

PRESSURE BIOSCIENCES INC
Form 10-Q
May 16, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the quarterly period ended March 31, 2016

or

☐ Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the transition period from _____ to _____

Commission File Number 0-21615

PRESSURE BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Massachusetts

(State or other jurisdiction of
incorporation or organization)

04-2652826

(I.R.S. Employer
Identification No.)

14 Norfolk Avenue

South Easton, Massachusetts

(Address of principal executive offices)

02375

(Zip Code)

(508) 230-1828

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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. (Check one):

Large accelerated filer ☐ Accelerated filer ☐

Non-accelerated filer ☐ Smaller reporting company ☒

Indicate by check mark whether the registrant is a shell company (as defined in Exchange Act Rule 12b-2 of the Exchange Act).

☐ Yes ☒ No

The number of shares outstanding of the Issuer's common stock as of May 13, 2016 was 27,649,437.

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PART I - FINANCIAL INFORMATION**Item 1. Financial Statements****PRESSURE BIOSCIENCES, INC. AND SUBSIDIARY****CONDENSED CONSOLIDATED BALANCE SHEETS****(UNAUDITED)**

| | March 31, 2016 | December 31, 2015 |
|---|--------------------|----------------------|
| ASSETS | | |
| CURRENT ASSETS | | |
| Cash and cash equivalents | \$93,387 | \$116,783 |
| Accounts receivable | 393,911 | 113,256 |
| Inventories, net of \$50,000 reserve at March 31, 2016 and December 31, 2015 | 966,549 | 1,038,371 |
| Prepaid income taxes | 7,381 | 7,381 |
| Prepaid expenses and other current assets | 337,505 | 213,926 |
| Total current assets | 1,798,733 | 1,489,717 |
| Investment in available-for-sale equity securities | 154,824 | 294,522 |
| Property and equipment, net | 13,951 | 20,149 |
| TOTAL ASSETS | \$1,967,508 | \$1,804,388 |
| LIABILITIES AND STOCKHOLDERS' DEFICIT | | |
| CURRENT LIABILITIES | | |
| Accounts payable | \$780,136 | \$941,389 |
| Accrued employee compensation | 214,119 | 176,009 |
| Accrued professional fees and other | 645,003 | 821,088 |
| Deferred revenue | 207,129 | 140,878 |
| Convertible debt, net of debt discount of \$0 at March 31, 2016 and December 31, 2015 | 100,000 | 100,000 |
| Other debt, net of discount of \$2,499 and \$3,041, respectively | 238,979 | 151,628 |
| Warrant derivative liability | 5,571,000 | 3,295,976 |
| Conversion option liability | 7,028,206 | 3,940,791 |
| Total current liabilities | 14,784,572 | 9,567,759 |
| LONG TERM LIABILITIES | | |
| Related party convertible debt, net of debt discount of \$288,930 and \$0, respectively | 2,074 | - |
| Convertible debt, net of debt discount of \$5,655,498 and \$5,223,658, respectively | 1,005,002 | 177,342 |
| Deferred revenue | 36,935 | 36,935 |
| TOTAL LIABILITIES | 15,828,583 | 9,782,036 |
| COMMITMENTS AND CONTINGENCIES (Note 5) | | |
| STOCKHOLDERS' DEFICIT | | |

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| | | |
|--|--------------------|--------------------|
| Series D Convertible Preferred Stock, \$.01 par value; 850 shares authorized; 300 shares issued and outstanding on March 31, 2016 and December 31, 2015, respectively (Liquidation value of \$300,000) | 3 | 3 |
| Series G Convertible Preferred Stock, \$.01 par value; 240,000 shares authorized; 86,570 shares issued and outstanding on March 31, 2016 and December 31, 2015, respectively | 866 | 866 |
| Series H Convertible Preferred Stock, \$.01 par value; 10,000 shares authorized; 10,000 shares issued and outstanding on March 31, 2016 and December 31, 2015, respectively | 100 | 100 |
| Series H2 Convertible Preferred Stock, \$.01 par value; 21 shares authorized; 21 shares issued and outstanding on March 31, 2016 and December 31, 2015, respectively | - | - |
| Series J Convertible Preferred Stock, \$.01 par value; 6,250 shares authorized; 3,546 shares issued and outstanding on March 31, 2016 and December 31, 2015, respectively | 36 | 36 |
| Series K Convertible Preferred Stock, \$.01 par value; 15,000 shares authorized; 11,416 shares issued and outstanding on March 31, 2016 and December 31, 2015, respectively | 114 | 114 |
| Common stock, \$.01 par value; 100,000,000 shares authorized; 23,309,898 and 23,004,898 shares issued and outstanding on March 31, 2016 and December 31, 2015, respectively | 233,100 | 230,050 |
| Warrants to acquire common stock | 5,416,681 | 5,416,681 |
| Additional paid-in capital | 26,240,345 | 26,036,733 |
| Accumulated other comprehensive income | (244,723) | (105,025) |
| Accumulated deficit | (45,507,597) | (39,557,206) |
| Total stockholders' deficit | (13,861,075) | (7,977,648) |
| TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT | \$1,967,508 | \$1,804,388 |

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

PRESSURE BIOSCIENCES, INC. AND SUBSIDIARY**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS****(UNAUDITED)**

| | For the Three Months Ended March 31, | |
|---|--|----------------|
| | 2016 | 2015 |
| Revenue: | | |
| Products, services, other | \$454,350 | \$359,364 |
| Grant revenue | 56,128 | 80,770 |
| Total revenue | 510,478 | 440,134 |
| Costs and expenses: | | |
| Cost of products and services | 221,699 | 190,783 |
| Research and development | 335,270 | 231,923 |
| Selling and marketing | 191,236 | 166,223 |
| General and administrative | 808,218 | 726,024 |
| Total operating costs and expenses | 1,556,423 | 1,314,953 |
| Operating loss | (1,045,945) | (874,819) |
| Other (expense) income: | | |
| Interest expense, net | (835,144) | (605,585) |
| Other expense | (912) | (36,913) |
| Change in fair value of derivative liabilities | (4,068,390) | (530,138) |
| Total other (expense) income | (4,904,446) | (1,172,636) |
| Net loss | (5,950,391) | (2,047,455) |
| Accrued dividends on convertible preferred stock | - | (16,668) |
| Net loss applicable to common shareholders | \$(5,950,391) | \$(2,064,123) |
| Net loss per share attributable to common stockholders - basic and diluted | \$(0.26) | \$(0.11) |
| Weighted average common stock shares outstanding used in the basic and diluted net loss per share calculation | 23,198,360 | 18,840,390 |

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

PRESSURE BIOSCIENCES, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(UNAUDITED)

| | For the Three Months Ended March 31, | |
|--|--|---------------|
| | 2016 | 2015 |
| Comprehensive Loss | | |
| Net loss | \$(5,950,391) | \$(2,047,455) |
| Other comprehensive loss | | |
| Unrealized loss on marketable securities | (139,698) | - |
| Comprehensive loss | \$(6,090,089) | \$(2,047,455) |

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

PRESSURE BIOSCIENCES, INC. AND SUBSIDIARY**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****(UNAUDITED)**

| | For the Three Months Ended March 31, | |
|---|--|-------------------|
| | 2016 | 2015 |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Net loss | \$(5,950,391) | \$(2,047,455) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 6,198 | 6,919 |
| Accretion of interest and amortization of debt discount | 839,234 | 425,226 |
| Gain on settlement of debt | (5,044) | - |
| Stock-based compensation expense | 101,462 | 54,890 |
| Amortization of third party fees paid in common stock and warrants | 105,200 | 46,744 |
| Change in fair value of derivative liabilities | 4,068,390 | 530,138 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (280,655) | (51,391) |
| Inventories | 71,822 | 51,557 |
| Prepaid expenses and other assets | 43,303 | (22,836) |
| Accounts payable | (161,253) | (115,670) |
| Accrued employee compensation | 38,110 | (16) |
| Deferred revenue and other accrued expenses | (109,834) | 71,412 |
| Net cash used in operating activities | (1,233,458) | (1,050,482) |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | |
| Purchases of property plant and equipment | - | - |
| Net cash used in investing activities | - | - |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Net proceeds from related party convertible debt | 96,667 | 6,300 |
| Payment of related party debt | - | (12,300) |
| Net proceeds from convertible debt | 1,025,500 | 1,054,750 |
| Payments on convertible debt | - | (500,500) |
| Net proceeds from non-convertible debt | 256,660 | 396,127 |
| Payments on non-convertible debt | (168,765) | (147,533) |
| Net cash provided by financing activities | 1,210,062 | 796,844 |
| NET DECREASE IN CASH | (23,396) | (253,638) |
| CASH AT BEGINNING OF YEAR | 116,783 | 473,948 |
| CASH AT END OF PERIOD | \$93,387 | \$220,310 |

