HEMISPHERX BIOPHARMA INC
Form 10-Q
November 14, 2018

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, 2018

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.)

2117 SW Highway 484, Ocala FL 34473

(Address of principal executive offices) (Zip Code)

(407) 839-0095

(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 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

48,189,570 shares of common stock were outstanding as of November 1, 2018.

PART I- FINANCIAL INFORMATION

ITEM 1: **Financial Statements**

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

(in thousands, except for share amounts)

(Unaudited)

	September 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$4,055	$1,412
Marketable securities	20	695
Accounts receivable	28	24
Assets held for sale	-	764
Prepaid expenses and other current assets	840	610
Total current assets	4,943	3,505
Property and equipment, net	7,976	8,586
Patent and trademark rights, net	879	858
Other assets	1,372	1,258
Total assets	$15,170	$14,207
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$791	$741
Accrued expenses	587	1,966
Convertible note payable	3,387	-
Current portion of financing obligation	197	-
Total current liabilities	4,962	2,707
Long-term liabilities:		
Note payable	-	1,835
Financing obligation arising from sale leaseback transaction (Note 14)	2,369	-
Redeemable warrants	1,400	962

Commitments and contingencies		
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 47,957,884 and 32,884,786, respectively	48	33
Additional paid-in capital	323,357	317,419
Accumulated other comprehensive (loss) income	-	11
Accumulated deficit	(316,966)	(308,760)
Total stockholders' equity	6,439	8,703
Total liabilities and stockholders' equity	$15,170	$14,207

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 September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
Revenues:				
Clinical treatment programs -United States	$11	$4	$35	$101
Clinical treatment programs - Europe	27	86	92	286
Total revenues	38	90	127	387
Costs and expenses:				
Production costs	208	399	602	887
Research and development	1,595	787	3,791	3,284
General and administrative	1,273	1,556	4,569	4,839
Total costs and expenses	3,076	2,742	8,962	9,010
Operating loss	(3,038)	(2,652)	(8,835)	(8,623)
Interest and other income (expense)	(10)	13	45	60
Interest expense and other finance costs	(59)	(51)	(252)	(70)
Settlement of litigation	—	—	474	—
Fair value of convertible note adjustment	(678)	—	(678)	—
Redeemable warrants valuation adjustment	696	1,438	826	2,361
Gain on sale of building	—	—	223	—
Gain (loss) on sale of short term marketable securities	11	—	(9)	6
Net loss	(3,078)	(1,252)	(8,206)	(6,266)
Other comprehensive income (loss):				
Reclassification adjustments for loss on sales of short term marketable securities included in net loss	9	—	9	(6)
Unrealized gain (loss) on marketable securities	(1)	11	(20)	40
Net comprehensive loss	$(3,070)	$(1,241)	$(8,217)	$(6,232)
Basic and diluted loss per share	$(0.07)	$(0.04)	$(0.19)	$(0.23)
Weighted average shares outstanding, basic and diluted	47,184,338	30,096,500	42,749,070	27,598,715

See accompanying notes to consolidated financial statements.

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES

Consolidated Statement of Changes in Stockholders' Equity

For the Nine Months Ended September 30, 2018

(in thousands except share data)

(Unaudited)

	Common Stock Shares	Common Stock $0.001 Par Value	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2017	32,884,786	$ 33	$317,419	$ 11	$ (308,760)	$ 8,703
Equity-based compensation	1,040,157	1	750	—	—	751
Warrants issued for building sale leaseback	—	—	1,149	—	—	1,149
Convertible note origination shares	500,000	—	84			84
Redeemable warrants	—	—	221	—	—	221
Common stock issuance, net of costs	12,701,936	13	3,405	—	—	3,418
Common stock issued to settle accounts payable	831,005	1	329	—	—	330
Net comprehensive loss	—	—	—	(11)	(8,206)	(8,217)
Balance at September 30, 2018	47,957,884	$ 48	$323,357	$ —	$ (316,966)	$ 6,439

See accompanying notes to consolidated financial statements.

