HEMISPHERX BIOPHARMA INC
Form 10-Q
May 15, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

Quarterly Report Pursuant to Section 13 or 15(d)

of the Securities Exchange Act of 1934

For the Quarterly Period Ended March 31, 2017

Commission File Number: 1-13441

HEMISPHERX BIOPHARMA, INC.

(Exact name of registrant as specified in its charter)

Delaware	52-0845822
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

1617 JFK Boulevard, Suite 500, Philadelphia, PA 19103

(Address of principal executive offices) (Zip Code)

(215) 988-0080

(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

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.

[X] 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 such shorter period that the registrant was required to submit and post such files).

[X] 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 definition 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 [X] Smaller reporting company
[ ] Emerging growth company

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

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

26,461,072 shares of common stock were outstanding as of May 1, 2017.

PART I - FINANCIAL INFORMATION

ITEM 1: **Financial Statements**

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

(in thousands, except for share and per share amounts)

	March 31,2017 (Unaudited)	December 31,2016 (Audited)
ASSETS		
Current assets:		
Cash and cash equivalents	$776	$2,408
Marketable securities	2,973	3,460
Accounts receivable	41	—
Assets held for sale	764	764
Prepaid expenses and other current assets	636	309
Total current assets	5,190	6,941
Property and equipment, net	9,257	9,514
Patent and trademark rights, net	870	872
Other assets	1,546	1,546
Total assets	$16,863	$18,873
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$927	$887
Accrued expenses	1,709	1,548
Total current liabilities	2,636	2,435
Redeemable warrants	1,279	940
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, par value $0.01 per share, authorized 5,000,000; issued and outstanding; none	-	-
Common stock, par value $0.001 per share, authorized 350,000,000 shares; issued and outstanding 26,186,998 and 24,202,921, respectively	26	24

Additional paid-in capital	316,238	315,980
Accumulated other comprehensive income (loss)	6	(5)
Accumulated deficit	(303,322)	(300,501)
Total stockholders' equity	12,948	15,498
Total liabilities and stockholders' equity	$16,863	$18,873

See accompanying notes to consolidated financial statements.

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Comprehensive Loss

(in thousands, except share and per share data)

(Unaudited)

	Three months ended March 31,	
	2017	2016
Revenues:		
Clinical treatment programs - US	$23	$39
Clinical treatment programs - Europe	61	-
Total revenues	84	39
Costs and expenses:		
Production costs	270	268
Research and development	1,391	1,002
General and administrative	1,664	2,448
Total costs and expenses	3,325	3,718
Operating loss	(3,241)	(3,679)
Interest and other income	26	61
Redeemable warrants valuation adjustment	393	-
Gain (loss) on sales of short term marketable securities	1	(107)
Gain from sale of income tax net operating losses and research credits	-	1,561
Net loss	(2,821)	(2,164)
Other comprehensive income:		
Reclassification adjustments for loss on sales of short term marketable securities included in net loss	(1)	107
Unrealized gain on marketable securities	12	40
Net comprehensive loss	$(2,810)	$(2,017)
Basic and diluted loss per share	$(0.11)	$(0.10)
Weighted average shares outstanding, basic and diluted	25,341,068	20,630,328

See accompanying notes to consolidated financial statements.

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HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES

Consolidated Statement of Changes in Stockholders' Equity

For the Three Months Ended March 31, 2017

(in thousands except share data)

(Unaudited)

	Common Stock Shares	Common Stock $0.001 Par Value	Additional Paid-In Capital	Accumulated Other Compre-hensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2016	24,202,921	$ 24	$ 315,980	$ (5)	$ (300,501)	$ 15,498
Equity-based compensation	40,105	—	52	—	—	52
Redeemable warrants	—	—	(734)	—	—	(734)
Common stock issuance, net of costs	1,818,185	2	873	—	—	875
Stock issued for accounts payable	125787	—	67	—	—	67
Net comprehensive income (loss)	—	—	—	11	(2,821)	(2,810)
Balance at March 31, 2017	26,186,998	$ 26	$ 316,238	$ 6	$ (303,322)	$ 12,948

See accompanying notes to consolidated financial statements.

