HEMISPHERX BIOPHARMA INC
Form 10-Q
November 16, 2015

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 September 30, 2015

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

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

247,516,987 shares of common stock were outstanding as of November 1, 2015.

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)

	September 30, 2015 (Unaudited)	December 31, 2014 (Audited)
ASSETS		
Current assets:		
Cash and cash equivalents	$1,161	$2,156
Marketable securities	11,214	13,952
Inventory-work in process	1,326	—
Prepaid expenses and other current assets	278	399
Total current assets	13,979	16,507
Property and equipment, net	11,501	4,601
Patent and trademark rights, net	883	861
Construction in progress	—	7,337
Other assets	134	134
Total assets	$26,497	$29,440
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$1,506	$2,081
Accrued expenses	1,818	2,333
Current portion of capital lease	3	22
Total current liabilities	3,327	4,436
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 247,557,287 and 204,004,818, respectively	248	204
Additional paid-in capital	313,185	302,729
Accumulated other comprehensive loss	(401)	(160)
Accumulated deficit	(289,862)	(277,769)
Total stockholders' equity	23,170	25,004
Total liabilities and stockholders' equity	$26,497	$29,440

See accompanying notes to consolidated financial statements.

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
Revenues:				
Clinical treatment programs	$23	$45	$106	$157
Total revenues	23	45	106	157
Costs and expenses:				
Production	353	306	1,232	923
Research and development	1,968	1,894	7,081	6,550
General and administrative	1,685	2,174	5,600	7,210
Total costs and expenses	4,006	4,374	13,913	14,683
Operating loss	(3,983)	(4,329)	(13,807)	(14,526)
Interest expense	(1)	(3)	(3)	(9)
Interest and other income/expense	181	130	343	414
Redeemable warrants valuation adjustment	—	—	—	1
Gain from sale of income tax net operating losses	—	—	1,374	1,126
Net loss	(3,803)	(4,202)	(12,093)	(12,994)
Other comprehensive income (loss):				
Unrealized gain (loss) on marketable securities	(215)	(169)	(241)	—
Net comprehensive loss	$(4,018)	$(4,371)	$(12,334)	$(12,994)
Basic and diluted loss per share	$(0.02)	$(0.02)	$(0.05)	$(0.07)
Weighted average shares outstanding, basic and diluted	246,774,460	190,677,576	232,307,548	184,434,475

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 Nine Months Ended September 30, 2015
(in thousands except share data)
(Unaudited)

	Common Stock Shares	Common Stock $0.001 Par Value	Additional Paid-In Capital	Accumulated Other Compre-hensive Loss	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2014	204,004,818	$204	$302,729	$(160)	$(277,769)	$25,004
Shares to settle accounts payable	2,558,779	3	669	—	—	672
Equity-based compensation	—	—	148	—	—	148
Shares sold at the market	40,993,690	41	9,639	—	—	9,680
Net comprehensive loss	—	—	—	(241)	(12,093)	(12,334)
Balance at September 30, 2015	247,557,287	$248	$313,185	$(401)	$(289,862)	$23,170

See accompanying notes to consolidated financial statements.

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows
For the Nine Months Ended September 30, 2015 and 2014
(in thousands)
(Unaudited)

	2015	2014
Cash flows from operating activities:		
Net loss	$(12,093)	$(12,994)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	663	500
Amortization and abandonment of patent and trademark rights	166	414
Redeemable warrants valuation adjustment	—	(1)
Equity-based compensation	148	260
Change in assets and liabilities:		
Inventories	(1,326)	—
Prepaid expenses and other current assets	121	123
Accounts payable	97	1,214
Accrued expenses	(515)	553
Net cash used in operating activities	(12,739)	(9,931)
Cash flows from investing activities:		
Purchase of property, equipment and construction in progress	(226)	(386)
Additions to patent and trademark rights	(188)	(187)
Deposits on capital leases refunded	—	2
Sales and maturities of short-term and long-term marketable securities	2,497	1,222
Net cash provided by investing activities	2,083	651
Cash flows from financing activities:		
Payments on capital leases	(19)	(24)
Proceeds from sale of stock, net of issuance costs	9,680	9,763
Net cash provided by financing activities	9,661	9,739
Net (decrease) increase in cash and cash equivalents	(995)	459
Cash and cash equivalents at beginning of period	2,156	803
Cash and cash equivalents at end of period	$1,161	$1,262
Supplemental disclosures of non-cash investing and financing cash flow information:		
Issuance of common stock for accounts payable	$672	$38
Supplemental disclosure of cash flow information:		
Cash paid for interest expense	$(3)	$(9)

