million. Accordingly the valuation discount on the Notes was reduced along with the principal. The Notes contain a conversion feature and the decline in our common stock price from \$0.97 to \$0.14 on September 30, 2016 partially offset the increase in the fair value of the Notes. The fair market value was calculated using a Binomial Lattice model. There were no Notes outstanding for the three months ended September 30 2015 as the Notes were issued November 9, 2015, January 11, 2016 and May 2, 2016.

*Change in Value of Warrant Liability.* The value of the common stock warrant liability decreased \$242,000 for the three months ended September 30, 2016. Common stock warrant liabilities were recorded on July 8, 2015, November 9, 2015, January 11, 2016 and May 2, 2016, as the common stock warrants issued with the July 8, 2015 public offering and with the Notes provide for certain anti-dilution protections in the event shares of common stock or securities convertible into shares of common stock are issued below the then-existing exercise price. The fair market value was calculated using the Black-Scholes valuation model, which resulted in \$179,000, \$1,000, \$39,000 and \$23,000 decreases for the three months ended September 30, 2016 for the common stock warrants issued with the July 8, 2015 public offering, November 9, 2015 Notes, the January 11, 2016 Notes and the May 2, 2016 Notes, respectively, as our stock price decreased from \$0.97 on March 31, 2016 and \$0.75 on May 2, 2016 to \$0.14 on September 30, 2016. There were no warrants outstanding that were required to be measured at fair value for the three months ended September 30, 2015.

### **Comparison of the Nine Months Ended September 30, 2016 and 2015**

*Sales.* Sales were \$645,000 for the nine months ended September 30, 2016, compared to \$143,000 sales for the nine months ended September 30, 2015. The increase of \$502,000 is the result of continued execution of a controlled commercial launch of the vBloc Rechargeable System at select surgical centers in the United States which began after we received FDA approval on January 14, 2015, and which resulted in sales of 51 units during the nine months ended September 30, 2016 versus six units during the comparable period from 2015.

*Cost of Goods Sold.* Cost of goods sold were \$342,000 for the nine months ended September 30, 2016, compared to \$54,000 cost of goods for the nine months ended September 30, 2015. The expense increase was driven primarily by the 480% increase in unit sales over the prior year period. The Company's gross margin percentage declined to 46.9% for the nine months ended September 30, 2016 from 62.2% in the prior year period due primarily to a reduction in average sales price and, to a lesser degree, by an increase in overhead costs applied to inventory.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses were \$15.1 million for the nine months ended September 30, 2016, compared to \$14.0 million for the nine months ended September 30, 2015. The increase of \$1.0 million, or 8.1%, was primarily due to a \$1.8 million increase in professional services expenses, primarily during the first two quarters of 2016, as well as a \$366,000 increase in severance expenses. These expense increases were partially offset by a \$1.3 million decrease in payroll-related expenses. The increase in professional services are the result of increasing commercialization efforts as we continue the controlled commercial launch of the vBloc Rechargeable System at select surgical centers in the United States.

## [Table of Contents](#)

**Research and Development Expenses.** Research and development expenses were \$3.9 million for the nine months ended September 30, 2016, compared to \$6.5 million for the nine months ended September 30, 2015. The decrease of \$2.6 million or 39.9%, was primarily due to decreases of \$1.6 million, \$587,000 and \$225,000 in payroll-related expenses, supply expenses and professional services expenses, respectively. The decreases are the result of a shift away from a research and development focus towards commercialization following FDA approval on January 14, 2015.

**Interest Expense.** Interest expense was \$3.4 million for the nine months ended September 30, 2016, compared to \$840,000 for the nine months ended September 30, 2015. The increase of \$2.6 million from the prior year is primarily due to the interest expense recognized during the period for the three closings of the Notes that occurred on November 9, 2015, January 11, 2016 and May 2, 2016 and increased interest costs due to significant conversions of amounts due under the Notes into common shares by holders of the Notes during the nine-months ended September 30, 2016 and, as a result, accelerations by of “make-whole” interest amounts due under the Notes. Additionally, approximately \$960,000 of debt issuance costs were recognized in the first two quarters of 2016 as interest expense as we elected the fair value alternative for the Notes. Interest expense recognized for the nine months ended September 30, 2015 included a \$187,000 success fee paid to Silicon Valley Bank required by the Loan and Security Agreement as a result of achieving FDA approval on January 14, 2015.