SUPPLEMENTAL INFORMATION

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| | | |
|---|-----------|-----------|
| Interest paid in cash | \$1,154 | \$203,311 |
| Income taxes paid in cash | - | - |
| NON CASH TRANSACTIONS: | | |
| Convertible debt exchanged for common stock | - | 138,000 |
| Reclassification of conversion option liabilities into equity | - | 661,464 |
| Accrued dividends on preferred stock | - | 16,668 |
| Unrealized loss from available-for-sale equity securities | 139,698 | - |
| Debt discount from derivative liability | 1,294,049 | - |
| Convertible debt held in escrow | 166,882 | - |

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

PRESSURE BIOSCIENCES, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS MARCH 31, 2016

(UNAUDITED)

1) Business Overview, Liquidity and Management Plans

Pressure BioSciences, Inc. (“we”, “our”, “the Company”) is focused on solving the challenging problems inherent in biological sample preparation, a crucial laboratory step performed by scientists worldwide working in biological life sciences research. Sample preparation is a term that refers to a wide range of activities that precede most forms of scientific analysis. Sample preparation is often complex, time-consuming and, in our belief, one of the most error-prone steps of scientific research. It is a widely-used laboratory undertaking – the requirements of which drive what we believe is a large and growing worldwide market. We have developed and patented a novel, enabling technology platform that can control the sample preparation process. It is based on harnessing the unique properties of high hydrostatic pressure. This process, called pressure cycling technology, or PCT, uses alternating cycles of hydrostatic pressure between ambient and ultra-high levels i.e., 35,000 pounds per square inch (“*psi*”) or greater to safely, conveniently and reproducibly control the actions of molecules in biological samples, such as cells and tissues from human, animal, plant and microbial sources.

Our pressure cycling technology uses internally developed instrumentation that is capable of cycling pressure between ambient and ultra-high levels at controlled temperatures and specific time intervals, to rapidly and repeatedly control the interactions of bio-molecules, such as deoxyribonucleic acid (“*DNA*”), ribonucleic acid (“*RNA*”), proteins, lipids and small molecules. Our laboratory instrument, the Barocycler®, and our internally developed consumables product line, which include our Pressure Used to Lyse Samples for Extraction (“*PULSE*”) tubes, and other processing tubes, and application specific kits such as consumable products and reagents, together make up our PCT Sample Preparation System (“*PCT SPS*”).

In 2015, together with an investment bank, we formed a subsidiary called Pressure BioSciences Europe (“PBI Europe”) in Poland. We have 49% ownership interest with the investment bank retaining 51%. As of now, PBI Europe does not have any operating activities but is expected to commence operations in 2016. Therefore, we don’t have control of the subsidiary and did not consolidate in our financial statements.

2) Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the liquidation of liabilities in the normal course of business. However, we have experienced negative cash flows from operations with respect to our pressure cycling technology

business since our inception. As of March 31, 2016, we do not have adequate working capital resources to satisfy our current liabilities and as a result, there is substantial doubt regarding our ability to continue as a going concern. We have been successful in raising cash through debt and equity offerings in the past and as described in Note 6, we completed an over-subscribed \$5.0 million debt financing on March 31, 2016 with a total amount raised of \$6.3 million. We have financing efforts in place to continue to raise cash through debt and equity offerings.

Management has developed a plan to continue operations. This plan includes obtaining equity or debt financing. During the three months ended March 31, 2016 we received \$1,684,549 net proceeds, in additional convertible and non-convertible debt. Although we have successfully completed financings and reduced expenses in the past, we cannot assure you that our plans to address these matters in the future will be successful.

We need substantial additional capital to fund normal operations in future periods. In the event that we are unable to obtain financing on acceptable terms, or at all, we will likely be required to cease our operations, pursue a plan to sell our operating assets, or otherwise modify our business strategy, which could materially harm our future business prospects. These financial statements do not include any adjustments that might result from this uncertainty.

3) Interim Financial Reporting

The accompanying unaudited condensed consolidated balance sheet as of December 31, 2015, which was derived from audited financial statements, and the unaudited interim condensed consolidated financial statements of Pressure BioSciences, Inc. have been prepared in accordance with accounting principles generally accepted in the United States of America (“generally accepted accounting principles” or “GAAP”) for interim financial information. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all material adjustments (consisting of only normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the three months ended March 31, 2016 are not necessarily indicative of the results that may be expected for the year ending December 31, 2016. For further information, refer to the audited consolidated financial statements and footnotes thereto included in the Company’s Annual Report on Form 10-K (the “Form 10-K”) for the fiscal year ended December 31, 2015 as filed with the Securities and Exchange Commission on April 5, 2016.

4) Summary of Significant Accounting Policies

Principles of Consolidation

The condensed consolidated financial statements include the accounts of Pressure BioSciences, Inc., and its wholly-owned subsidiary PBI BioSeq, Inc. All intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

To prepare our condensed consolidated financial statements in conformity with accounting principles generally accepted in the United States of America, we are required to make significant estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. In addition, significant estimates were made in projecting future cash flows to quantify deferred tax assets, the costs associated with fulfilling our warranty obligations for the instruments that we sell, and the estimates employed in our calculation of fair value of stock options awarded and warrant derivative liability. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from the estimates and assumptions used.

Concentrations

Credit Risk

Our financial instruments that potentially subject us to concentrations of credit risk consist primarily of cash, cash equivalents, and trade receivables. We have cash investment policies which, among other things, limit investments to investment-grade securities. We perform ongoing credit evaluations of our customers, and the risk with respect to trade receivables is further mitigated by the fact that many of our customers are government institutions, large pharmaceutical and biotechnology companies, and academic laboratories.

The following table illustrates the level of concentration as a percentage of total revenues during the three months ended March 31, 2016 and 2015.

| | For the Three Months Ended March 31, 2016 2015 | | | |
|--------------------|---|------|--|--|
| Top Five Customers | 46 % | 64 % | | |
| Federal Agencies | 11 % | 26 % | | |

The following table illustrates the level of concentration as a percentage of net accounts receivable balance as of March 31, 2016 and December 31, 2015:

| | March 31, 2016 | | December, 31, 2015 | |
|--------------------|----------------------|--|-----------------------|--|
| Top Five Customers | 55 % | | 93 % | |
| Federal Agencies | 0 % | | 1 % | |

Product Supply

BIT Group, Inc. of California has been our sole contract manufacturer for our PCT NEP3229 and NEP2320 instrumentation. However, the Company has reached agreement for a Massachusetts-based contract manufacturer to assemble its future instrumentation builds starting with the new NEP2320 Extreme Barocycler instrument, effective in May 2016.

Investment in Available-For-Sale Equity Securities

As of March 31, 2016, we held 601,500 shares of common stock of Everest Investments Holdings S.A. (“Everest”), a Polish publicly traded company listed on the Warsaw Stock Exchange. We account for this investment in accordance with ASC 320 “*Investments — Debt and Equity Securities*” as securities available for sale. On March 31, 2016, our balance sheet reflected the fair value of our investment in Everest to be \$154,824, based on the closing price of Everest shares of \$0.26 per share on that day. The carrying value of our investment in Everest common stock held will change from period to period based on the closing price of the common stock of Everest as of the balance sheet date. This change in market value will be recorded by us on a quarterly basis as an unrealized gain or loss in Comprehensive Income or Loss.