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 (collectively, “Hemispherx”, “Company”, “we or “us”). The Company has three domestic subsidiaries: BioPro Corp., BioAegean Corp. and Core Biotech Corp., all 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.

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, 2014 and 2013, contained in the Company’s Annual Report on Form 10-K for the year ended December 31, 2014.

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 of 14,845,888 and warrants of 2,232,392 which totaled 17,078,280 shares and equivalent common shares consisting of stock options of 14,959,480 and warrants of 8,535,422 which totaled 23,494,902 shares for the nine months ended September 30, 2015 and 2014, respectively, are excluded from the calculation of diluted net loss per share since their effect is anti-dilutive, due to the net loss of the Company.

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 800,000 and 955,000 options or equity warrants granted in the nine months ended September 30, 2015 and 2014, respectively.

Stock option for employees' activity during the nine months ended September 30, 2015 is as follows:

Stock option activity for employees:

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

			Term (Years)	
Outstanding January 1, 2015	11,287,888	$1.64	4.61	$—
Granted	800,000	0.25	—	—
Forfeited	(565,000)	1.75	—	—
Outstanding September 30, 2015	11,522,888	$1.54	4.45	$—
Vested and expected to vest September 30, 2015	11,522,888	$1.54	4.45	$—
Exercisable September 30, 2015	10,929,674	$1.58	4.05	$—

Unvested stock option activity for employees:

	Number of Options	Weighted Average Exercise Price	Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Unvested January 1, 2015	710,594	$1.38	8.76	$—
Granted	800,000	0.25	—	—
Vested	(917,380)	0.96	—	—
Forfeited	—	—	—	—
Unvested September 30, 2015	593,214	$0.50	8.69	$—

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, 2015	3,800,000	$1.36	4.75	$—
Granted	—	—	—	—
Exercised	—	—	—	—
Forfeited	(477,000)	1.83	—	—
Outstanding September 30, 2015	3,323,000	$1.29	4.57	$—
Vested and expected to vest September 30, 2015	3,323,000	$1.29	4.57	$—
Exercisable September 30, 2015	3,323,000	$1.29	4.57	$—

Unvested stock option activity for non-employees during the year:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Unvested January 1, 2015	33,333	$2.60	9.08	$—
Options granted	—	—	—	—
Options vested	(33,333)	2.60	—	—
Options forfeited	—	—	—	—
Unvested September 30, 2015	—	$—	0.00	$—

The impact on the Company’s results of operations of recording equity-based compensation for the nine months ended September 30, 2015 and 2014 was to increase general and administrative expenses by approximately $148,000 and $260,000, respectively, which had no impact on earnings per share.

As of September 30, 2015 and 2014, respectively, there was $231,000 and $301,000 of unrecognized equity-based compensation cost related to options granted under the Equity Incentive Plan. Generally, the Company's stock options will become recognizable within a 12 month period.

Warrants:

The Company has 2,232,392 warrants outstanding as of September 30, 2015. The Company has not issued any warrants for the nine months ended September 30, 2015 and 2014.

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)	
	September 30, 2015	December 31, 2014
Inventory work-in-process, January 1	$—	$—
Production[(1)]	1,326	—
Spoilage	—	—
Inventory work-in-process, end of period	$1,326	$—

(1) Commercial sales of Alferon® will not resume until new batches of commercial filled and finished product are produced and released by the FDA. We are 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.