**Change in Value of Convertible Notes Payable.** The value of the Notes payable declined \$200,000 during the nine months ended September 30, 2016. The Notes contain a conversion feature and the decline in the Company’s common stock price from \$1.95 at December 31, 2015, \$1.33 on January 11, 2016, \$0.68 at May 2, 2016, to \$0.14 on September 30, 2016 was the primary driver of the reduction in the fair value of the Notes. The fair market value was calculated using a Binomial Lattice model. There were no Notes outstanding for the nine months ended September 30, 2015 as the Notes were issued November 9, 2015. However, the decline in the fair value of the Notes was partially offset by the significant reduction of the principal amounts due under the Notes during the third quarter from \$15.6 million to \$5.6 million.

**Change in Value of Warrant Liability.** The value of the common stock warrant liability decreased \$3.3 million for the nine months ended September 30, 2016, primarily due to the decrease in the market value of the Company’s common stock compared with the exercise price of warrants. Common stock warrant liabilities were recorded on July 8, 2015, November 9, 2015, January 11, 2016, and May 2, 2016 as the common stock warrants issued with the July 8, 2015 public offering and with the Notes provide for certain anti-dilution protections in the event shares of common stock or securities convertible into shares of common stock are issued below the then-existing exercise price. The fair market value was calculated using the Black-Scholes valuation model, which resulted in \$2.6 million, \$104,000, \$500,000 and \$140,000 decreases for the nine months ended September 30, 2016 for the common stock warrants issued with the July 8, 2015 public offering, November 9, 2015 Notes, the January 11, 2016 Notes and the May 2, 2016 Notes, respectively, as our stock price decreased from \$1.95 on December 31, 2015 and \$1.33 on January 11, 2016 and \$0.75 on May 2, 2016 to \$0.14 on September 30, 2016. There were no warrants outstanding that were required to be measured at fair value for the nine months ended September 30, 2015.

## **Liquidity and Capital Resources**

As of September 30, 2016, we had \$6.8 million in cash and cash equivalents. Of this amount \$2.8 million was invested in short-term money market funds that are not considered to be bank deposits and are not insured or guaranteed by the Federal Deposit Insurance Company or other government agency. These money market funds seek to preserve the value of the investment at \$1.00 per share; however, it is possible to lose money investing in these funds. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. At times, such deposits may be in excess of insured limits. We have not experienced any losses on our deposits of cash and cash equivalents. We have financed our operations to date principally through the sale of equity securities, debt financing and interest earned on investments. As of September 30, 2016, we had \$6.8 million of cash and cash equivalents to fund our anticipated operations through 2016. On November 4, 2015, we entered into a securities purchase agreement (the Purchase Agreement) with institutional investors to issue \$25.0 million of Notes along with the accompanying warrants. \$1.5 million of the Notes was funded at the initial closing on November 9, 2015 (the First Closing). An additional \$11.0 million of the Notes were funded at the second closing on January 11, 2016 (the Second Closing). Pursuant to an amendment to the Purchase Agreement (the First Amendment) entered into on May 2, 2016, the remaining \$12.5 million would be funded at two separate closings, with \$6.25 million of the Notes funded on May 2, 2016. The remaining amount, up to \$6.25 million, may be funded at the fourth closing, which can occur no later than December 1, 2016 (the Fourth Closing). In order for the Fourth Closing to occur, the holders of the Notes must waive certain conditions which are not currently satisfied due to the recent declines in the Company’s stock price as detailed in Note 6 of the Notes to Condensed Consolidated Financial Statements. Such waivers have not yet been either requested or provided. Our anticipated operations include plans to continue the controlled commercial launch of vBloc Therapy, delivered via the vBloc Rechargeable System, which was approved by the FDA on January 14, 2015. We believe that we have the flexibility to manage the growth of our expenditures and operations. In order to accelerate the execution of our business plans we intend to raise additional funds.



## [Table of Contents](#)

### ***Nasdaq Listing Notices***

In May 2016, we received written notices from the Nasdaq Stock Market Nasdaq stating that we were not in compliance with the following two Nasdaq listing requirements: (i) the requirement that we have a minimum of \$2.5 million stockholders' equity (the Stockholders' Equity Requirement) and (ii) the \$1.00 minimum bid price stock price requirement (the Minimum Bid Requirement).