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

For the Three Months Ended March 31, 2017 and 2016

(in thousands)

(Unaudited)

	2017	2016
Cash flows from operating activities:		
Net loss	$ (2,821)	$ (2,164)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	261	300
Redeemable warrants valuation adjustment	(393)	—
Amortization and abandonment of patent and trademark rights	13	30
Equity-based compensation	52	52
Realized loss on sale of marketable securities	(1)	107
Change in assets and liabilities:		
Accounts receivable	(41)	—
Prepaid expenses and other current assets	(327)	(28)
Accounts payable	103	182
Accrued expenses	161	478
Net cash used in operating activities	(2,993)	(1,043)
Cash flows from investing activities:		

Sale of marketable securities	500	—
Purchase of property, equipment and construction in progress	(3)	—
Lease deposit refund	—	2
Additions to patent and trademark rights	(11)	(62)
Net cash provided by (used in) investing activities	486	(60)
Cash flows from financing activities:		
Payments on capital leases	—	(1)
Proceeds from sale of stock, net of issuance costs	875	2
Net cash provided by financing activities	875	1
Net decrease in cash and cash equivalents	(1,632)	(1,102)
Cash and cash equivalents at beginning of period	2,408	2,115
Cash and cash equivalents at end of period	$ 776	$ 1,013
Supplemental disclosures of non-cash investing and financing cash flow information:		
Unrealized gain on marketable securities	$ 12	$ 147
Stock issued for accounts payable	$ 67	$ —
Fair value of redeemable warrants granted	$ 734	$ —

See accompanying notes to consolidated financial statements.

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 1: Basis of Presentation

The consolidated financial statements include the financial statements of Hemispherx Biopharma, Inc. and its wholly-owned subsidiaries ("Company"). The Company has two domestic subsidiaries: BioPro Corp. and BioAegean Corp., both of which are incorporated in Delaware and are dormant. The Company also has a foreign subsidiary, Hemispherx Biopharma Europe N.V./S.A., which was established in Belgium in 1998. All significant intercompany balances and transactions have been eliminated in consolidation.

The Company has incurred numerous years of substantial operating losses as it pursued its clinical and pre-clinical development activities and appropriate regulatory approval processes before any such products can be sold and marketed. As of March 31, 2017, our accumulated deficit was approximately $303,000,000. The Company has not yet generated significant revenues from our products and may incur substantial losses in the future. The Company evaluated these conditions and events that may raise substantial doubt about the Company's ability to continue as a going concern; however, the Company believes that it has alleviated the substantial doubt by implementing certain actions. The Company reexamined its fundamental priorities in terms of direction, corporate culture and its ability to fund operations. As a result, there were significant changes at the Company including the Company restructuring its executive management team, initiating the pursuit of international sales of clinical grade materials, and implementing a cost saving program which assisted the Company in gained efficiencies and eliminated redundancies within its workforce. In addition, the Company is in the process of selling an underutilized building adjacent to its New Jersey manufacturing facility site. Also, the Company is committed to a focused business plan oriented toward finding senior co-development partners with the capital and expertise needed to commercialize the many potential therapeutic aspects of our experimental drugs and our approved drug Alferon N. Lastly, the Company plans to access the public equity markets to raise further capital.

In the opinion of Management, all adjustments necessary for a fair presentation of such consolidated financial statements have been included. Such adjustments consist of normal recurring items. Interim results are not necessarily indicative of results for a full year.

The interim consolidated financial statements and notes thereto are presented as permitted by the Securities and Exchange Commission ("SEC"), and do not contain certain information which will be included in the Company's annual consolidated financial statements and notes thereto.

These consolidated financial statements should be read in conjunction with the Company's consolidated financial statements for the years ended December 31, 2016 and 2015, contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2016.

Note 2: Net Loss Per Share

Basic and diluted net loss per share is computed using the weighted average number of shares of common stock outstanding during the period. Equivalent common shares, consisting of stock options and warrants which amounted to 10,881,033 and 15,504,000 shares for the three months ended March 31, 2017 and 2016, respectively, are excluded from the calculation of diluted net loss per share since their effect is anti-dilutive.