Note 5: Marketable Securities

Marketable securities consist of mutual funds. For the nine months ended September 30, 2015, it was determined that some of the Marketable Securities had other than temporary impairments of approximately $54,000. There were no other than temporary impairments of Marketable Securities for the nine months ended September 30, 2014. At September 30, 2015 and December 31, 2014, all securities were classified as available for sale investments and were measured as Level 1 instruments of the fair value measurements standard (see "Note 12: Fair Value").

Securities classified as available for sale consisted of:

September 30, 2015
(in thousands)

Securities	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Short-Term Investments	Long Term Investments
Mutual Funds	$11,615	$—	$(401)	$11,214	$11,214	$—
Totals	$11,615	$—	$(401)	$11,214	$11,214	$—

December 31, 2014
(in thousands)

Securities	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Short-Term Investments	Long Term Investments
Mutual Funds	$14,112	$—	$(160)	$13,952	$13,952	$—
Totals	$14,112	$—	$(160)	$13,952	$13,952	$—

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:

September 30, 2015
(in thousands)

		Less Than 12 Months		12 Months or Greater		Totals	
Securities	Total number in loss position	Fair Values	Unrealized Losses	Fair Values	Unrealized Losses	Total Fair Value	Total Unrealized Losses
Mutual Funds	2	$5,330	$(194)	$5,884	$(207)	$11,214	$(401)
Totals	2	$5,330	$(194)	$5,884	$(207)	$11,214	$(401)

December 31, 2014
(in thousands)

		Less Than 12 Months		12 Months or Greater		Totals	
Securities	Total number in loss position	Fair Values	Unrealized Losses	Fair Values	Unrealized Losses	Total Fair Value	Total Unrealized Losses
Mutual Funds	2	$5,928	$(106)	$8,024	$(54)	$13,952	$(160)
Totals	2	$5,928	$(106)	$8,024	$(54)	$13,952	$(160)

Note 6: Accrued Expenses

Accrued expenses consist of the following:

	(in thousands)	
	September 30, 2015	December 31, 2014
Compensation	$973	$1,806
Professional fees	301	404
Other expenses	524	123
Other liabilities	20	—
	$1,818	$2,333

The Company maintained a balance of legal fees from a law firm of $587,000 which the Company agreed to pay with the issuance of 2,105,982 shares of the Company's common stock. The Company agreed to use the Company's share price of $0.27 as of May 6, 2015 to settle the balance due; however, the Company agreed to pay the difference if the law firm receives less from the sale of the Company's common stock than the balance due within sixty days after the sale of shares is completed. The Company's share price was $0.17 as of September 30, 2015. As a result of the drop in share price, the Company accrued an additional $211,000 which has been included within the accrual for professional fees above.

Note 7: Property and Equipment

	(in thousands)	
	September 30, 2015	December 31, 2014
Land, buildings and improvements	$11,603	$4,209
Furniture, fixtures, and equipment	5,476	5,307
Leasehold improvements	85	85
Total property and equipment	17,164	9,601
Less: accumulated depreciation and amortization	(5,663)	(5,000)
Property and equipment, net	$11,501	$4,601

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 five to thirty-nine years.

As of February 28, 2015, the Company had completed and put into service the construction and installation of property and equipment within its New Brunswick, NJ facility. All amounts within construction in progress were reclassed to property and equipment during the current period. As of December 31, 2014, construction in progress was $7,337,000.