On July 19, 2016, we received a letter from Nasdaq granting us an extension until November 14, 2016 to regain compliance with the Stockholders' Equity Requirement. The extension was granted based on the plan we submitted to Nasdaq to regain compliance with the Stockholders' Equity Requirement through a combination of note conversions and accelerated principal amortizations and infusions of equity capital prior to the deadline.

We received a notice of delisting on November 9, 2016, and intend to appeal to Nasdaq for a hearing before the Listing Qualification Panel prior to being delisted. The basis for the Company's appeal of the Nasdaq delisting notices is expected to consist of:

- Fourth quarter 2016 reductions in the Company's operating expense levels
- On November 7, 2016, the Company filed a preliminary proxy statement for a special meeting of our stockholders in order to obtain approval for, among other things, an increase in the number of common shares authorized to be issued and the authorization to effect a reverse-split of its common stock. While obtaining shareholder approval of each of these proposals is not certain, the Company believes it will be able to obtain stockholder approval for the authorized share increase and reverse stock split in December 2016.
- After stockholder approval is obtained, the Company intends to declare a reverse-split of its outstanding shares of common stock in such a ratio to increase its minimum bid stock price above the \$1.00 minimum required by Nasdaq while maintaining its current authorized share count,
- After stockholder approval is obtained to increase the number of authorized shares and the reverse stock split is implemented, the Company intends to conduct a firm commitment underwritten public offering consisting of common stock and warrants to purchase common stock in amounts sufficient to increase the Company's shareholder equity above the \$2.5 million Nasdaq minimum and to provide funding for the Company's operations for the foreseeable future. The Company has not yet obtained any commitments to participate in the offering, and does not expect to obtain any commitments until after the stockholder meeting has occurred.

Failure of the Company to receive shareholder approval in December 2016 on the proposals to increase the number of authorized shares and the authorization of a reverse stock split will likely result in Nasdaq delisting and will significantly impair the Company's ability to raise the additional capital necessary to continue operations beyond the first quarter of 2017.

### ***Sales Agreement—June 2014***

On June 13, 2014, we entered into a sales agreement with Cowen and Company, LLC (Cowen) to sell shares of our common stock having aggregate gross sales proceeds of up to \$25.0 million, from time to time, through an "at-the-market" equity offering program under which Cowen will act as our sales agent (the Cowen ATM). We will determine, at our sole discretion, the timing and number of shares to be sold under the Cowen ATM. We will pay Cowen a commission for its services in acting as agent in the sale of common stock equal to 3.0% of the gross sales price per share of all shares sold through it as agent under the sales agreement. As of December 31, 2015, we had sold 367,903 shares under the Cowen ATM at a weighted-average selling price of \$20.60 per share for gross proceeds of \$7.6 million before deducting offering expenses. There have been no shares sold under the Cowen ATM subsequent to December 31, 2015 through November 11, 2016. We were restricted from issuing shares under the Cowen ATM until November 9, 2016 per the terms of the Notes.

### ***Sales Agreement—July 2015***

On July 8, 2015, we closed a public offering where we sold 2,133,333 units at an aggregate price of \$7.50 per unit, for gross proceeds of \$16.0 million, before deducting estimated offering expenses of approximately \$1.4 million, of which \$532,000 was assigned to the warrants. Each unit consisted of: (A)(i) one share of common stock or (ii) one pre-funded Series C warrant to purchase one share of common stock at an exercise price equal to \$7.50 per share (Series C Warrant); and (B) one Series A warrant to purchase one share of common stock at an exercise price equal initially to \$9.00 per share (Series A Warrant). Each purchaser of a unit could elect to receive a Series C Warrant in lieu of a share of common stock. No Series C Warrants were issued.

## [Table of Contents](#)

The Series A Warrants are exercisable for a period of 42 months from the closing date of the public offering. The exercise price and number of shares of common stock issuable on the exercise of the Series A Warrants are subject to adjustment upon the issuance of any shares of common stock or securities convertible into shares of common stock below the then-existing exercise price, with certain exceptions, and in the event of any stock split, reverse stock split, recapitalization, reorganization or similar transaction. The holder of the Series A Warrant does not have the right to exercise any portion of the Series A Warrant if the holder, together with its affiliates, would, subject to certain limited exceptions, beneficially own in excess of 9.99% of our common stock outstanding immediately after the exercise or 4.99% as may be elected by the purchaser.