Debt Issuance Costs

In April 2015, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2015-03, “Simplifying the Presentation of Debt Issuance Costs” (“ASU 2015-03”). ASU 2015-03 requires that debt issuance costs be presented as a direct deduction from the carrying amount of the related debt liability, consistent with the presentation of debt discounts. Prior to the issuance of ASU 2015-03, debt issuance costs were required to be presented as deferred charge assets, separate from the related debt liability. ASU 2015-03 does not change the recognition and measurement requirements for debt issuance costs. The Company early-adopted ASU 2015-03 as of the end of its Fiscal 2015, and applied its provisions retrospectively.

Computation of Loss per Share

Basic loss per share is computed by dividing loss available to common shareholders by the weighted average number of common shares outstanding. Diluted loss per share is computed by dividing loss available to common shareholders by the weighted average number of common shares outstanding plus additional common shares that would have been outstanding if dilutive potential common shares had been issued. For purposes of this calculation, convertible preferred stock, common stock dividends, and warrants and options to acquire common stock, are all considered common stock equivalents in periods in which they have a dilutive effect and are excluded from this calculation in periods in which these are anti-dilutive to our net loss.

The following table illustrates our computation of loss per share for the three months ended March 31, 2016 and 2015:

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| | For the Three Months Ended March 31, | |
|---|--|----------------|
| | 2016 | 2015 |
| Numerator: | | |
| Net loss | \$(5,950,391) | \$(2,047,455) |
| Preferred dividends accrued | - | (16,668) |
| Net loss applicable to common shareholders | \$(5,950,391) | \$(2,064,123) |
| Denominator for basic and diluted loss per share: | | |
| Weighted average common stock shares outstanding | 23,198,360 | 18,840,390 |
| Loss per common share - basic and diluted | \$(0.26) | \$(0.11) |

The following table presents securities that could potentially dilute basic loss per share in the future. For all periods presented, the potentially dilutive securities were not included in the computation of diluted loss per share because these securities would have been anti-dilutive to our net loss. The Series D Convertible Preferred Stock, Series G Convertible Preferred Stock, Series H Convertible Preferred Stock, Series J Convertible Preferred Stock and Series K Convertible Preferred Stock are presented below as if they were converted into common shares according to the conversion terms.

| | For the Three Months Ended March 31, | |
|---------------------------------------|--|------------|
| | 2016 | 2015 |
| Stock options | 5,460,250 | 3,406,250 |
| Convertible debt | 25,226,800 | 8,555,938 |
| Common stock warrants | 26,998,401 | 19,182,201 |
| Convertible preferred stock: | | |
| Series D Convertible Preferred Stock | 750,000 | 750,000 |
| Series G Convertible Preferred Stock | 865,700 | 865,700 |
| Series H Convertible Preferred Stock | 1,000,000 | 1,000,000 |
| Series H2 Convertible Preferred Stock | 2,100,000 | 2,100,000 |
| Series J Convertible Preferred Stock | 3,546,000 | 3,546,000 |
| Series K Convertible Preferred Stock | 11,416,000 | 11,416,000 |
| | 77,363,151 | 50,822,089 |

Accounting for Stock-Based Compensation Expense

We maintain equity compensation plans under which incentive stock options and non-qualified stock options are granted to employees, independent members of our Board of Directors and outside consultants. We recognize stock-based compensation expense over the requisite service period using the Black-Scholes formula to estimate the fair value of the stock options on the date of grant.

Determining Fair Value of Stock Option Grants

Valuation and Amortization Method - The fair value of each option award is estimated on the date of grant using the Black-Scholes pricing model based on certain assumptions. The estimated fair value of employee stock options is amortized to expense using the straight-line method over the vesting period.

Expected Term - The Company uses the simplified calculation of expected life, as the Company does not currently have sufficient historical exercise data on which to base an estimate of expected term. Using this method, the expected term is determined using the average of the vesting period and the contractual life of the stock options granted.

Expected Volatility - Expected volatility is based on the Company's historical stock volatility data over the expected term of the award.

Risk-Free Interest Rate - The Company bases the risk-free interest rate used in the Black-Scholes valuation method on the implied yield currently available on U.S. Treasury zero-coupon issues with an equivalent remaining term.

Forfeitures - The Company records stock-based compensation expense only for those awards that are expected to vest. The Company estimated a forfeiture rate of 5% for awards granted based on historical experience and future expectations of options vesting. The Company used this historical rate as our assumption in calculating future stock-based compensation expense.

The Company recognized stock-based compensation expense of \$101,462 and \$54,890 for the three months ended March 31, 2016 and 2015, respectively. The following table summarizes the effect of this stock-based compensation expense within each of the line items of our costs and expenses within our Condensed Consolidated Statements of Operations:

| | For the Three Months Ended March 31, | |
|--|--|----------|
| | 2016 | 2015 |
| Research and development | \$20,381 | \$11,343 |
| Selling and marketing | 12,690 | 6,975 |
| General and administrative | 68,391 | 36,572 |
| Total stock-based compensation expense | \$101,462 | \$54,890 |

Fair Value of Financial Instruments

Due to their short maturities, the carrying amounts for cash and cash equivalents, accounts receivable, accounts payable, and accrued expenses approximate their fair value. Long-term liabilities are primarily related to convertible debentures and deferred revenue with carrying values that approximate fair value.

Fair Value Measurements

The Company follows the guidance of FASB ASC Topic 820, “*Fair Value Measurements and Disclosures*” (“ASC 820”) as it related to all financial assets and financial liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis.

The Company generally defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date (exit price). The Company uses a three-tier fair value hierarchy, which classifies the inputs used in measuring fair values. These tiers include: Level 1, defined as observable inputs such as quoted prices for identical instruments in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring the Company to develop its own assumptions.

Financial assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company has determined that its financial assets are classified within Level 1 and its financial liabilities are currently classified within Level 3 in the fair value hierarchy. The development of the unobservable inputs for Level 3 fair value measurements and fair value calculations are the responsibility of the Company's management.

The following tables set forth the Company's financial assets and liabilities that were accounted for at fair value on a recurring basis as of March 31, 2016:

| Fair value measurements at March 31, 2016 using: | | | | | |
|--|----------------|---|---|---|--|
| | March 31, 2016 | Quoted prices in active markets (Level 1) | Significant other observable inputs (Level 2) | Significant unobservable inputs (Level 3) | |
| Available-For-Sale Equity Securities | 154,824 | 154,824 | - | - | |
| Total Financial Assets | \$ 154,824 | \$ 154,824 | \$ - | \$ - | |

| | March 31, 2016 | Quoted prices in active markets (Level 1) | Significant other observable inputs (Level 2) | Significant unobservable inputs (Level 3) | |
|--|----------------|---|---|---|--|
| Series D Preferred Stock Purchase Warrants | \$ 256,420 | - | - | \$ 256,420 | |
| Warrants Issued with Convertible Debt | 5,314,580 | - | - | 5,314,580 | |
| Conversion Option Derivative Liabilities | 7,028,206 | - | - | 7,028,206 | |
| Total Derivatives | \$ 12,599,206 | \$ - | \$ - | \$ 12,599,206 | |

The following table provides a summary of the changes in fair value, including net transfers in and/or out, of the derivative financial instruments, measured at fair value on a recurring basis using significant unobservable inputs for the three months ended March 31, 2016:

| | December 31, 2015 | Issuance fair value | Change in fair value | March 31, 2016 |
|--|-------------------|---------------------|----------------------|----------------|
| Series D Preferred Stock Purchase Warrants | \$ 173,526 | \$ - | \$ 82,894 | \$ 256,420 |
| Warrants Issued with Convertible Debt | 3,122,450 | 1,087,254 | 1,104,876 | 5,314,580 |
| Conversion Option Derivative Liabilities | 3,940,791 | 1,535,290 | 1,552,125 | 7,028,206 |

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| | | | | |
|-------------------|-------------|-------------|-------------|--------------|
| Total Derivatives | \$7,236,767 | \$2,622,544 | \$2,739,895 | \$12,599,206 |
|-------------------|-------------|-------------|-------------|--------------|

The amounts above valued at issuance includes \$1,328,495 that was charged directly to “change in fair value of derivative liabilities” at issuance.