Note 8: Stockholders’ Equity

The Equity Incentive Plan of 2009 ("2009 Plan"), effective June 24, 2009, authorizes the grant of non-qualified and incentive stock options, stock appreciation rights, restricted stock and other stock awards. A maximum of 15,000,000 shares of common stock is reserved for potential issuance pursuant to awards under the 2009 Plan. In September 2015, the Company's shareholders approved the following amendments to the 2009 Plan: (1) increased the number of shares authorized to be issued under the Equity Incentive Plan from 15,000,000 to 22,000,000; (2) required a gradual vesting period of options issued under the Equity Incentive Plan over a three year period; (3) revised the definition of “change in control” to make it less “liberal” by amending the provision that a change in control occurs upon stockholder approval of a merger, consolidation or sale or disposition by the Company of all or substantially all of its assets (a “Business Combination”) to state that such a change in control occurs upon the consummation of the Business Combination; and (4) clarified that the definition of change in control has a double trigger – For a Participant to get the benefit resulting from a change in control, such Participant must have been terminated other than for cause within a two year period. Unless sooner terminated, the 2009 Plan will continue in effect for a period of 10 years from its effective date. For the nine months ended September 30, 2015 and 2014, there were 800,000 and 955,000 options granted by the Company, respectively.

On July 23, 2012, the Company entered into a Equity Distribution Agreement (the “EDA”) with Maxim Group LLC ("Maxim") pursuant to which the Company may sell up to $75,000,000 worth of its shares of Common Stock from time to time through Maxim, as sales agent. Under the EDA, Maxim is entitled to a fixed commission rate of 4.0% of the gross sales price of Shares sold under the 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 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 EDA or terminate the EDA. Up until August 4, 2015, the shares were sold pursuant to the Company's Universal Shelf Registration Statement on Form S-3, declared effective by the Securities

and Exchange Commission on July 2, 2012. Since August 4, 2015, the shares are being sold pursuant to the Company's Universal Shelf Registration Statement on Form S-3, declared effective by the Securities and Exchange Commission on August 4, 2015 (the “2015 Universal Shelf”). On September 14, 2012, the Company filed a Prospectus Supplement with the SEC increasing the number of shares covered by the Prospectus from 12,000,000 to 20,000,000 shares under the EDA. On October 5, 2012, the Company filed an updated Prospectus Supplement increasing the number of shares covered by the Prospectus to 40,000,000 shares to be allocated for public sale under the Prospectus Supplement pursuant to the EDA. On December 23, 2013, the Company filed an updated Prospectus Supplement with the Securities and Exchange Commission to revise the EDA for an aggregate of 90,000,000 shares to be allocated for public sale under the Prospectus Supplement pursuant to the EDA. On March 6, 2015, the Company filed an updated Prospectus Supplement increasing the number of shares covered by the Prospectus

to 117,600,000 shares. On August 5, 2015, the Company filed an updated Prospectus Supplement to reflect that sales under the EDA are now being conducted pursuant to the 2015 Universal Shelf.

For the nine months ended September 30, 2015, the Company had sold 40,993,690 shares of the EDA that resulted in net cash proceeds of approximately $9,680,000 after direct expenses along with commissions paid to Maxim for approximately $299,000.

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. In the event that the issuance of any Restricted Shares for a purpose prohibited by the above mentioned limitations are in the Company’s best interests, our Board is required to seek stockholder approval before we could use such shares for that purpose. Our Board is required to specify to stockholders the use of proceeds for the sale of such shares, why the use of the shares for that purpose is necessary and the number of authorized shares that would be needed. On September 16, 2015, the Company's stockholders approved up to an additional 60,000,000 of the remaining Restricted Shares for use in capital raising transactions.

The Company plans to allocate the net proceeds from the offering towards research and development, operations and general and administrative purposes related to the commercialization of Ampligen® and Alferon® related products, including, but not limited to, the following: (1) Costs to finalize the upgrade of the Alferon N Injection® manufacturing facility and to prepare for the FDA pre-approval inspections of the Ampligen® facility, (2) Manufacture of commercial product, (3) Potential new preclinical and/or clinical studies in order to gain commercial approval for Ampligen® and broader approvals for Alferon® and Alferon LDO®, (4) Working capital to build and maintain sufficient inventory by procuring raw materials, supplies and other items for the New Brunswick manufacturing facility, as well as to remunerate outside contractors for necessary services, such as, final filling and finishing operations in order to meet any anticipated demand from normal operations as well as through the possible pursuit of other disease areas and/or geographic regions that may present themselves, (5) Pursuit of potential partnering opportunities for Ampligen®, (6) Potential establishment of sales and marketing capabilities, as well as consideration towards the expansion of our manufacturing capacity, and (7) working capital for general and administrative expenses.