Note 3: Equity-Based Compensation

The fair value of each option and equity warrant award is estimated on the date of grant using a Black-Scholes-Merton option pricing valuation model. Expected volatility is based on the historical volatility of the price of the Company's stock. The risk-free interest rate is based on U.S. Treasury issues with a term equal to the expected life of the option and equity warrant. The Company uses historical data to estimate expected dividend yield, expected life and forfeiture rates. There were no options or equity warrants granted in the three months ended March 31, 2017 and 2016.

Stock option for employees' activity during the three months ended March 31, 2017 is as follows:

Stock option activity for employees:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding January 1, 2017	836,256	$ 16.82	4.47	$ —
Granted	—	—	—	—
Forfeited	(5,048)	25.47	—	—
Outstanding March 31, 2017	831,208	$ 16.77	4.24	$ —
Vested and expected to vest March 31, 2017	831,208	$ 16.77	4.24	$ —
Exercisable March 31, 2017	786,936	$ 16.54	3.24	$ —

Unvested stock option activity for employees:

	Number of Options	Weighted Average Exercise Price	Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding January 1, 2017	90,625	$ 1.72	9.33	$ —
Granted	—	—	—	—
Vested	(46,354)	1.58	—	—
Forfeited	—	—	—	—
Outstanding March 31, 2017	44,271	$ 1.87	8.91	$ —

Stock option activity for non-employees:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value

			(Years)		
Outstanding January 1, 2017	271,500	$ 10.41	4.66	$	—
Granted	—	—	—		—
Exercised	—	—	—		—
Forfeited	(5,590)	15.08	—		—
Outstanding March 31, 2017	265,910	$ 10.31	4.41	$	—
Vested and expected to vest March 31, 2017	265,910	$ 10.31	4.41	$	—
Exercisable March 31, 2017	254,104	$ 10.69	4.11	$	—

Unvested stock option activity for non-employees:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding January 1, 2017	26,389	$ 1.65	8.61	$ —
Granted	—	—	—	—
Vested	(11,771)	1.64	—	—
Forfeited	(2,812)	1.68	—	—
Outstanding March 31, 2017	11,806	$ 1.65	9.41	$ —

The impact on the Company’s results of operations of recording equity-based compensation for the three months ended March 31, 2017 and 2016 was to increase costs and expenses by approximately $52,000 and $52,000, respectively, which had no impact on earnings per share.

As of March 31, 2017 and 2016, respectively, there was $135,000 and $168,000 of unrecognized equity-based compensation cost related to options granted under the Equity Incentive Plan.

On January 26, 2016, the Board, based on the recommendation of its Compensation Committee, established two programs - the 2016 Senior Executive Deferred Cash Performance Award Plan for Dr. William A. Carter and Thomas K. Equels, the Company’s two primary executive officers, and the 2016 Voluntary Incentive Stock Award Plan for Company employees and Board members other than Dr. Carter and Mr. Equels. Both Plans include a Base Pay Supplement provision.

The Company maintains a record of the number of shares of stock represented by each Incentive Right issued out of the 2016 Voluntary Incentive Stock Award Plan. During the three months ended March 31, 2016, the Company granted rights to 53,051 incentive shares associated with the Plan and recorded $21,000 in equity-based compensation. There were no incentive shares issued during the quarter ended March 31, 2017.

Note 4: Inventories

The Company uses the lower of first-in, first-out ("FIFO") cost or market method of accounting for inventory.

Inventories consist of the following:	(in thousands) March 31, 2017	December 31, 2016
Inventory work-in-process, January 1	$—	$ 1,326
Production	—	—
Transfer to other assets	—	(1,326)
Spoilage	—	—
Inventory work-in-process, end of period	$—	$ —

Commercial sales of Alferon® will not resume until new batches of commercial filled and finished product are produced and released by the FDA. The Company is continuing the validation of Alferon® production and production of new Alferon® API inventory commenced in February 2015. While the facility is approved by the FDA under the Biological License Application ("BLA") for Alferon®, this status will need to be reaffirmed by an FDA pre-approval inspection. The Company will also need the FDA's approval to release commercial product once it has submitted satisfactory stability and quality release data. Due to the Company extending the timeline of Alferon® production to an excess of one year, the Company reclassified Alferon® Work-In-Process inventory to other assets within the Company's balance sheet.