The following tables set forth the Company’s financial assets and liabilities that were accounted for at fair value on a recurring basis as of December 31, 2015:

| | December 31, 2015 | Fair value measurements at December 31, 2015 using: | | |
|--------------------------------------|-------------------|---|---|---|
| | | Quoted prices in active markets (Level 1) | Significant other observable inputs (Level 2) | Significant unobservable inputs (Level 3) |
| Available-For-Sale Equity Securities | 294,522 | 294,522 | - | - |
| Total Financial Assets | \$294,522 | \$294,522 | \$ - | \$ - |

| | December 31, 2015 | Quoted prices in active markets (Level 1) | Significant other observable inputs (Level 2) | Significant unobservable inputs (Level 3) |
|--|-------------------|---|---|---|
| | | | | |
| Series D Preferred Stock Purchase Warrants | \$173,526 | - | - | \$ 173,526 |
| Warrants Issued with Convertible Debt | 3,122,450 | - | - | 3,122,450 |
| Conversion Option Derivative Liabilities | 3,940,791 | - | - | 3,940,791 |
| Total Derivatives | \$7,236,767 | \$- | \$ - | \$ 7,236,767 |

The following table provides a summary of the changes in fair value, including net transfers in and/or out, of the derivative financial instruments, measured at fair value on a recurring basis using significant unobservable inputs for the three months ended March 31, 2015:

| | January 1, 2015 | Change in Fair Value | Reclassified to Equity | March 31, 2015 |
|--|-----------------|----------------------|------------------------|----------------|
| Series D Preferred Stock Purchase Warrants | \$159,875 | \$51,031 | - | \$210,906 |

The assumptions for the binomial pricing model are represented in the table below for the warrants issued in the Series D private placement reflected on a per share common stock equivalent basis.

| Assumptions | November 10, 2011 | | Warrants revalued at December 31, 2015 | | Warrants revalued at March 31, 2016 | |
|---------------------------|----------------------|---|---|---|---|---|
| Expected life (in months) | 60.0 | | 11.0 | | 7.0 | |
| Expected volatility | 104.5 | % | 104.9 | % | 103.6 | % |
| Risk-free interest rate | 0.875 | % | 0.65 | % | 0.39 | % |
| Exercise price | \$ 0.81 | | \$ 0.25 | | \$ 0.25 | |
| Fair value per warrant | \$ 0.54 | | \$ 0.16 | | \$ 0.24 | |

The assumptions for the binomial pricing model are represented in the table below for the warrants issued with the Convertible Debt throughout the period reflected on a per share common stock equivalent basis.

| Assumptions | At Issuance Fair value | | Warrants revalued at December 31, 2015 | | Warrants revalued at March 31, 2016 | |
|---------------------------|---------------------------|---|---|---|--|---|
| Expected life (in months) | 60.0 | | 55.0-60.0 | | 48.0-60.0 | |
| Expected volatility | 118.3 - 138.3 | % | 136.3-141.6 | % | 138.3 -142.2 | % |
| Risk-free interest rate | 1.23-1.69 | % | 1.29-1.76 | % | 1.21 | % |
| Exercise price | \$0.40 | | 0.40 | | \$0.40 | |
| Fair value per warrant | \$ 0.19-\$0.40 | | 0.30 | | \$0.40 | |

The assumptions for the binomial pricing model are represented in the table below for the conversion options reflected on a per share common stock equivalent basis.

| Assumptions | At Issuance fair value | | Conversion options revalued at December 31, 2015 | | Conversion options revalued at March 31, 2016 | |
|---------------------------|---------------------------|---|--|---|--|---|
| Expected life (in months) | 6-24 | | 18-24 | | 12-24 | |
| Expected volatility | 104.2-153.8 | % | 112.2-114.7 | % | 112.03-113.67 | % |
| Risk-free interest rate | 0.05-0.99 | % | 1.06 | % | 0.59-0.73 | % |

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| | | | |
|----------------------------------|---------------|---------------|---------------|
| Exercise price | \$0.28-\$0.35 | \$0.28 | \$0.28 |
| Fair value per conversion option | \$0.09-\$0.30 | \$0.14-\$0.33 | \$0.27-\$0.30 |

5) Commitments and Contingencies

Operating Leases

Our corporate offices are currently located at 14 Norfolk Avenue, South Easton, Massachusetts 02375. We are currently paying \$4,800 per month, on a lease extension, signed on December 29, 2015, that expires December 31, 2016, for our corporate office.

On November 1, 2014 we signed a lease for lab space in Medford, MA. We subsequently expanded our space in Medford. The lease expires December 30, 2017 and requires monthly payments of \$5,385 subject to annual cost of living increases.

Rental costs are expensed as incurred. During the three months ended March 31, 2016 and 2015 we incurred \$33,877 and \$22,722 in rent expense, respectively for the use of our corporate office and research and development facilities.

Government Grants

We have received a \$1.05 million NIH SBIR Phase II Grant. Under the grant, the NIH has committed to pay the Company to develop a high-throughput, high pressure-based DNA Shearing System for Next Generation Sequencing and other genomic applications.

6) Convertible Debt and Other Debt

We entered into Subscription Agreements (the “Subscription Agreement”) with various individuals (each, a “Purchaser”) between July 23, 2015 and March 31, 2016, pursuant to which the Company sold Senior Secured Convertible Debentures (the “Debentures”) and warrants to purchase shares of common stock equal to 50% of the number of shares issuable pursuant to the subscription amount (the “Warrants”) for an aggregate purchase price of \$6,319,549 (the “Purchase Price”).

The Company issued a principal aggregate amount of \$6,951,504 in Debentures which includes a 10% original issue discount on the Purchase Price. The Debenture does not accrue any additional interest during the first year it is outstanding but accrues interest at a rate equal to 10% per annum for the second year it is outstanding. The Debenture

has a maturity date of two years from issuance. The Debenture is convertible any time after its issuance date. The Purchaser has the right to convert the Debenture into shares of the Company's common stock at a fixed conversion price equal to \$0.28 per share, subject to applicable adjustments. In the second year that the Debenture is outstanding, any interest accrued shall be payable quarterly in either cash or common stock, at the Company's discretion.

At any time after the Issuance Date, the Company has the option, subject to certain conditions, to redeem some or all of the then outstanding principal amount of the Debenture for cash in an amount equal to the sum of (i) 120% of the then outstanding principal amount of the Debenture, (ii) accrued but unpaid interest and (iii) any liquidated damages and other amounts due in respect of the Debenture.

Warrants

The Company issued warrants exercisable into a total of 11,284,909 shares of our common stock. The Warrants issued in this transaction are immediately exercisable at an exercise price of \$0.40 per share, subject to applicable adjustments including full ratchet anti-dilution in the event that we issue any securities at a price lower than the exercise price then in effect. The Warrants have an expiration period of five years from the original issue date. The Warrants are subject to adjustment for stock splits, stock dividends or recapitalizations and also include anti-dilution price protection for subsequent equity sales below the exercise price.

Subject to the terms and conditions of the Warrants, at any time commencing six months from the Final Closing, the Company has the right to call the Warrants for cancellation if the volume weighted average price of its Common Stock on the OTC QB Market (or other primary trading market or exchange on which the Common Stock is then traded) equals or exceeds three times the per share exercise price of the Warrants for 15 out of 20 consecutive trading days.

Security Agreement

In connection with the Subscription Agreement and Debenture, the Company entered into Security Agreements with the Purchasers whereby the Company agreed to grant to Purchasers an unconditional and continuing, first priority security interest in all of the assets and property of the Company to secure the prompt payment, performance and discharge in full of all of Company's obligations under the Debentures, Warrants and the other Transaction Documents.

The Company determined that the conversion feature of the Debentures met the definition of a liability in accordance with ASC 815-40 and therefore bifurcated the conversion feature on each debt agreement and accounted for it as a derivative liability. The fair value of the conversion feature was accounted for as a note discount and are amortized to interest expense over the life of the loan. The fair value of the conversion feature was reflected in the conversion option liability line in the condensed consolidated balance sheets.