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

For the Nine Months Ended September 30, 2018 and 2017

(in thousands)

(Unaudited)

	2018		2017	
Cash flows from operating activities:				
Net loss	$	(8,206)	$	(6,266)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation of property and equipment		658		739
Redeemable warrants valuation adjustment		(826)		(2,361)
Fair value of convertible note adjustment		678		-
Amortization of patent and trademark rights		46		48
Equity-based compensation		751		286
Realized loss on sale of marketable securities		(11)		(6)
Gain on sale of building		(223)		-
Amortization of finance and debt issuance costs		208		13
Change in assets and liabilities:				
Accounts receivable		(4)		(42)
Prepaid expenses and other current assets		(230)		(317)
Other assets		-		211
Accounts payable		277		174
Accrued expenses		(1,339)		340

Net cash used in operating activities	(8,221)	(7,181)
Cash flows from investing activities:		
Proceeds from sale of marketable securities	675	1,699
Purchase of property, equipment and construction in progress	(48)	(20)
Proceeds from sale of building	1,050	-
Purchase of patent and trademark rights	(67)	(36)
Net cash provided by investing activities	1,610	1,643
Cash flows from financing activities:		
Proceeds from lease financing obligation	4,080	-
Finance and debt issuance costs	(498)	(90)
Financing obligation payment	(181)	-
Proceeds from note payable	3,020	1,543
Payoff of mortgage note payable	(1,957)	-
Security deposits paid	(114)	-
Proceeds from sale of stock, net of issuance costs	4,904	2,180
Net cash provided by financing activities	9,254	3,633
Net increase (decrease) in cash and cash equivalents	2,643	(1,905)
Cash and cash equivalents at beginning of period	1,412	2,408
Cash and cash equivalents at end of period	$ 4,055	$ 503
Supplemental disclosures of non-cash investing and financing cash		

flow information:				
Unrealized gain on marketable securities	$	20	$	40
Stock issued to settle accounts payable	$	330	$	747

See accompanying notes to consolidated financial statements.

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 1: Business and Basis of Presentation

Hemispherx Biopharma, Inc. and its subsidiaries (collectively, "Hemispherx", "Company", "we" or "us") are an immuno-pharma research and development ("R&D") and commercial growth company focused on unmet medical needs in immunology, especially immuno-oncology. We have established a strong foundation of laboratory, pre-clinical and clinical data with respect to the development of natural interferon and nucleic acids to enhance the natural antiviral defense system of the human body and to aid the development of therapeutic products for the treatment of cancers, viral infections, and chronic diseases.

Our flagship products include Ampligen®, an experimental therapeutic, and Alferon N Injection®.Ampligen represents an experimental Ribonucleic Acid ("RNA") being developed for globally important viral diseases and disorders of the immune system. Hemispherx' platform technology includes components for the potential treatment of various severely debilitating and life-threatening diseases.Alferon N Injection is approved for a category of Sexually Transmitted Disease ("STD") infection.

In August 2016, we received approval of our New Drug Application ("NDA") from Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica ("ANMAT") for commercial sale of Ampligen in the Argentine Republic for the treatment of severe Chronic Fatigue Syndrome ("CFS"). The product will be marketed by GP Pharm, our commercial partner in Latin America.

Hemispherx is also 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 drug, Ampligen, and our approved drug, Alferon N Injection. 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, 2017 and 2016, contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2017.

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 462,358 and 5,970,948 for the three months ended September 30, 2018 and 2017, respectively; and 20,865,626 and 9,392,453 shares for the nine months ended September 30, 2018 and 2017, 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 4,676,221 and 1,340,672 options granted in the nine months ended September 30, 2018 and 2017, respectively.

Stock option for employees' activity during the nine months ended September 30, 2018 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, 2018	1,203,918	$ 5.91	6.89	$ —
Granted	3,322,873	0.35	—	—
Forfeited	(120,000)	5.28	—	—
Expired	(137,917)	29.08	—	—
Outstanding September 30, 2018	4,268,874	$ 0.85	9.13	$ —
Vested and expected to vest September 30, 2018	4,268,874	$ 0.85	9.13	$ —
Exercisable September 30, 2018	1,296,610	$ 4.43	7.59	$ —

Unvested stock option activity for employees:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Unvested January 1, 2018	366,149	$ 0.48	9.62	$ —
Granted	3,322,873	0.35	—	—
Vested	(716,757)	0.40	—	—
Unvested September 30, 2018	2,972,265	$ 0.35	9.57	$ —

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, 2018	834,876	$ 2.70	6.69	$	—
Granted	1,352,348	0.34	—		—
Forfeited	(93,854)	6.26	—		—
Expired	(15,250)	35.34	—		—
Outstanding September 30, 2018	2,078,120	$ 0.76	8.62	$	—
Vested and expected to vest September 30, 2018	2,078,120	$ 0.76	8.62	$	—
Exercisable September 30, 2018	624,261	$ 2.00	7.39	$	—

Unvested stock option activity for non-employees:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Unvested January 1, 2018	464,659	$ 0.36	7.84	$ —
Granted	1,352,348	0.34	—	—
Vested	(363,148)	0.38	—	—
Unvested September 30, 2018	1,453,859	$ 0.34	8.99	$ —

Stock-based compensation expense was approximately $751,000 and $286,000 for the nine months ended September 30, 2018 and 2017 resulting in an increase in general and administrative expenses and loss per share of $0.02 and $0.01, respectively.