Note 5: Marketable Securities

Marketable securities consist of mutual funds. For the three months ended March 31, 2017 and 2016, it was determined that none of the marketable securities had other-than-temporary impairments. At March 31, 2017 and December 31, 2016, all securities were classified as available for sale investments and were measured as Level 1 instruments of the fair value measurements standard.

Securities classified as available for sale consisted of:

March 31, 2017

(in thousands)

Securities	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Short-Term Investments	Long Term Investments
Mutual Funds	$ 2,967	$ 6	$ —	$2,973	$ 2,973	$ —
Totals	$ 2,967	$ 6	$ —	$2,973	$ 2,973	$ —

December 31, 2016

(in thousands)

Securities	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Short-Term Investments	Long Term Investments
Mutual Funds	$ 3,465	$ —	$ (5)	$3,460	$ 3,460	$ —
Totals	$ 3,465	$ —	$ (5)	$3,460	$ 3,460	$ —

Unrealized losses on investments

Investments with continuous unrealized losses for less than 12 months and 12 months or greater and their related fair values were as follows:

There were no investments in a loss position as of March 31, 2017.

December 31, 2016

(in thousands)

	Total	Less Than 12 Months		12 Months or Greater		Totals	
Securities	Number In Loss Position	Fair Values	Unrealized Losses	Fair Values	Unrealized Losses	Total Fair Value	Total Unrealized Losses
Mutual Funds	1	$1,853	$ (13)	$ —	$ —	$1,853	$ (13)
Totals	1	$1,853	$ (13)	$ —	$ —	$1,853	$ (13)

Note 6: Accrued Expenses

Accrued expenses consist of the following:

	(in thousands)	
	March 31, 2017	December 31, 2016
Compensation	$277	$ 297
Professional fees	528	604
Clinical trial expenses	393	158
Other expenses	511	489
	$1,709	$ 1,548

Note 7: Property and Equipment

	(in thousands)	
	March 31, 2017	December 31, 2016
Land, buildings and improvements	$10,530	$ 10,530
Furniture, fixtures, and equipment	5,625	5,630
Total property and equipment	16,155	16,160
Less: accumulated depreciation and amortization	(6,898)	(6,646)
Property and equipment, net	$9,257	$ 9,514

Property and equipment are recorded at cost. Depreciation and amortization are computed using the straight-line method over the estimated useful lives of the respective assets, ranging from three to thirty-nine years. The Company also reclassified an underutilized building as an asset held for resale totaling $764,000 adjacent to its New Jersey manufacturing facility site that it is in the process of selling.

Note 8: Stockholders' Equity

(a) Preferred Stock

The Company is authorized to issue 5,000,000 shares of $0.01 par value preferred stock with such designations, rights and preferences as may be determined by the Board of Directors. There were no Preferred Shares issued and outstanding as of March 31, 2017 and December 31, 2016.

(b) Common Stock

The Company's stockholders approved an amendment to the Company's corporate Charter at the Annual Shareholder Meeting held in Philadelphia, PA that concluded on December 8, 2011. This amendment increased the Company's authorized shares from 200,000,000 to 350,000,000 with specific limitations and restrictions on the usage of 75,000,000 of the 150,000,000 newly authorized shares.

On September 16, 2015, the Company's stockholders removed the limitations and restrictions on 67,000,000 shares. The Company's stockholders approved up to an additional 60,000,000 shares for use in capital raising transactions and 7,000,000 shares for use in the Equity Plan of 2009. On August 29, 2016, the Company effected a 12 to 1 reverse stock split of the outstanding shares, in order to become compliant with the NYSE regulations. This did not affect the number of authorized shares.