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 2015, the FASB issued Accounting Standards Updates (“ASU”) 2015-01 through 2015-16. 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, 2014, the Company had approximately $151,000,000 of federal net operating loss carryforwards (expiring in the years 2018 through 2034) available to off-set future federal taxable income. The Company also had approximately $36,000,000 of Pennsylvania state net operating loss carryforwards (expiring in the years 2018 through 2034) and approximately $28,000,000 of New Jersey state net operating loss carryforwards (expiring in the years 2033 through 2034) available to off-set future state taxable income.

In January 2015, the Company effectively sold $14,291,000 of its approximately $28,000,000 of New Jersey state net operating loss carryforwards (for the year 2013) for approximately $1,374,000. 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 U.S. Generally Accepted Accounting Principles ("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.

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 quoted 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.

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 had certain warrants with a cash settlement feature in the unlikely occurrence of a Fundamental Transaction which are measured at fair value. The fair value recalculation of the Liability resulting from the issuance of the Warrants ("Call") and existence of the Fundamental Transaction ("Put") related to the May 2009 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 recomputed the fair value of the Warrants at 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 redeemable warrants expired in May and November 2014. The balance of the redeemable warrants was $0 as of September 30, 2015 and December 31, 2014.

Fair value at September 30, 2014, was estimated using the following assumptions:

Underlying price per share	$0.19 - $0.27
Exercise price per share	$1.31 - $1.65
Risk-free interest rate	0.06% - 0.23%
Expected holding period	0.38 - 1.64 yrs.
Expected volatility	69.74% - 113.56%
Expected dividend yield	None

While the assumptions remain consistent from period to period (e.g., utilizing historical stock prices), the numbers input may change from period to period (e.g., the actual historical prices input for the relevant period).

As of September 30, 2014, 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 of September 30, 2015:

(in thousands)

	Total	Level 1	Level 2	Level 3
Assets:				
Marketable Securities-unrestricted	$11,214	$11,214	$—	$—

The changes in Level 3 Liabilities measured at fair value on a recurring basis are summarized as follows:

	Fair Value of Redeemable Warrants (in thousands)	
	2015	2014
Balance at January 1	$—	$14
Fair value adjustment at March 31	—	—
Balance at March 31	$—	$14
Fair value adjustment at June 30	—	$(1)
Balance at June 30	$—	$13
Fair value adjustment at September 30	—	$—
Balance at September 30	$—	$13

Note 13: Agreements

On March 9, 2015, the Company executed an agreement with Emerge Health Pty Ltd. ("Emerge") to seek approval of Ampligen® for CFS in Australia and New Zealand and to commence distribution of Ampligen® in both countries on a named-patient basis, where deemed appropriate. The parties intend to collaborate on seeking regulatory approval from Australia's Therapeutic Goods Administration ("TGA") and New Zealand's Medicines and Medical Devices Safety Authority ("Medsafe"). Under this five year exclusive license to sell, market, and distribute Ampligen in Australia and New Zealand to treat CFS, Emerge will implement regulatory-compliant programs to educate physicians about Ampligen® for CFS and seek orphan drug designation and approval of Ampligen® to treat CFS. Hemispherx will support these efforts and will supply Ampligen® at a predetermined transfer price. The Company has the right to buy out of the agreement at a price equal to three times Ampligen® sales for the preceding 12 months if exercised within the first two years or two times such sales if exercised after year three.