The exercise price of the Series A Warrants issued July 8, 2015 was reduced to \$2.40 per share on November 9, 2015 as a result of the issuance of the Notes and was further reduced to \$1.50 per share on December 31, 2015, \$0.97 per share on January 29, 2016, \$0.26 on June 30, 2016, \$0.19 on August 1, 2016, \$0.13 on September 30, 2016 and \$0.08 on October 31, 2016 as a result of conversions of principal and interest amounts outstanding under the Notes into shares of common stock.

### ***Senior Amortizing Convertible Notes***

On November 4, 2015, we entered into the Purchase Agreement to issue and sell to four institutional investors 7% senior amortizing convertible notes due 2017 in three separate closings. The Notes are convertible into shares of our common stock at a price equal to \$4.35 per share with an aggregate principal amount of \$25.0 million. Each Note was sold with a warrant to purchase a share of common stock (the Warrants) with an exercise price of \$4.65 per share. We issued and sold Notes and Warrants for aggregate total proceeds of \$12.5 million in two separate closings through March 31, 2016, and after entering into the First Amendment, which provided that the scheduled third closing would be split into two separate closings, issued and sold Notes and Warrants for aggregate total proceeds of \$6.25 million in the third closing, which occurred on May 2, 2016 (the Third Closing). We may issue and sell Notes and Warrants for aggregate total proceeds of up to \$6.25 million in the Fourth Closing. In order for the Fourth Closing to occur, the holders of the Notes must waive certain conditions which are not currently satisfied due to the recent declines in the Company's stock price, as detailed in Note 6 to the Notes to Condensed Consolidated Financial Statements. Additionally, the Second Amendment provided the holders' consents to the Company reducing the conversion price of the Notes from time to time in order to incentivize the holders of the Notes to convert their Notes to common shares. In addition, at the Fourth Closing, the holders of the Notes will be obligated to purchase at least 50% of the aggregate principal of the Notes they convert, either on a voluntary or installment conversion basis, on and after July 1, 2016, up to an aggregate principal amount of \$6.25 million, although no individual holder would be obligated to purchase more Notes than originally scheduled in the First Amendment.

### ***Description of the Notes***

The Notes are payable in monthly installments, accrue interest at a rate of 7.0% per annum from the date of issuance and will mature 24 months after the First Closing, unless converted or redeemed earlier. The Notes may be repaid, at our election, in either cash or shares of our common stock at a discount to the then-current market price. The Notes are also convertible from time to time, at the election of the holders, into shares of our common stock at an initial conversion price of \$4.35 per share. The conversion price was adjusted to \$1.09 per share on January 29, 2016, the 16th trading day following the Reverse Stock Split, per the terms of the Notes.

The holder of each Note has the right to convert any portion of such Note unless the holder, together with its affiliates, beneficially owns in excess of 4.99% of the number of shares of our common stock outstanding immediately after giving effect to the conversion, as such percentage ownership is determined in accordance with the terms of the Notes. However, any holder may increase or decrease such percentage to any other percentage, but in no event above 9.99%, provided that any increase of such percentage will not be effective until 61 days after providing us notice.

The First Closing occurred on November 9, 2015. At the First Closing, we issued and sold Notes with an aggregate principal amount of \$1.5 million, along with Warrants exercisable for 117,520 shares.

The Second Closing occurred on January 11, 2016 after we received approval of the offering by our stockholders and the satisfaction of certain customary closing conditions. At the Second Closing, we issued and sold Notes with an aggregate principal amount of \$11.0 million, along with Warrants exercisable for 861,842 shares.

The Third Closing occurred on May 2, 2016 after we entered into the First Amendment and satisfied certain closing conditions. At the Third Closing, we issued and sold Notes with an aggregate principal amount of \$6.25 million, along with Warrants exercisable for 489,684 shares.

At the Fourth Closing we may issue and sell Notes with an aggregate principal amount of up to \$6.25 million, along with Warrants exercisable for 489,682 shares.