On July 23, 2012, the Company entered into an equity distribution agreement (the "Maxim EDA") with Maxim Group LLC ("Maxim") pursuant to which the Company could sell up to $75,000,000 worth of its shares of common stock from time to time through Maxim, as sales agent. Under the Maxim EDA, Maxim is entitled to a fixed commission rate of 4.0% of the gross sales price of Shares sold under the Maxim EDA, up to aggregate gross proceeds of $10,000,000, and thereafter, at a fixed commission rate of 3.0% of the gross sales price of Shares sold under the Maxim EDA. Sales of the Shares, if any, may be made in transactions that are deemed to be "at-the-market" offerings as defined in Rule 415 under the Securities Act of 1933, as amended, including sales made by means of ordinary brokers' transactions, including on the NYSE MKT, at market prices or as otherwise agreed with Maxim. The Company has no obligation to sell any of the Shares and may at any time suspend offers under the Maxim EDA or terminate the Maxim EDA. Up until August 4, 2015, the shares were being sold pursuant to the Company's Universal Shelf Registration Statement on Form S-3, declared effective by the SEC on July 2, 2012. After August 4, 2015, the shares were sold pursuant to the Company's Universal Shelf Registration Statement on Form S-3, declared effective by the SEC on August 4, 2015 (the "2015 Universal Shelf"). On August 4, 2015, the Company and Maxim Group LLC amended their July 23, 2012 EDA solely for the purpose of adding the registrant's new registration statement on Form S-3 (File No 333-205228) to the definition of "registration statement" as the old registration statement expired. On December 15, 2015, the Company filed a Prospectus Supplement reducing all offerings pursuant to its existing equity distribution agreement with Maxim Group LLC to $0. No shares of common stock were sold through the Maxim EDA during the first quarter of 2017 or 2016.

On December 15, 2015, the Company entered into an Equity Distribution Agreement with Chardan Capital Markets, LLC (the "Chardan Agreement") to create an at-the-market equity program under which it may sell shares of its common stock (the "Shares") from time to time through Chardan Capital Markets, LLC, as sales agent ("Chardan"). Under the Chardan Agreement, Chardan will be entitled to a commission at a fixed commission rate of 3.0% of the gross sales price of Shares sold under the Chardan Agreement. Sales of the Shares, if any, under the Chardan Agreement may be made in transactions that are deemed to be "at-the-market" offerings as defined in Rule 415 under the Securities Act of 1933, as amended, including sales made by means of ordinary brokers' transactions, including on the NYSE MKT, at market prices or as otherwise agreed with Chardan. The Company has no obligation to sell any of the Shares, and may at any time suspend offers under the Chardan Agreement or terminate the Chardan Agreement. The Shares would be issued pursuant to the Company's previously filed and effective Registration Statement on Form S-3 (File No. 333-205228). Effective August 26, 2016 the Company halted all future offers and sales of common stock under the Chardan Agreement reducing all offerings pursuant to its existing equity distribution agreement with Chardan to $0. No shares of common stock were sold through the Chardan Agreement during the first quarter of 2017 or 2016.

On February 1, 2017, the Company entered into Securities Purchase Agreements (each, a "February Purchase Agreement") with certain investors for the sale by us of 1,818,185 shares of its common stock at a purchase price of $0.55 per share. Concurrently with the sale of the common stock, pursuant to the February Purchase Agreement, the Company also sold unregistered warrants to purchase 1,363,639 shares of common stock for aggregate net proceeds of approximately $875,000. The warrants have an exercise price of $0.75 per share, are exercisable six months after issuance, and will expire five years from the initial exercise date. Pursuant to an engagement agreement, the Company paid its placement agent an aggregate fee equal to 7% of the gross proceeds received by the Company from the sale of the securities in the offering and granted to its placement agent or its designees warrants to purchase up to 5% of the aggregate number of shares sold in the transactions amounting to 90,910 unregistered warrants. The placement agent warrants have substantially the same terms as the investor warrants, except that the placement agent warrants will

expire on February 1, 2022 and have an exercise price equal to $0.6875 per share of common stock.

On September 6, 2016, the Company entered into Securities Purchase Agreements with certain investors for the sale by the Company of 3,333,334 shares of its common stock at a purchase price of $1.50 per share and sold warrants to purchase 2,500,000 shares of Common Stock for aggregate net proceeds of $4,520,000. Subject to certain ownership limitations, the warrants are initially exercisable six-month after issuance at an exercise price equal to $2.00 per share of Common Stock, subject to adjustments as provided under the terms of the warrants. The warrants are exercisable for five years from the initial exercise date. The Company received net proceeds from the foregoing transaction of approximately $4,520,000 after deducting certain fees due to the placement agent and the Company's transaction expenses. The net proceeds received by the Company from tis offering will be used for preparation for technology transfer opportunities, expenses related to Ampligen® manufacturing, working capital and general corporate purposes. Pursuant to an engagement agreement, the Company paid its placement agent an aggregate fee equal to 7% of the gross proceeds received by the Company from the sale of the securities in the offering and granted to its placement agent or its designees warrants to purchase up to 5% of the aggregate number of shares sold in the transactions amounting to 166,667 unregistered warrants. The placement agent warrants have substantially the same terms as the investor warrants, except that the placement agent warrants will expire September 1, 2021 and have an exercise price equal to $1.875 per share of common stock.