The proceeds from these convertible debts were allocated between the host debt instrument and the convertible option based on the residual method. The estimated fair value of the convertible option was determined using a binomial formula, resulting in allocations to the convertible option and accounted for as a liability in the Company's condensed consolidated balance sheet. In accordance with the provisions of ASC 815-40, the gross proceeds are offset by debt discounts, which are amortized to interest expense over the expected life of the debt.

ASC 470-20 states that the proceeds from the issuance of debt with detachable stock warrants should be allocated between the debt and warrants on the basis of their relative fair market values. The debt discount will be amortized to interest expense over the two year term of these loans. We amortized \$839,234 of the debt discount to interest expense in 2016. The warrants issued in connection with the convertible debentures are classified as warrant derivative liabilities because the warrants are entitled to certain rights in subsequent financings and the warrants contain “down-round protection” and therefore, do not meet the scope exception for treatment as a derivative under ASC 815, Derivatives and Hedging, (“ASC 815”). Since “down-round protection” is not an input into the calculation of the fair value of the warrants, the warrants cannot be considered indexed to the Company’s own stock which is a requirement for the scope exception as outlined under ASC 815. The estimated fair value of the warrants was determined using the binomial model, resulting in an allocation of \$2,840,446 to the total warrants out of the gross proceeds of \$6,319,549. The fair value will be affected by changes in inputs to that model including our stock price, expected stock price volatility, the contractual term, and the risk-free interest rate. We will continue to classify the fair value of the warrants as a liability until the warrants are exercised, expire or are amended in a way that would no longer require these warrants to be classified as a liability, whichever comes first.

The specific terms of the convertible debts and outstanding balances as of March 31, 2016 are listed in the table below.

Fixed Rate Convertible Notes

| Inception Date | Term | Loan Amount | Outstanding Balance | Original Issue Discount | Interest Rate | Deferred Finance Fees | Discount related to Fair value of conversion feature and warrants |
|--------------------|-----------|-------------|---------------------|-------------------------|---------------|-----------------------|---|
| July 22, 2015 | 24 months | \$2,180,000 | \$2,180,000 | \$218,000 | 1 10 % | \$388,532 | \$2,163,074 |
| September 25, 2015 | 24 months | 1,100,000 | 1,100,000 | 110,000 | 1 10 % | 185,956 | 1,022,052 |
| October 2, 2015 | 24 months | 150,000 | 150,000 | 15,000 | 1 10 % | 26,345 | 140,832 |
| October 6, 2015 | 24 months | 30,000 | 30,000 | 3,000 | 1 10 % | 5,168 | 26,721 |
| October 14, 2015 | 24 months | 50,000 | 50,000 | 5,000 | 1 10 % | 8,954 | 49,377 |
| November 2, 2015 | 24 months | 250,000 | 250,000 | 25,000 | 1 10 % | 43,079 | 222,723 |
| November 10, 2015 | 24 months | 50,000 | 50,000 | 5,000 | 1 10 % | 8,790 | 46,984 |
| November 12, 2015 | 24 months | 215,000 | 215,000 | 21,500 | 1 10 % | 38,518 | 212,399 |
| November 20, 2015 | 24 months | 200,000 | 200,000 | 20,000 | 1 10 % | 37,185 | 200,000 |
| December 4, 2015 | 24 months | 170,000 | 170,000 | 17,000 | 1 10 % | 37,352 | 170,000 |
| December 11, 2015 | 24 months | 360,000 | 360,000 | 36,000 | 1 10 % | 75,449 | 360,000 |
| December 18, 2015 | 24 months | 55,000 | 55,000 | 5,500 | 1 10 % | 11,714 | 55,000 |
| December 31, 2015 | 24 months | 100,000 | 100,000 | 10,000 | 1 10 % | 20,634 | 100,000 |
| January 11, 2016 | 24 months | 100,000 | 100,000 | 10,000 | 1 10 % | 24,966 | 80,034 |
| January 20, 2016 | 24 months | 50,000 | 50,000 | 5,000 | 1 10 % | 9,812 | 40,188 |
| January 29, 2016 | 24 months | 300,000 | 300,000 | 30,000 | 1 10 % | 60,887 | 239,113 |
| February 26, 2016 | 24 months | 200,000 | 200,000 | 20,000 | 1 10 % | 43,952 | 156,048 |
| March 10, 2016 | 24 months | 125,000 | 125,000 | 12,500 | 1 10 % | 18,260 | 106,740 |
| March 18, 2016 | 24 months | 360,000 | 360,000 | 36,000 | 1 10 % | 94,992 | 265,008 |
| March 24, 2016 | 24 months | 106,667 | 106,667 | 10,667 | 1 10 % | 15,427 | 91,240 |
| March 31, 2016 | 24 months | 167,882 | 167,882 | 16,788 | 1 10 % | 2,436 | 165,446 |
| | | \$6,319,549 | \$6,319,549 | \$631,955 | | \$1,158,408 | \$5,912,979 |

1 The original issue discount is reflected in the first year.

2 The annual interest starts accruing in the second year.

The closings above on March 10, 24, and 31, 2016 included \$264,667 of proceeds received from related parties.

At any time after six months from the Inception Date, the Company has the right to prepay the above Debentures in cash for 120% of the principal amount outstanding and any accrued interest. As of March 31, 2016, a total of approximately \$291,000 convertible debentures were issued to related parties.

The following table provides a summary of the changes in convertible debt, net of unamortized discount, during 2016:

| | 2016 |
|---|-------------|
| Balance at January 1, | \$277,342 |
| Issuance of convertible debt, face value | 1,550,504 |
| Original issue discount | (140,955) |
| Debt discount from derivative liabilities (embedded conversion option and warrants) | (1,143,817) |
| Deferred financing fees | (275,232) |
| Accretion of interest and amortization of debt discount to interest expense through March 31, | 839,234 |
| Balance at March 31, | 1,107,076 |
| Less: current portion | 100,000 |
| Convertible debt, long-term portion | \$1,007,076 |

Other Notes

On January 6, 2016 we signed a Merchant Agreement with a lender. Under the agreement we received \$250,000 in exchange for rights to all customer receipts until the lender is paid \$322,500, which is collected at the rate of \$1,280 per business day. The payments were secured by second position rights to all customer receipts until the loan has been paid in full. \$138,840 of the proceeds were used to pay off the outstanding balance of a previous loan from another lender. The Company recognized a gain on the settlement of the previous loan of \$5,044 which was credited to interest expense. The Company paid \$2,500 in fees in connection with this loan. The note was still outstanding as of March 31, 2016 with a balance of \$175,774.

On January 20, 2016, we borrowed \$50,000 from an individual with no interest or fees. We paid back the loan in March 2016.

On February 8, 2016 we signed a Merchant Agreement with a lender. Under the agreement we received \$100,000 in exchange for third position rights to all customer receipts until the lender is paid \$129,900, which is collected at the rate of \$927 per business day. The Company paid \$2,000 in fees in connection with this loan. The note was still outstanding as of March 31, 2016 with a balance of \$65,704.

7) Stockholders' Deficit

Preferred Stock

We are authorized to issue 1,000,000 shares of preferred stock with a par value of \$0.01. Of the 1,000,000 shares of preferred stock:

- 1) 20,000 shares have been designated as Series A Junior Participating Preferred Stock (“*Junior A*”)
- 2) 313,960 shares have been designated as Series A Convertible Preferred Stock (“*Series A*”)
- 3) 279,256 shares have been designated as Series B Convertible Preferred Stock (“*Series B*”)
- 4) 88,098 shares have been designated as Series C Convertible Preferred Stock (“*Series C*”)
- 5) 850 shares have been designated as Series D Convertible Preferred Stock (“*Series D*”)
- 6) 500 shares have been designated as Series E Convertible Preferred Stock (“*Series E*”)
- 7) 240,000 shares have been designated as Series G Convertible Preferred Stock (“*Series G*”)
- 8) 10,000 shares have been designated as Series H Convertible Preferred Stock (“*Series H*”)
- 9) 21 shares have been designated as Series H2 Convertible Preferred Stock (“*Series H2*”)
- 10) 6,250 shares have been designated as Series J Convertible Preferred Stock (“*Series J*”)
- 11) 15,000 shares have been designated as Series K Convertible Preferred Stock (“*Series K*”)

As of March 31, 2016, there were no shares of Junior A, and Series A, B, C and E issued and outstanding. See our Annual Report on Form 10-K for the year ended December 31, 2015 for the pertinent disclosures of preferred stock.