## [Table of Contents](#)

The following table summarizes the installment amounts and additional conversions by the holders of the Notes issued at the First Closing through September 30, 2016:

	<u>Principal</u>	<u>Interest</u>	<u>Total</u>	<u>Common Shares</u>
Installment amount at December 31, 2015	\$ 65,217	\$ 23,651	\$ 88,868	56,967
Holder conversions during the quarter ended December 31, 2015	18,261	2,375	20,636	13,228
<b>Balance, December 31, 2015</b>	<b>83,478</b>	<b>26,026</b>	<b>109,504</b>	<b>70,195</b>
Installment amount at February 29, 2016	65,217	23,681	88,898	91,953
Installment amount at March 31, 2016	65,217	14,827	80,044	88,960
Holder conversions during the quarter ended March 31, 2016	104,784	12,762	117,546	106,684
<b>Balance, March 31, 2016</b>	<b>318,696</b>	<b>77,296</b>	<b>395,992</b>	<b>357,792</b>
Installment amount at April 30, 2016	65,217	13,853	79,070	101,764
Installment amount at May 31, 2016	65,217	13,082	78,299	148,467
Installment amount at June 30, 2016	54,217	11,275	65,492	251,320
Holder conversions during the quarter ended June 30, 2016	1,627	174	1,801	2,000
<b>Balance, June 30, 2016</b>	<b>504,974</b>	<b>115,680</b>	<b>620,654</b>	<b>861,343</b>
Installment amount at July 31, 2016	65,217	10,148	75,365	386,492
Installment amount at August 31, 2016	46,957	5,830	52,787	321,505
Holder conversions during the quarter ended September 30, 2016	882,852	78,634	961,486	5,076,930
<b>Balance, September 30, 2016</b>	<b>\$1,500,000</b>	<b>\$210,292</b>	<b>\$1,710,292</b>	<b>6,646,270</b>

The following table summarizes the installment amounts and additional conversions by the holders of the Notes issued at the Second Closing through September 30, 2016:

	<u>Principal</u>	<u>Interest</u>	<u>Total</u>	<u>Common Shares</u>
Installment amount at March 2, 2016	\$ 404,762	\$ 149,300	\$ 554,062	*
Holder conversions during the quarter ended March 31, 2016	987,000	124,050	1,111,050	1,048,167
<b>Balance, March 31, 2016</b>	<b>1,391,762</b>	<b>273,350</b>	<b>1,665,112</b>	<b>1,048,167</b>
Installment amount at April 29, 2016	404,762	149,497	554,259	713,334
Installment amount at May 31, 2016	291,428	86,518	377,946	716,625
Installment amount at June 30, 2016	404,762	82,913	487,675	1,598,908
Holder conversions during the quarter ended June 30, 2016	25,373	2,995	28,368	29,000
<b>Balance, June 30, 2016</b>	<b>2,518,087</b>	<b>595,273</b>	<b>3,113,360</b>	<b>4,106,034</b>
Installment amount at July 31, 2016	213,429	47,457	260,886	1,337,879
Installment amount at August 31, 2016	631,429	116,511	747,940	4,536,725
Installment amount at September 30, 2016	404,762	45,846	450,608	3,618,881
Holder conversions during the quarter ended September 30, 2016	4,868,679	418,847	5,287,526	29,277,719
<b>Balance, September 30, 2016</b>	<b>\$8,636,386</b>	<b>\$1,223,934</b>	<b>\$9,860,320</b>	<b>42,877,238</b>

## [Table of Contents](#)

The following table summarizes the installment amounts and additional conversions by the holders of the Notes issued at the Third Closing through September 30, 2016:

	<u>Principal</u>	<u>Interest</u>	<u>Total</u>	<u>Common Shares</u>
Installment amount at June 30, 2016	\$ 212,158	\$ 90,659	\$ 302,817	1,162,000
Holder conversions during the quarter ended June 30, 2016	—	—	—	—
<b>Balance, June 30, 2016</b>	<u>212,158</u>	<u>90,659</u>	<u>302,817</u>	<u>1,162,000</u>
Installment amount at July 31, 2016	147,368	32,374	179,742	921,757
Cash Payment – July 31, 2016 installment	42,105	6,107	48,212	*
Installment amount at August 31, 2016	336,842	62,059	398,901	2,427,886
Installment amount at September, 2016	263,158	41,822	304,980	2,416,643
Holder conversions during the quarter ended September 30, 2016	<u>1,915,698</u>	<u>175,092</u>	<u>2,090,790</u>	<u>10,869,063</u>
<b>Balance September 30, 2016</b>	<u>\$2,917,329</u>	<u>\$408,113</u>	<u>\$3,325,442</u>	<u>17,797,349</u>

\* Cash payments

During the third quarter of 2016, \$9.8 million of aggregate principal amount of the Notes were converted by holders of the Notes into approximately 60.2 million shares of our common stock. Between October 1, 2016 and November 11, 2016 \$3.2 million of aggregate principal amount of Notes were converted by holders of the Notes into approximately 39.7 million shares of our common stock.