The common stock issued in the above two offerings were offered and sold by the Company pursuant to an effective shelf registration statement on Form S-3, which was initially filed with the SEC on June 25, 2015 and subsequently declared effective on August 4, 2015 (File No. 333-205228) and the base prospectus dated as of August 4, 2015 contained therein. The Company filed a prospectus supplements related to these two offerings with the SEC on February 3, 2017 and September 1, 2016, respectively, in connection with the sale of the common stock.

The Equity Incentive Plan of 2009, effective June 24, 2009, as amended and giving effect to the 12 to 1 reverse stock split, authorizes the grant of non-qualified and incentive stock options, stock appreciation rights, restricted stock and other stock awards. A maximum of 22,000,000 shares of common stock is reserved for potential issuance pursuant to awards under the Equity Incentive Plan of 2009. Unless sooner terminated, the Equity Incentive Plan of 2009 will continue in effect for a period of 10 years from its effective date. For the three months ended March 31, 2017, there were no options granted by the Company.

Note 9: **Cash and Cash Equivalents**

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents.

Note 10: Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update No. 2014-09 (ASU 2014-09), *Revenue from Contracts with Customers*. ASU 2014-09 will eliminate transaction- and industry-specific revenue recognition guidance under current U.S. GAAP and replace it with a principle based approach for determining revenue recognition. ASU 2014-09 will require that companies recognize revenue based on the value of transferred goods or services as they occur in the contract. ASU 2014-09 also will require additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. ASU 2014-09 is effective for reporting periods beginning after December 15, 2017, and early adoption is not permitted. Entities can transition to the standard either retrospectively or as a cumulative-effect adjustment as of the date of adoption. Upon the Company realizing operating revenues from the sale of commercialized product, the Company’s adoption of this guidance may have an impact on the Company’s financial statement presentation or disclosures.

In January 2016, the (“FASB”) has issued Accounting Standards Update (ASU) No. 2016-01, *Financial Instruments – Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*. The new guidance is intended to improve the recognition and measurement of financial instruments. The new guidance is

effective for public companies for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. The new guidance permits early adoption of the own credit provision. The Company believes that the adoption of the guidance may have an impact on the Company's financial statement presentation or disclosures.

In February 2016, the FASB issued ASU 2016-02 - *Leases,* which amends the existing accounting standards for lease accounting, including requiring lessees to recognize most leases on their balance sheets and making targeted changes to lessor accounting. ASU 2016-02 will be effective for annual reporting periods beginning after December 15, 2018, and early adoption of is permitted as of the standard's issuance date. ASU 2016-02 allows a modified retrospective transition approach for all leases existing at, or entered into after, the date of initial application, with an option to use certain transition relief. The Company has not adopted ASU 2016-02 and believes such adoption may have an impact on the Company's financial statement presentation or disclosures.

In August 2016, the FASB issued ASU 2016-15 - Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments (a consensus of the Emerging Issues Task Force). The new guidance is intended to address the diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows under Topic 230, Statement of Cash Flows, and other Topics. The guidance addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice. The amendments apply to all entities, including both business entities and not-for-profit entities that are required to present a statement of cash flows under Topic 230. The amendments are effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. If an entity early adopts the amendments in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. An entity that elects early adoption must adopt all of the amendments in the same period. The amendments in this Update should be applied using a retrospective transition method to each period presented. The Company believes that the adoption of the guidance may not have a material impact on the Company’s financial statement presentation or disclosures.

In 2017, the FASB also issued Accounting Standards Updates (“ASU”) 2017-01 through 2017-08 These updates did not have a significant impact on the financial statements.