As of September 30, 2018, and 2017, respectively, there was $1,145,000 and $537,000 of unrecognized equity-based compensation cost related to options granted under the Equity Incentive Plan.

Note 4: Inventories

The Company uses the lower of first-in, first-out (“FIFO”) cost or net realizable value method of accounting for inventory.

Commercial sales of Alferon in the U.S. will not resume until new batches of commercial filled and finished product are produced and released by the Food and Drug Administration (“FDA”). While the facility is approved by the FDA under the Biologics License Application (“BLA”) for Alferon, this status will need to be reaffirmed by an FDA pre-approval inspection. We will also need the FDA’s approval to release commercial product once we have submitted satisfactory stability and quality release data. Currently, the manufacturing process is on hold and there is no definitive timetable to have the facility back online. We estimate we will need approximately $10,000,000 to commence the manufacturing process. Due to the Company extending the timeline of Alferon production to an excess of one year, we reclassified Alferon work in process inventory of $1,115,000 to other assets within our balance sheet as of September 30, 2018 and due to the high cost estimates to bring the facility back online. The above estimated cost includes additional funds needed for the revalidation process in our facility to initiate commercial manufacturing, thereby readying ourselves for an FDA Pre-Approval Inspection. If we are unable to gain the necessary FDA approvals related to the manufacturing process and/or final product of new Alferon inventory, our operations most

likely will be materially and/or adversely affected. In light of these contingencies, there can be no assurances that the approved Alferon N Injection product will be returned to production on a timely basis, if at all, or that if and when it is again made commercially available, it will return to prior sales levels.

The Alferon work in process is currently compliant with our internal protocols, is stored in a controlled state, and we regularly monitor the stability of the product. All of these factors contribute to the potential sale of the Alferon work in process, after validation lots have been produced and including a successful pre-approval inspection.

Note 5: Marketable Securities

Marketable securities consist of mutual funds. For the nine months ended September 30, 2018 and 2017, it was determined that none of the marketable securities had other-than-temporary impairments. On September 30, 2018 and December 31, 2017, 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:

September 30, 2018

(in thousands)

Securities	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Short-Term Investments	Long Term Investments
Mutual Funds	$ 21	$ -	$ `(1)	$ 20	$ 20	$ —
Totals	$ 21	$ -	$ (1)	$ 20	$ 20	$ —

December 31, 2017

(in thousands)

Securities	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Short-Term Investments	Long Term Investments
Mutual Funds	$ 684	$ 11	$ —	$ 695	$ 695	$ —
Totals	$ 684	$ 11	$ —	$ 695	$ 695	$ —

Unrealized losses on investments

As of September 30, 2018, there was no investment in a loss position.

Note 6: Accrued Expenses

Accrued expenses consist of the following:

(in thousands)

	September 30, 2018	December 31, 2017
Compensation	$255	$ 569
Professional fees	66	506
Clinical trial expenses	61	310
Other expenses	205	581
	$587	$ 1,966

Note 7: Property and Equipment

	(in thousands)	
	September 30, 2018	December 31, 2017
Land, buildings and improvements	$10,547	$ 10,547
Furniture, fixtures, and equipment	5,042	5,625
Total property and equipment	15,589	16,172
Less: accumulated depreciation and amortization	(7,613)	(7,586)
Property and equipment, net	$7,976	$ 8,586

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.

On March 16, 2018, the Company sold land and a building for $4,080,000 and concurrently entered into an agreement to lease the property back for ten years. The lease payments are initially $408,000 per year for two years through March 31, 2020 and will escalate in subsequent years. (See Note 14 – Financing Obligation Arising from Sale Leaseback Transaction for more details on the sale leaseback of the property and equipment).

In February 2018, the Company sold the building located adjacent to its manufacturing facility located at 5 Jules Lane, New Brunswick, New Jersey to an unaffiliated party. The purchase price was $1,050,000 and the Company netted $963,000 in cash.