On August 3, 2015, the Company executed a multi-year agreement with Impatients, N.V., a Netherlands based company doing business as myTomorrows, for the commencement and management of an Early Access Program (“EAP”) in Europe and Turkey (the “Territory”) related to Chronic Fatigue Syndrome. MyTomorrows, as Hemispherx’ exclusive service provider and distributor in the Territory, will perform EAP activities. These activities will be directed to (a) the education of physicians and patients regarding the possibility of early access to innovative medical treatments not yet the subject of a Marketing Authorization (regulatory approval) through named-patient use, compassionate use, expanded access and hospital exemption (b) patient and physician outreach related to a patient-physician platform, (c) the securing of Early Access Approvals (exemptions and/or waivers required by regulatory authorities for medical treatments prior to Marketing Authorization) for the use of such treatments, (d) the distribution and sale of such treatments pursuant to such Early Access Approvals, (e) pharmacovigilance (drug safety) activities and/or (f) the collection of data such as patient-reported outcomes, doctor-reported experiences and registry data. Hemispherx will support these efforts and will supply Ampligen to myTomorrows at a predetermined transfer price. In the event that the Company receives Marketing Authorization in any country in the Territory, we will pay myTomorrows a royalty on products sold. The parties will establish a Joint Steering Committee composes of representative of both parties to oversee the EAP.

On August 6, 2015, the Company executed an agreement with Emerge to seek approval of Alferon N Injection® in Australia and New Zealand and to commence distribution of Alferon® in both countries on a named-patient basis, for treating genital warts and other infections and diseases to which patients in Australia and New Zealand have become refractory to recombinant interferon. Hemispherx and Emerge will collaborate on seeking regulatory approval from Australia’s TGA and New Zealand’s Medsafe. Under a five year exclusive license to sell, market, and distribute Alferon N Injection® in Australia and New Zealand, Emerge will implement regulatory-compliant programs to educate physicians about Alferon®. Hemispherx will support these efforts and will supply Alferon® at a predetermined transfer price. We have the right to buy out of the agreement at a price equal to three times Alferon® sales for the

preceding 12 months if exercised within the first two years or two times such sales if exercised after year three.

On September 28, 2015, the Company and William A. Carter, M.D., agreed to extend the period for notice of non-renewal to December 1, 2015 as provided within the June 11, 2010 Amended and Restated Engagement Agreement entered into between the Company and Dr. Carter related to patent development. The agreement terminates on December 31, 2015; however, the Agreement automatically renews for a successive one year period after the termination date unless written notice of refusal to renew is given by either party at least 90 days prior to the termination date or the expiration of any renewal period.

Note 14: Subsequent Events

The Company evaluated subsequent events through the date on which these financial statements were issued and determined that no subsequent event constituted a matter that required adjustment to the financial statements for the nine months ended September 30, 2015.

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

Special Note Regarding Forward-Looking Statements

Certain statements in this Report, including statements under “Item 1. Legal Proceedings” and “Item 1A. Risk Factors” in Part II, contain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended, which we refer to as the Exchange Act. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Forward-looking statements reflect our current views with respect to future events and are based on assumptions and are subject to risks, uncertainties and other important factors. We discuss many of these risks, uncertainties and other important factors in greater detail under “Item 1A. Risk Factors” in Part II in this Report. Because the risk factors referred to above and in our Annual Report on Form 10-K for our most recent fiscal year filed with the Securities and Exchange Commission could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us, you should not place undue reliance on any such forward-looking statements.

Further, these forward-looking statements represent our estimates and assumptions only as of the date such forward-looking statements are made. You should carefully read this Report completely and with the understanding that our actual future results may be materially different from what we expect. We can give no assurances that any of the events anticipated by the forward-looking statements will occur or, if any of them do, what impact they will have on our business, results of operations and financial condition. Any forward-looking statement speaks only as of the date on which it is made and we undertake no obligation to update any forward-looking statement or statements to reflect events or circumstances after the date on which such statement is made or reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which will arise