Note 11: Funds Received from Sale of Income Tax Net Operating Losses

As of December 31, 2016, the Company has approximately $174,000,000 of federal net operating loss carryforwards (expiring in the years 2018 through 2036) available to offset future federal taxable income. The Company also has approximately $36,000,000 of Pennsylvania state net operating loss carryforwards (expiring in the years 2018 through 2033) and approximately $8,000,000 of New Jersey state net operating loss carryforwards (expiring in 2036) available to offset future state taxable income.

In January 2016, the Company effectively sold $16,000,000 of its New Jersey state net operating loss carryforward for the year 2014 for approximately $1,320,000, and also sold New Jersey research and development credits for $241,000. In December 2016, the Company effectively sold $14,000,000 of its New Jersey state net operating loss carryforward for the year 2015 for approximately $1,120,000, and also sold New Jersey research and development credits for $189,000. The utilization of certain state net operating loss carry-forwards may be subject to annual limitations. With no tax due for the foreseeable future, the Company has determined that the accounting for interest or penalties related to the payment of tax is not necessary at this time.

Note 12: Fair Value

The Company is required under GAAP to disclose information about the fair value of all the Company's financial instruments, whether or not these instruments are measured at fair value on the Company's consolidated balance sheets.

The Company estimates that the fair values of cash and cash equivalents, other assets, accounts payable and accrued expenses approximate their carrying values due to the short-term maturities of these items. The Company also has certain warrants with a cash settlement feature in the unlikely occurrence of a Fundamental Transaction. The fair value of the redeemable warrants ("Warrants") related to the Company's August 2016 and February 2017 common stock and warrant issuance, are calculated using a Monte Carlo Simulation. While the Monte Carlo Simulation is one of a number of possible pricing models, the Company has determined it to be industry accepted and fairly presented the fair value of the Warrants. As an additional factor to determine the fair value of the Put's liability, the occurrence probability of a Fundamental Transaction event was factored into the valuation.

The Company recomputes the fair value of the Warrants at the issuance date and the end of each quarterly reporting period. Such value computation includes subjective input assumptions that are consistently applied each period. If the Company were to alter its assumptions or the numbers input based on such assumptions, the resulting fair value could be materially different.

The Company utilized the following assumptions to estimate the fair value of the August 2016 Warrants:

	March 31, 2017	December 31, 2016
Underlying price per share	$0.55	$0.69
Exercise price per share	$1.88 - $2.00	$1.88 - $2.00
Risk-free interest rate	1.81%-1.86%	1.86%
Expected holding period	4.40	4.70
Expected volatility	85%	85%
Expected dividend yield	-	-

The Company utilized the following assumptions to estimate the fair value of the January 2017 Warrants:

	March 31, 2017	February 1, 2017
Underlying price per share	$0.55	$0.64
Exercise price per share	$0.69-$0.75	$0.69-$0.75
Risk-free interest rate	1.90%	1.86%-1.93%
Expected holding period	4.80-4.90	5.00
Expected volatility	85%	80%-85%
Expected dividend yield	-	-

The significant assumptions using the Monte Carlo Simulation approach for valuation of the Warrants are:

(i) *Risk-Free Interest Rate*. The risk-free interest rates for the Warrants are based on U.S. Treasury constant maturities for periods commensurate with the remaining expected holding periods of the warrants.

(ii) *Expected Holding Period*. The expected holding period represents the period of time that the Warrants are expected to be outstanding until they are exercised. The Company utilizes the remaining contractual term of the Warrants at each valuation date as the expected holding period.

(iii)

Expected Volatility. Expected stock volatility is based on daily observations of the Company's historical stock values for a period commensurate with the remaining expected holding period on the last day of the period for which the computation is made.

(iv) *Expected Dividend Yield*. Expected dividend yield is based on the Company's anticipated dividend payments over the remaining expected holding period. As the Company has never issued dividends, the expected dividend yield is $-0- and this assumption will be continued in future calculations unless the Company changes its dividend policy.