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 September 30, 2018 and December 31, 2017. Of our authorized preferred stock, 250,000 shares have been designated as Series A Junior Participating Preferred Stock.

(b) Common Stock

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The Company is authorized to issue 350,000,000 shares of $0.001 par value common stock with specific limitations and restrictions on the usage of 75,000,000. In September 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. In August 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 September 6, 2016, we entered into a Securities Purchase Agreement (the "September Purchase Agreement") with certain investors for the sale by us of 3,333,334 shares of our common stock registered under our S-3 shelf registration statement on at a purchase price of $1.50 per share. Concurrently with the sale of the common stock, pursuant to the September Purchase Agreement, we also sold unregistered warrants to purchase 2,500,000 shares of common stock for aggregate gross proceeds of $5,000,000. 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. Pursuant to an engagement agreement, we paid our placement agent an aggregate fee equal to 7% of the gross proceeds received by us from the sale of the securities in the offering and granted to our 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 on September 1, 2021 and have an exercise price equal to $1.875 per share of common stock.

On February 1, 2017, we entered into Securities Purchase Agreements (each, a “February Purchase Agreement”) with certain investors for the sale by us of 1,818,185 shares of our 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, we also sold unregistered warrants to purchase 1,363,639 shares of common stock for aggregate gross proceeds of approximately $1,000,000. 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, we paid our placement agent an aggregate fee equal to 7% of the gross proceeds received by us from the sale of the securities in the offering and granted to our 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. The Company subsequently registered the shares issuable upon exercise of the warrants on form S-1.

The common stock issued in the above referenced September 6, 2016 and February 1, 2017 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 in June 2015 and subsequently declared effective on August 4, 2015 (Registration No. 333-205228) and the base prospectus dated as of August 4, 2015 contained therein. The Company filed a prospectus supplements related to these offerings with the SEC on September 1, 2016 and February 3, 2017, respectively, in connection with the sale of the common stock. The common stock issued pursuant to the above June 1, 2017 exercise of warrants were issued pursuant to an effective registration statement on Form S-1, which was initially filed with the SEC in May 2017 as subsequently amended and declared effective on May 23, 2017 (Registration No. 333-217671) and the prospectus supplement filed with the SEC on May 23, 2017

The Board of Directors approved up to $500,000 for all directors, officers and employees to buy company shares from the Company at the market price. As of September 30, 2018, the Company issued 855,154 shares of its common stock at prices between $0.27 and $0.69 per share directly to executives and employees, for $348,300 in a series of private transactions pursuant to stock purchase agreements.

On June 1, 2017, the exercise price of Warrants issued in September 2016 was changed to $0.50. As a result, the warrant holders exercised these options and purchased 2,370,000 shares of Company common stock. The Company realized net proceeds of $1,055,000 from this exercise. In conjunction with the foregoing, the Company also issued 2,370,000 series A warrants with an exercise price of $0.60 per share, an initial exercise date of December 1, 2017 and expiring March 6, 2022 (the “Series A Warrants”) and 7,584,000 series B warrants with exercise price of $0.60, an initial exercise date December 1, 2017 per share and expiring March 1, 2018 (the “Series B Warrants” and, along with the Series A Warrants, the “Warrants”). The foregoing transactions are hereinafter referred to as the “Exchange Transaction”.

In addition, on July 10, 2017, the warrant holders exercised the remaining 130,000 warrants issued in September 2016 and purchased 130,000 shares of common stock. The Company realized net proceeds of $65,000 from this exercise. In conjunction with the foregoing the Company issued 130,000 Series A Warrants and 416,000 Series B Warrants (with an exercise price of $0.60 and an initial exercise date January 10, 2018 on the three-month anniversary of the of the initial exercise date).

The 2,800,000 warrants with an expiration date of March 1, 2018 and an exercise price on $0.45 were exercised in January and February 2018. The Company realized proceeds of $1,260,000 from these exercises.

Pursuant to an engagement agreement, the Company paid its placement agent an aggregate fee equal to 7% and 10.5%, respectively, of the gross proceeds received by the Company from the sale of the securities in the offerings 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 and 107,759, respectively, unregistered warrants. The placement agent warrants have substantially the same terms as the investor warrants, except that the 166,667 placement agent warrants issued in September 2017 will expire September 1, 2021 and have an exercise price equal to $1.875 per share of common stock and the 107,759 placement agent warrants issued in June 2017 will expire June 1, 2022 and have an exercise price of $0.625.