Stock Options and Warrants

Our stockholders approved our amended 2005 Equity Incentive Plan (the “Plan”) pursuant to which an aggregate of 1,800,000 shares of our common stock were reserved for issuance upon exercise of stock options or other equity awards made under the Plan. Under the Plan, we may award stock options, shares of common stock, and other equity interests in the Company to employees, officers, directors, consultants, and advisors, and to any other persons the Board of Directors deems appropriate. As of March 31, 2016, options to acquire 1,720,750 shares were outstanding under the Plan with 79,250 shares available for future grant under the Plan.

On December 12, 2013 at the Company’s special meeting the shareholders approved the 2013 Equity Incentive Plan (the “2013 Plan”) pursuant to which 3,000,000 shares of our common stock were reserved for issuance upon exercise of stock options or other equity awards. Under the 2013 Plan, we may award stock options, shares of common stock, and other equity interests in the Company to employees, officers, directors, consultants, and advisors, and to any other persons the Board of Directors deems appropriate. As of March 31, 2016 1,675,500 options have been granted under the 2013 Plan.

On November 29, 2015 the Company’s Board of Directors adopted the 2015 Nonqualified Stock Option Plan (the “2015 Plan”) pursuant to which 5,000,000 shares of our common stock were reserved for issuance upon exercise of non-qualified stock options. Under the 2015 Plan, we may award non-qualified stock options in the Company to employees, officers, directors, consultants, and advisors, and to any other persons the Board of Directors deems appropriate. As of March 31, 2016, non-qualified options to acquire 2,068,000 shares were outstanding under the Plan with 2,932,000 shares available for future grants under the 2015 Plan.

All of the outstanding non-qualified options had an exercise price that was at or above the Company’s common stock share price on March 31, 2016.

The following tables summarize information concerning options and warrants outstanding and exercisable:

| | Stock Options | | Warrants | | Total | |
|-------------------------------|---------------------|--------------|---------------------|--------------|------------|-------------|
| | Weighted Average | Price | Weighted Average | Price | Shares | Exercisable |
| | Shares | per share | Shares | per share | | |
| Balance outstanding, 01/01/15 | 3,406,250 | \$0.51 | 19,182,201 | \$0.49 | 22,588,451 | 16,611,528 |

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| | | | | | | |
|--------------------------------|------------|--------|--------------|--------|--------------|------------|
| Granted | 2,500,000 | 0.40 | 10,901,426 | 0.40 | 13,401,426 | |
| Exercised | - | | - | - | - | |
| Expired | (205,000) | 1.00 | (791,678) | 0.31 | (996,678) | |
| Forfeited | (130,000) | 0.70 | - | - | (130,000) | |
| Balance outstanding, 12/31/15 | 5,571,250 | \$0.44 | 29,291,949 | \$0.49 | 34,863,199 | 31,664,469 |
| Granted | - | - | 2,929,552 | 0.40 | 2,929,552 | |
| Exercised | - | | - | - | - | |
| Expired | (111,000) | 1.00 | (5,223,100) | 0.40 | (5,334,100) | |
| Forfeited | - | - | - | - | - | |
| Balance outstanding, 3/31/2016 | 5,460,250 | \$0.43 | 26,998,401 | \$0.45 | 32,458,651 | 29,658,673 |

| Range of Exercise Prices | Options Outstanding | | | Options Exercisable | | |
|--------------------------|---------------------|--------------|----------|---------------------|--------------|----------|
| | Weighted Average | | | Weighted Average | | |
| | Number of | Remaining | Exercise | Number of | Remaining | Exercise |
| | Options | Contractual | Price | Options | Contractual | Price |
| | | Life (Years) | | | Life (Years) | |
| \$0.30 - \$0.39 | 1,675,500 | 8.5 | \$ 0.30 | 1,085,024 | 8.5 | \$ 0.30 |
| 0.40 - 0.49 | 2,811,000 | 9.5 | 0.40 | 601,498 | 8.4 | 0.40 |
| 0.50 - 0.59 | 226,250 | 6.4 | 0.50 | 226,250 | 6.4 | 0.50 |
| 0.60 - 0.69 | 402,500 | 3.9 | 0.60 | 402,500 | 3.9 | 0.60 |
| 1.00 - 1.25 | 345,000 | 2.5 | 1.00 | 345,000 | 2.5 | 1.00 |
| \$0.30 - \$1.25 | 5,460,250 | 8.2 | \$ 0.43 | 2,660,272 | 6.8 | \$ 0.48 |

As of March 31, 2016, the total estimated fair value of unvested stock options to be amortized over their remaining vesting period was \$647,398. The non-cash, stock-based compensation expense associated with the vesting of these options is expected to be \$273,013 for the remainder of 2016, \$217,137 in 2017 and \$157,248 in 2018.

Common Stock Issuances

On various dates from January to March 2016 the Company issued 305,000 shares of restricted common stock to investor relations firms for services rendered.

8) Subsequent Events

On May 9, 2016, the Company received a \$200,000, three-month, non-convertible loan from an investor. Loan terms include 12% annualized interest and the award of a three-year warrant to purchase 100,000 shares of the Company's common stock at an exercise price set at \$0.55.

On May 6, 2016, all remaining Series K preferred shareholders except one converted their preferred stock into approximately 4.3 million shares of the Company's common stock.

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

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). In some cases, forward-looking statements are identified by terms such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements. Such statements include, without limitation, statements regarding:

our need for, and our ability to raise, additional equity or debt financing on acceptable terms, if at all;

our need to take additional cost reduction measures, cease operations or sell our operating assets, if we are unable to obtain sufficient additional financing;

our belief that we have sufficient liquidity to finance normal operations;

the options we may pursue in light of our financial condition;

the amount of cash necessary to operate our business;

the anticipated uses of grant revenue and the potential for increased grant revenue in future periods;

our plans and expectations with respect to our continued operations;

our belief that PCT has achieved initial market acceptance in the mass spectrometry and other markets;

the expected increase in the number of pressure cycling technology ("PCT") and constant pressure ("CP") based units installed and the increase in revenues from the sale of consumable products and extended service contracts;

the expected development and success of new instrument and consumables product offerings;

the potential applications for our instrument and consumables product offerings;

the expected expenses of, and benefits and results from, our research and development efforts;

the expected benefits and results from our collaboration programs, strategic alliances and joint ventures;

our expectation of obtaining additional research grants from the government in the future;

our expectations of the results of our development activities funded by government research grants;

the potential size of the market for biological sample preparation;

general economic conditions;

the anticipated future financial performance and business operations of our company;

our reasons for focusing our resources in the market for genomic, proteomic, lipidomic and small molecule sample preparation;

the importance of mass spectrometry as a laboratory tool;

the advantages of PCT over other current technologies as a method of biological sample preparation in biomarker discovery, forensics, and histology and for other applications;

the capabilities and benefits of our PCT sample preparation system, consumables and other products;

our belief that laboratory scientists will achieve results comparable with those reported to date by certain research scientists who have published or presented publicly on PCT and our other products;

our ability to retain our core group of scientific, administrative and sales personnel; and

our ability to expand our customer base in sample preparation and for other applications of PCT and our other products.

These forward-looking statements are only predictions and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements, expressed or implied, by such forward-looking statements. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this Quarterly Report on Form 10-Q. Except as otherwise required by law, we expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statement contained in this Quarterly Report on Form 10-Q to reflect any change in our expectations or any change in events, conditions or circumstances on which any of our forward-looking statements are based. Factors that could cause or contribute to differences in our future financial and other results include those discussed in the risk factors set forth in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2015. We qualify all of our forward-looking statements by these cautionary statements.