### ***Description of the Warrants***

Each Warrant is exercisable immediately and for a period of 60 months from the date of the issuance of the Warrant. Upon the completion of the Fourth Closing, the Warrants will entitle the holders of the Warrants to purchase, in aggregate, 1,958,728 shares of our common stock, subject to certain adjustments. The Warrants are initially exercisable at an exercise price equal to \$4.65, subject to adjustment on the eighteen month anniversary of issuance, and certain other adjustments. The exercise price and number of shares of common stock issuable on the exercise of the Warrants is subject to adjustment upon the issuance of any shares of common stock or securities convertible into shares of common stock below the then-existing exercise price, with certain exceptions, and in the event of any stock split, reverse stock split, recapitalization, reorganization or similar transaction. The holder of each Warrant does not have the right to exercise any portion of such Warrant if the holder, together with its affiliates, beneficially owns in excess of 4.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Warrants. However, any holder may increase or decrease such percentage to any other percentage, but in no event above 9.99%, provided that any increase of such percentage will not be effective until 61 days after providing us notice.

## [Table of Contents](#)

The exercise price of the Warrants issued November 9, 2015 was reduced to \$1.09 per share on January 29, 2016, the 16th trading day following the Reverse Stock Split, per the terms of the Warrants. The exercise price of the Warrants issued January 11, 2016 and May 2, 2016 remains \$4.65 per share per the terms of the Warrants. All of the Warrants issued with the Notes remain subject to adjustment on the eighteen month anniversary of issuance.

### ***Net Cash Used in Operating Activities***

Net cash used in operating activities was \$17.1 million and \$17.2 million for the nine months ended September 30, 2016 and 2015, respectively. Net cash used in operating activities primarily reflects the net loss for those periods, less noncash expenses for stock-based compensation, depreciation and amortization, change in value of convertible notes payable, change in value of warrant liability, and partially offset by changes in operating assets and liabilities.

### ***Net Cash Used in Investing Activities***

Net cash used in investing activities was \$12,000 and \$37,000 for the nine months ended September 30, 2016 and 2015, respectively. Net cash used in investing activities for the nine months ended September 30, 2016 and 2015 is attributable to the purchase of property and equipment.

### ***Net Cash Provided by Financing Activities***

Net cash provided by financing activities was \$16.0 million and \$17.9 million for the nine months ended September 30, 2016 and 2015, respectively. Net cash provided by financing activities for the nine months ended September 30, 2016 was due to \$17.25 million in gross proceeds from the issuance of the Notes on January 11, 2016 and May 2, 2016, offset by \$727,000 of debt issuance costs and principal repayments of \$447,000 on the Notes. Net cash provided by financing activities for the nine months ended September 30, 2015 was due to gross proceeds of \$16.0 million from the July 8, 2015 public offering and ATM draws of \$6.7 million, offset by 3.0 million in principal repayments on our long-term debt and \$1.7 million in financing costs

### ***Operating Capital and Capital Expenditure Requirements***

We received FDA approval on January 14, 2015 for vBloc Therapy, delivered via the vBloc Rechargeable System, and have begun a controlled commercial launch at select surgical centers in the United States. We had our first commercial sales within the United States in 2015 and for the year ended December 31, 2015 we recognized \$292,000 in revenue. For the nine months ended September 30, 2016 we recognized \$348,000 in revenue. We anticipate that we will continue to incur net losses for the next several years as we develop our products, commercialize our vBloc Rechargeable System, develop the corporate infrastructure required to sell our products, operate as a publicly-traded company and pursue additional applications for our technology platform.