(v) *Expected Probability of a Fundamental Transaction.* The possibility of the occurrence of a Fundamental Transaction triggering a Put right is extremely remote. As discussed above, a Put right would only arise if a Fundamental Transaction 1) is an all cash transaction; (2) results in the Company going private; or (3) is a transaction involving a person or entity not traded on a national securities exchange. The Company believes such an occurrence is highly unlikely because:

a. The Company only has one product that is FDA approved but which will not be available for commercial sales for at least approximately 18 months;

b. The Company may have to perform additional clinical trials for FDA approval of its flagship product;

c. Industry and market conditions continue to include a global market recession, adding risk to any transaction;

d. Available capital for a potential buyer in a cash transaction continues to be limited;

e. The nature of a life sciences company is heavily dependent on future funding and high fixed costs, including Research & Development;

f. The Company has minimal revenues streams which are insufficient to meet the funding needs for the cost of operations or construction at their manufacturing facility; and

g. The Company's Rights Agreement and Executive Agreements make it less attractive to a potential buyer.

With the above factors utilized in analysis of the likelihood of the Put's potential Liability, the Company estimated the range of probabilities related to a Put right being triggered as:

Range of Probability	Probability	
Low	0.5	%
Medium	1.0	%
High	5.0	%

The Monte Carlo Simulation has incorporated a 5.0% probability of a Fundamental Transaction to date for the life of the securities.

(vi) *Expected Timing of Announcement of a Fundamental Transaction.* As the Company has no specific expectation of a Fundamental Transaction, for reasons elucidated above, the Company utilized a discrete uniform probability distribution over the Expected Holding Period to model in the potential announcement of a Fundamental Transaction occurring during the Expected Holding Period.

(vii) *Expected 100 Day Volatility at Announcement of a Fundamental Transaction*. An estimate of future volatility is necessary as there is no mechanism for directly measuring future stock price movements. Daily observations of the Company's historical stock values for the 100 days immediately prior to the Warrants' grant dates, with a floor of 100%, were utilized as a proxy for the future volatility.

(viii) *Expected Risk-Free Interest Rate at Announcement of a Fundamental Transaction*. The Company utilized a risk-free interest rate corresponding to the forward U.S. Treasury rate for the period equal to the time between the date forecast for the public announcement of a Fundamental Transaction and the Warrant expiration date for

each simulation.

(ix) *Expected Time Between Announcement and Consummation of a Fundamental Transaction.* The expected time between the announcement and the consummation of a Fundamental Transaction is based on the Company's experience with the due diligence process performed by acquirers, and is estimated to be six months. The Monte Carlo Simulation approach incorporates this additional period to reflect the delay Warrant Holders would experience in receiving the proceeds of the Put.

While the assumptions remain consistent from period to period (e.g., utilizing historical stock prices), the numbers input change from period to period (e.g., the actual historical prices input for the relevant period). The carrying amount and estimated fair value of the above Warrants was approximately $1,279,000 at March 31, 2017 and 940,000 at December 31, 2016.

The Company applies FASB ASC 820 (formerly Statement No. 157 *Fair Value Measurements*) that defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. The guidance does not impose any new requirements around which assets and liabilities are to be measured at fair value, and instead applies to asset and liability balances required or permitted to be measured at fair value under existing accounting pronouncements. The Company measures its warrant liability for those warrants with a cash settlement feature at fair value.

FASB ASC 820-10-35-37 (formerly SFAS No. 157) establishes a valuation hierarchy based on the transparency of inputs used in the valuation of an asset or liability. Classification is based on the lowest level of inputs that is significant to the fair value measurement. The valuation hierarchy contains three levels:

Level 1 – Quoted prices are available in active markets for identical assets or liabilities at the reporting date. Generally, this includes debt and equity securities that are traded in an active market.

Level 2 – Observable inputs other than Level 1 prices such as quote prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Generally, this includes debt and equity securities that are not traded in an active market.

Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. Level 3 assets and liabilities include financial instruments whose value is determined using pricing models, discounted cash flow methodologies, or other valuation techniques, as well as instruments for which the determination of fair value requires significant management judgment or estimation. As of March, 2017, the Company has classified the warrants with cash settlement features as Level 3. Management evaluates a variety of inputs and then estimates fair value based on those inputs. As discussed above, the Company utilized the Monte Carlo Simulation Model in valuing these warrants.

The table below presents the balances of assets and liabilities measured at fair value on a recurring basis by level within the hierarchy as:

	(in thousands) As of March 31, 2017			
	Total	Level 1	Level 2	Level 3
Assets:				
Marketable securities	$2,973	$2,973	$ -	$-
Liabilities:				
Redeemable warrants	$1,279	-	-	$1,279