OVERVIEW

We are focused on solving the challenging problems inherent in biological sample preparation, a crucial laboratory step performed by scientists worldwide working in biological life sciences research. Sample preparation is a term that refers to a wide range of activities that precede most forms of scientific analysis. Sample preparation is often complex, time-consuming and, in our belief, one of the most error-prone steps of scientific research. It is a widely-used laboratory undertaking – the requirements of which drive what we believe is a large and growing worldwide market. We have developed and patented a novel, enabling technology platform that can control the sample preparation process. It is based on harnessing the unique properties of high hydrostatic pressure. This process, called pressure cycling technology, or PCT, uses alternating cycles of hydrostatic pressure between ambient and ultra-high levels i.e., 35,000 pounds per square inch (“*psi*”) or greater to safely, conveniently and reproducibly control the actions of molecules in biological samples, such as cells and tissues from human, animal, plant and microbial sources.

Our pressure cycling technology uses internally developed instrumentation that is capable of cycling pressure between ambient and ultra-high levels at controlled temperatures and specific time intervals, to rapidly and repeatedly control the interactions of bio-molecules, such as deoxyribonucleic acid (“*DNA*”), ribonucleic acid (“*RNA*”), proteins, lipids and small molecules. Our laboratory instrument, the Barocycler®, and our internally developed consumables product line, which include our Pressure Used to Lyse Samples for Extraction (“*PULSE*”) tubes, and other processing tubes, and application specific kits such as consumable products and reagents, together make up our PCT Sample Preparation System (“*PCT SPS*”).

We have experienced negative cash flows from operations with respect to our pressure cycling technology business since our inception. As of March 31, 2016, we did not have adequate working capital resources to satisfy our current liabilities and as a result we have substantial doubt about our ability to continue as a going concern. Based on our current projections, including equity financing subsequent to March 31, 2016, we believe we will have the cash resources that will enable us to continue to fund normal operations into the foreseeable future.

We need substantial additional capital to fund normal operations in future periods. If we are able to obtain additional capital or otherwise increase our revenues, we may increase spending in specific research and development applications and engineering projects and may hire additional sales personnel or invest in targeted marketing programs. In the event that we are unable to obtain financing on acceptable terms, or at all, we will likely be required to cease our operations, pursue a plan to sell our operating assets, or otherwise modify our business strategy, which could materially harm our future business prospects.

We hold 14 United States and 10 foreign patents covering multiple applications of PCT in the life sciences field. Our pressure cycling technology employs a unique approach that we believe has the potential for broad use in a number of established and emerging life sciences areas, including;

sample preparation for genomic, proteomic, and small molecule studies;

pathogen inactivation;

protein purification;

control of chemical (particularly enzymatic) reactions; and

immunodiagnostics (clinical laboratory testing).

We reported a number of accomplishments in the first four months of 2016:

On January 12, 2016 SCIEX, a global leader in life science analytical technologies (Framingham, MA) and a wholly-owned subsidiary of Danaher Corporation (NYSE: DHR), announced an exclusive co-marketing agreement with PBI to improve protein quantification in complex samples.

On January 28, 2016 in a report focused on the exclusive co-marketing agreement between SCIEX and PBI, Emerging Growth LLC indicated the combination of the two company's technologies could result in superior biological insights and discoveries and in rapid and dramatic revenue growth for PBI.

On February 3, 2016 SCIEX and Children's Medical Research Institute (Sydney, Australia) announced they had joined forces to advance the promise of precision medicine. The partners stated they would benefit from SCIEX's exclusive collaborators, including Pressure BioSciences, and PBI's PCT platform for increased protein quantitation and reproducibility.

On March 14, 2016 the Company announced that it would participate in a SCIEX workshop on new innovations towards industrialized proteomics at the US HUPO scientific conference in Boston.

On April 12, 2016, the Company announced it had been added to the high-performing Richmond Club Index. The Richmond Index has outperformed the S&P 500 Index by an average of 11% each year for the past ten years.

Results of Operations

Comparison for the three months ended March 31, 2016 and 2015

Revenue

We recognized total revenue of \$510,478 for the three months ended March 31, 2016 as compared to \$440,134 during the three months ended March 31, 2015, an increase of \$70,344 or 16%. This increase is attributable to increases in

the sales of our products and services as detailed below.

Products, Services, Other. Revenue from the sale of products and services increased 26% to \$454,350 for the three months ended March 31, 2016 as compared to \$359,364 during the three months ended March 31, 2015. This increase was primarily attributable to an increase in the sale of pressure-based instrument systems. Sales of consumables also increased for the three months ended March 31, 2016 to \$44,234 compared to \$39,835 during the same period in the prior year, an increase of 11%.

Grant Revenue. During the three months ended March 31, 2016, we recorded grant revenue of \$56,128 compared to grant revenue of \$80,770 in the comparable period in 2015. Work on the \$1.05 million NIH grant decreased during the first quarter as we needed to wait for certain significant parts to be manufactured. These parts are expected to be received during the second quarter of 2016, which should result in an increase in grant work beginning in the third quarter of the 2016 calendar year.

Cost of Products and Services

The cost of products and services was \$221,699 for the three months ended March 31, 2016 compared to \$190,783 for the comparable period in 2015. The cost of products and services increased with the concomitant increase in the sales of instrument systems and consumables. Gross profit margin on products and services was 51% for the three months ended March 31, 2016, as compared to 47% for the prior period.

Research and Development

Research and development expenditures were \$335,270 during the three months ended March 31, 2016 as compared to \$231,923 in the same period in 2015, an increase of \$103,347 or 45%. This increase resulted primarily from: (i) the addition of a full-time, Ph.D. level electrical engineer, a key contributor to the development of our new Barocycler NEP2320 Extreme, initially required for the SCIEX co-marketing deal, (ii) our support of Dr. Bruce McCord and Team who are developing an enhanced rape kit test, based on the PCT Platform, (iii) rent increase related to the additional R&D space necessary for growth, and (iv) additional travel, lab supplies, and unused PTO (“paid time off”).

Research and development expense recognized in the three months ended March 31, 2016 and 2015 included \$20,381 and \$11,343 of non-cash, stock-based compensation expense, respectively.

Selling and Marketing

Selling and marketing expenses increased to \$191,236 for the three months ended March 31, 2016 from \$166,223 for the comparable period in 2015, an increase of \$25,013 or 15%. This increase is primarily attributed to expenses incurred to attend additional tradeshows, more active marketing, and to the generation of data by our collaborative partners that can be used to introduce new and upgraded products and services.

During the three months ended March 31, 2016 and 2015, selling and marketing expense included \$12,690 and \$6,975 of non-cash, stock-based compensation expense, respectively.

General and Administrative

General and administrative costs totaled \$808,218 for the three months ended March 31, 2016 as compared to \$726,024 for the comparable period in 2015, an increase of \$82,194 or 11%. We increased spending on patent/trademark activities, as well as investor and public relations, in outside consulting services, and in other activities that we believed would augment and support our successful 2015/2016 fund raising efforts.

During the three months ended March 31, 2016 and 2015, general and administrative expense included \$68,391 and \$36,572 of non-cash, stock-based compensation expense, respectively.

Operating Loss

Our operating loss was \$1,045,945 for the three months ended March 31, 2016 as compared to \$874,819 for the comparable period in 2015, an increase of \$171,126 or 20%. This increase was primarily due to increases in expenditures in R&D and in G&A, as described above.

Other Income (Expense), Net

Interest (Expense) Income

Interest expense was \$835,144 for the three months ended March 31, 2016 as compared to interest expense of \$605,585 for the three months ended March 31, 2015. We amortized \$839,234 of debt discounts in the three months ended March 31, 2016. We recorded \$70,560 of amortized debt discount and \$130,760 of prepayment penalties for the three months ended March 31, 2015 related primarily to the sale of senior secured convertible debentures.

Change in fair value of warrant derivative liability

During the three months ended March 31, 2016, we recorded non-cash expense of \$1,217,722 for warrant revaluation in our consolidated statements of operations due to an increase in the fair value of the warrant liability related to warrants issued in our private placement offerings. We recorded \$51,031 non-cash income in the prior comparable period. This increase in fair value was primarily due to the increase in price of the Company's common stock at March 31, 2016 as compared to the price on March 31, 2015. The components for determining the fair value of the warrants are contained in the table in Note 4 of the accompanying condensed consolidated financial statements.