We have financed our operations to date principally through the sale of equity securities, debt financing and interest earned on investments. As of September 30, 2016, we had \$6.8 million of cash and cash equivalents to fund our anticipated operations through 2016 and early 2017. In order to decrease our rate of usage of remaining cash and to increase the length of time we can continue to operate with existing cash balances, we have taken actions beginning in the third quarter of 2016 to reduce cash operating expenses and have taken further expense reduction actions early in the fourth quarter of 2016. Because we currently do not have a sufficient number of common shares available to sell in order to raise additional capital for operations, we are in the process of seeking stockholder approval to increase the number of common shares authorized to be issued along with authorization to effect a reverse-split of our shares of common stock. On November 7, 2016, we filed a preliminary proxy statement for a special meeting of our stockholders in order to obtain approval for, among other things, an increase in the number of common shares authorized to be issued and the authorization to effect a reverse split of our common stock. While obtaining shareholder approval of each of these proposals is not certain, we believe that we will be able to obtain stockholder approval for the authorized share increase and reverse stock split in December 2017.

If we are able to obtain stockholder approval for the authorized share increase and the reverse stock split, and are able to raise sufficient funds through sale of our equity, our anticipated operations include continuing the controlled commercial launch of vBloc Therapy, delivered via the vBloc Rechargeable System, which was approved by the FDA on January 14, 2015. In order to execute our business plans we will need to raise additional funds in the future. Obtaining funds through the sale of additional equity and debt securities may result in dilution to our stockholders. If we raise additional funds through the issuance of debt securities, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. The sale of additional equity may require us to obtain approval from our stockholders to increase the number of shares of common stock we have authorized under our certificate of incorporation. We may require additional capital beyond our currently forecasted amounts. Any such required additional capital may not be available on reasonable terms, if at all. If we are unable to obtain additional financing, we may be required to reduce the scope of, delay, or eliminate some or all of, our planned research, development and commercialization activities, which could materially harm our business. In addition, if we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to products or proprietary technologies, or grant licenses on terms that are not favorable.

## [Table of Contents](#)

Our forecast of the period of time through which our financial resources will be adequate to support our operations, the costs to complete development of products and the cost to commercialize our products are forward-looking statements and involve risks and uncertainties, and actual results could vary materially and negatively as a result of a number of factors, including the factors discussed in Part I, Item 1A, *Risk Factors*, of our Annual Report on Form 10-K for the year ended December 31, 2015. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

Because of the numerous risks and uncertainties associated with the development of medical devices, such as our vBloc Rechargeable System, we are unable to estimate the exact amounts of capital outlays and operating expenditures necessary to complete the development of the products and successfully deliver a commercial product to the market. Our future capital requirements will depend on many factors, including, but not limited to, the following:

- the cost and timing of establishing sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our vBloc Rechargeable System and any products that we may develop;
- the rate of market acceptance of our vBloc Rechargeable System and vBloc Therapy and any other product candidates;
- the cost and timing of obtaining adequate coding, coverage or payment levels for our vBloc Rechargeable System and vBloc Therapy by government healthcare programs and other third-party payors;
- the cost of filing and prosecuting patent applications and defending and enforcing our patent and other intellectual property rights;
- the cost of defending, in litigation or otherwise, any claims that we infringe third-party patent or other intellectual property rights;
- the effect of competing products and market developments;
- the cost of explanting clinical devices;
- the terms and timing of any collaborative, licensing or other arrangements that we may establish;
- any revenue generated by sales of our vBloc Rechargeable System or our future products;
- the scope, rate of progress, results and cost of our clinical trials and other research and development activities;
- the cost and timing of obtaining any further required regulatory approvals;
- the cost of any recalls or other field actions required either by us or by regulatory bodies in those countries in which we market our products; and
- the extent to which we invest in products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

### **Critical Accounting Policies and Estimates**

We prepare our consolidated financial statements in accordance with accounting principles generally accepted in the United States. In doing so, we have to make estimates and assumptions that affect our reported amounts of assets, liabilities and expenses, as well as related disclosure of contingent assets and liabilities. In many cases, we could reasonably have used different accounting policies and estimates. In some cases, changes in the accounting estimates are reasonably likely to occur from period to period. Accordingly, actual results could differ materially from our estimates. To the extent that there are material differences between these estimates and actual results, our financial condition or results of operations will be affected. We base our estimates on past experiences and other assumptions that we believe are reasonable under the circumstances, and we evaluate these estimates on an ongoing basis.

During the nine months ended September 30, 2016, there were no material changes to our significant accounting policies which are fully described in Note 2 to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2015.

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

As of September 30, 2016, we did not have any off-balance sheet arrangements.

## Recent Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board (FASB) issued *Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting (Accounting Standards Update No. 2016-09 (ASU 2016-09))*. ASU 2016-09 modifies several aspects of the accounting for share-based payment awards, including income tax consequences, and classification on the statement of cash flows. This guidance will be effective for interim and annual reporting periods beginning after December 15, 2016. We are currently evaluating the impact of adopting ASU 2016-09 on our consolidated financial statements.

## [Table of Contents](#)

In May 2014, FASB issued *Revenue from Contracts with Customers, Topic 606 (Accounting Standards Update No. 2014-09 (ASU 2014-09))*, which provides a framework for the recognition of revenue, with the objective that recognized revenues properly reflect amounts an entity is entitled to receive in exchange for goods and services. This guidance will be effective for interim and annual reporting periods beginning after December 15, 2017. We are currently evaluating the impact of adopting ASU 2014-09 on our consolidated financial statements.

There have been no other significant changes in recent accounting pronouncements during the nine months ended September 30, 2016 as compared to the recent accounting pronouncements described in our Annual Report on Form 10-K for the year ended December 31, 2015.

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

Our exposure to market risk is confined to our cash and cash equivalents. As of September 30, 2016, we had \$11.5 million in cash and cash equivalents. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. We also seek to maximize income from our investments without assuming significant risk. To achieve our goals, we may maintain a portfolio of cash equivalents and investments in a variety of securities of high credit quality. The securities in our investment portfolio, if any, are not leveraged, are classified as either available for sale or held-to-maturity and are, due to their very short-term nature, subject to minimal interest rate risk. We currently do not hedge interest rate exposure. Because of the short-term maturities of our cash equivalents, we do not believe that an increase in market rates would have any material negative impact on the value of our investment portfolio. We have no investments denominated in foreign currencies and therefore our investments are not subject to foreign currency exchange risk.

### **ITEM 4. CONTROLS AND PROCEDURES**

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

Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act), defines the term “disclosure controls and procedures” as those controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms and that such information is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Based on their evaluation as of September 30, 2016, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms.

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

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2016 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**

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

### **ITEM 1A. RISK FACTORS**

There have been no material changes during the three months ended September 30, 2016 to the risk factors set forth in Part I, Item 1A, *Risk Factors*, of our Annual Report on Form 10-K for the year ended December 31, 2015 and in Part II, Item 1A, *Risk Factors*, of our Quarterly Report on Form 10-Q for the Quarter ended March 31, 2016.



[Table of Contents](#)

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

*Unregistered Sales of Equity Securities*

None.

*Uses of Proceeds from Sale of Registered Securities*

None.

*Purchases of Equity Securities*

None.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.



**EXHIBIT INDEX**

<b><u>Exhibit Number</u></b>	<b><u>Description of Document</u></b>
3.1	Fifth Amended and Restated Certificate of Incorporation of the Company. (Incorporated herein by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-3 filed on May 9, 2014 (File No. 333-195855)).
3.2	Certificate of Amendment to Fifth Amended and Restated Certificate of Incorporation. (Incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on January 8, 2016 (File No. 1-33818)).
3.3	Certificate of Amendment to Fifth Amended and Restated Certificate of Incorporation. (Incorporated herein by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed on January 8, 2016 (File No. 1-33818)).
3.4	Amended and Restated Bylaws of the Company, as currently in effect. (Incorporated herein by reference to Exhibit 3.4 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed on July 6, 2007 (File No. 333-143265)).
† 10.1	Executive Employment Agreement, by and between EnteroMedics Inc. and Scott Youngstrom, dated October 3, 2016 (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 6, 2016).
31.1*	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	Financial statements from the Quarterly Report on Form 10-Q of the Company for the quarter ended September 30, 2016, formatted in Extensible Business Reporting Language: (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Comprehensive Loss, (iv) the Condensed Consolidated Statements of Cash flows and (v) the Notes to Condensed Consolidated Financial Statements.

\* Filed herewith.

† Indicates management contract or compensation plan or agreement.

# Confidential portions of this exhibit (indicated by asterisks) have been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

## CERTIFICATION

I, Dan W. Gladney, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of EnteroMedics 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 consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ DAN W. GLADNEY

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**Dan W. Gladney**  
**President and Chief Executive Officer**

Date: November 14, 2016

## CERTIFICATION

I, Scott P. Youngstrom certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of EnteroMedics 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 consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Scott P. Youngstrom

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**Scott P. Youngstrom**  
**Chief Financial Officer**  
**and Chief Compliance Officer**

Date: November 14, 2016