Change in fair value of conversion option liability

During the three months ended March 31, 2016, we recorded non-cash income of \$2,850,668 for conversion option revaluation expense in our condensed consolidated statements of operations due to an increase in the fair value of the conversion option liability related to convertible debt. This increase in fair value was primarily due to the increase in price of the Company's common stock on March 31, 2016 as compared to the price on March 31, 2015 or the date the debt was incurred during the quarter and the shorter time to maturity of the debt. For the three months ended March

31, 2015 we recorded non-cash income \$354,666 for conversion option liability revaluation. For the three months ended March 31, 2016 and 2015, we recorded a non-cash expense of \$1,298,544 and \$124,441, respectively upon issuance of convertible debt to account for the excess of fair value of the conversion option liability embedded in the debt instruments over the amount of the debt incurred and the change in fair value during the period. The components for determining the fair value of the conversion option liabilities are contained in the table in Note 4 of the accompanying condensed consolidated financial statements.

Other Expense

Other Expense totaled \$912 for the three months ended March 31, 2016 as compared to \$36,913 for the comparable period in 2015.

Net Loss Applicable to Common Shareholders

During the three months ended March 31, 2016, we recorded a net loss to common shareholders of \$5,950,391 or \$(0.26) per share, as compared to a net loss to common shareholders of \$2,064,123 or \$(0.11) per share in the three months ended March 31, 2015. Net loss per share increased by \$0.15 due to the increased net loss to common shareholders as detailed above. The weighted average common shares outstanding for the period increased because of the issuance of shares of common stock to investor relations firms for services rendered.

Liquidity and Financial Condition

We have experienced negative cash flows from operations with respect to our pressure cycling technology business since our inception. As of March 31, 2016, we did not have adequate working capital resources to satisfy our current liabilities and as a result, we have substantial doubt regarding our ability to continue as a going concern. We have been successful in raising cash through debt and equity offerings in the past and as described in Note 6, we completed an over-subscribed \$5 million PIPE through March 31, 2016, raising a total of \$6.3 million between July 2015 and March 2016. We have efforts in place to continue to raise cash through debt and equity offerings.

We will need substantial additional capital to fund our operations in future periods. In the event that we are unable to obtain financing on acceptable terms, or at all, we will likely be required to cease our operations, pursue a plan to sell our operating assets, or otherwise modify our business strategy, which could materially harm our future business prospects.

Net cash used in operations for the three months ended March 31, 2016 was \$1,233,458 as compared to \$1,050,482 for the three months ended March 31, 2015. The increase in cash used in operations in 2016 is principally due to the increase in loss from operations.

Cash used in investing activities for the three months ended March 31, 2016 and 2015 was not significant.

Net cash provided by financing activities for the three months ended March 31, 2016 was \$1,210,062 as compared to \$796,844 for the same period in the prior year. The cash from financing activities in the period ending March 31, 2016 included \$1,122,167 from senior secured convertible debt. We also received \$256,600 from non-convertible debt, net of fees, less payment on non-convertible debt of \$168,765. In the prior year we received \$1,054,750 from convertible debt and \$396,127 in proceeds from non-convertible debt.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

This Item 3 is not applicable to us as a smaller reporting company and has been omitted.

ITEM 4. CONTROLS AND PROCEDURES

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Securities Exchange Act of 1934 filings are 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 our management, including our President and Chief Executive Officer (Principal Executive Officer) and Chief Financial Officer (Principal Financial Officer), as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, as ours are designed to do, and management was necessarily required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As of March 31, 2016, we carried out an evaluation, under the supervision and with the participation of our management, including our Principal Executive Officer and Principal Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934. Based upon that evaluation, our Principal Executive Officer and Principal Financial Officer concluded that our disclosure controls and procedures were not effective.

Our conclusion that our disclosure controls and procedures were not effective as of March 31, 2016 is due to the continued presence of the material weaknesses in our internal control over financial reporting identified in our Annual Report on Form 10-K for the year ended December 31, 2015. These material weaknesses are the following:

We identified a lack of sufficient segregation of duties. Specifically, this material weakness is such that the design over these areas relies primarily on detective controls and could be strengthened by adding preventative controls to properly safeguard Company assets.

Management has identified a lack of sufficient personnel in the accounting function due to our limited resources with appropriate skills, training and experience to perform the review processes to ensure the complete and proper application of generally accepted accounting principles, particularly as it relates to valuation of warrants and other complex debt /equity transactions. Specifically, this material weakness resulted in audit adjustments to the annual consolidated financial statements and revisions to related

disclosures, valuation of warrants and other equity transactions.

Limited policies and procedures that cover recording and reporting of financial transactions.

We continue to plan to remediate those material weaknesses as follows:

Improve the effectiveness of the accounting group by augmenting our existing resources with additional consultants or employees to assist in the analysis and recording of complex accounting transactions, and to simultaneously achieve desired organizational structuring for improved segregation of duties. We plan to mitigate this identified deficiency by hiring an independent consultant once we generate significantly more revenue or raise significant additional working capital.

Improve expert review and achieve desired segregation procedures by strengthening cross approval of various functions including quarterly internal audit procedures where appropriate.

During the period covered by this Report, we implemented and performed additional substantive procedures, such as supervisory review of work papers and consistent use of financial models used in equity valuations, to ensure our condensed consolidated financial statements as of and for the three month period ended March 31, 2016, are fairly stated in all material respects in accordance with GAAP. We have not, however, been able to fully remediate the material weaknesses due to our limited financial resources. Our remediation efforts are largely dependent upon our securing additional financing to cover the costs of implementing the changes required. If we are unsuccessful in securing such funds, remediation efforts may be adversely affected in a material manner.

Except as described above, there have been no changes in our internal controls over financial reporting that occurred during the period ended March 31, 2016 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently involved in any litigation that we believe could have a material adverse effect on our financial condition or results of operations. There is no action, suit, proceeding, inquiry or investigation before or by any court, public board, government agency, self-regulatory organization or body pending or, to the knowledge of the executive officers of our company or any of our subsidiaries, threatened against or affecting our company, our common stock, any of our subsidiaries or of our companies or our subsidiaries' officers or directors in their capacities as such, in which an adverse decision could have a material adverse effect.

Item 1A. Risk Factors

Factors that could cause or contribute to differences in our future financial and operating results include those discussed in the risk factors set forth in Item 1 of our Annual Report on Form 10-K for the year ended December 31, 2015. The risks described in our Form 10-K and this Report are not the only risks that we face. Additional risks not presently known to us or that we do not currently consider significant may also have an adverse effect on the Company. If any of the risks actually occur, our business, results of operations, cash flows or financial condition could suffer.

There have been no material changes to the risk factors set forth in Item 1 of our Annual Report on Form 10-K for the year ended December 31, 2015.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Please refer to Note 6, Convertible Debt and Other Debt, for a discussion of the sale of unregistered securities that took place for the quarter ended March 31, 2016.

In addition, on various dates from January to March 2016 the Company issued 305,000 shares of restricted common stock to investor relations firms for services rendered.

Item 3. Defaults upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibits

- 31.1 Principal Executive Officer and Principal Financial Officer Certification Pursuant to Item 601(b)(31) of Regulation S-K, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1* Principal Executive Officer Certification Pursuant to Item 601(b)(32) of Regulation S-K, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2* Principal Financial Officer Certification Pursuant to Item 601(b)(32) of Regulation S-K, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 101.INS XBRL Instance Document
- 101.SCH XBRL Taxonomy Extension Schema Document
- 101.CAL XBRL Taxonomy Extension Calculation Linkbase Document
- 101.DEF XBRL Taxonomy Extension Definition Linkbase Document
- 101.LAB XBRL Taxonomy Extension Label Linkbase Document
- 101.PRE XBRL Taxonomy Extension Presentation Linkbase Document

* In accordance with SEC Release 33-8238, Exhibits 32.1 and 32.2 are furnished and not filed.

SIGNATURES

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

PRESSURE BIOSCIENCES, INC.

Date: May 16, 2016 By: */s/ Richard T. Schumacher*

Richard T. Schumacher

President & Chief Executive Officer

(Principal Executive Officer and Principal Financial Officer)