On August 23, 2017, the Holders of the Series A Warrants and Series B Warrants exchanged all of their Warrants for new warrants (respectively, the “Series A Exchange Warrants” and the “Series B Exchange Warrants” and, collectively, the “Exchange Warrants”) identical to the Warrants except as follows: The exercise price of both Exchange Warrants is $0.45 per share, subject to adjustment therein, and the number of Series B Exchange Warrants issued was proportionately reduced so that all Exchange Warrants in the Exchange Transaction do not exceed 19.9% of the number of the Company’s issued and outstanding shares of Common Stock as of May 31, 2017, the date of the

Exchange Transaction offer letters. The issuance of the Exchange Warrants by the Company and the shares of Common Stock issuable upon exercise of the Exchange Warrants is exempt from registration pursuant to Sections 3(a)(9) and 4(a)(2) of the Securities Act of 1933, as amended (the "Securities Act").

On July 23, 2012, the Company entered into an equity distribution agreement with Maxim (the "EDA") pursuant to which it could sell up to $75,000,000 worth of our 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. 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.

On November 27, 2017, the Company reactivated the EDA. During the nine months ended September 30, 2018, the Company sold an aggregate of 1,524,802 shares under the EDA for proceeds of $682,000 net of $20,000 in commissions. Pursuant to a prospectus supplement dated February 7, 2018, the Company was able to sell up to 6,549,157 of its common stock (inclusive of shares already sold under the prospectus supplement) under the EDA. The actual number of shares, that the Company can sell, and the proceeds to be received there from are dependent upon the market price of its common stock.

Effective with the semi-monthly period ended April 30, 2017, all of the members of the Company's Board of Directors agreed to accept 100% of their directors' fees in the form of options to purchase Company Common Stock. This program was terminated as of August 31, 2017. In this regard, options to purchase 206,082 shares of Company common stock were issued with exercise prices ranging from $0.36 to $0.67, a holding period of 10 years and vesting over three years. In addition, commencing with the semi-monthly period ended June 15, 2017, certain officers of the Company and certain other employees of the Company, agreed to accept 20% of their salary in options to purchase Company Common Stock. This program was also terminated as of August 31, 2017. In this regard, options to purchase 214,866 shares of Company common stock were issued with exercise prices ranging from $0.36 to $0.67, a holding period of 10 years and vesting over three years.

As part of the cash conservation program adopted on August 28, 2017, starting with the month of September 2017, the directors agreed to defer 100% of their fees until cash is available. In consideration of this deferral, 226,023 options were issued to each of the two independent directors in February 2018 with an exercise price of $0.37; 152,053 options were issued to each of the two independent directors in May 2018 with an exercise price of $0.30, and 98,098 options were issued in July 2018 with an exercise price of $0.31. All of the foregoing options and the options discussed below are exercisable for a period of 10 years with a vesting period of three years. This program was suspended as of July 15, 2018 and all remaining deferred fees were paid in July 2018.This Program was reactivated as of August 16, 2018 with the understanding that options would not be issued on the deferred amounts until the 2018 Equity Incentive Plan was approved by the stockholders and the securities issuable thereunder were registered with the SEC.The 2018 Equity Incentive Plan was approved by the stockholders and the securities issuable thereunder were registered with the SEC and, on October 17, 2018, 172,786 options were issued to each of the two independent directors with an exercise price on $0.22.

Also as part of the cash conservation program adopted on August 28, 2017, starting with the month of September 2017, certain officers agreed to defer 40% of their salaries until cash is available. In consideration of this deferral, 884,459 options were issued to these officers in February 2018 with an exercise price of $0.37; 599,168 options were issued to these officers in May 2018 with an exercise price of $0.30, and 389,249 options were issued to these officers in July 2018 with an exercise price of $0.31. This program was suspended as of July 15, 2018 and all remaining deferred salaries were paid on July 2018. This Program was reactivated as of August 16, 2018 for 50% of their salaries with the understanding that options would not be issued on the deferred amounts until the 2018 Equity Incentive Plan was approved by the shareholders and the plan registered with the SEC. The 2018 Equity Incentive Plan has been approved by the shareholders and registered with the SEC and on October 17, 2018, 808,712 options were issued to these officers with an exercise price on $0.22 for a period of ten years with a vesting period of one year.

Also as part of the cash conservation program adopted on August 28, 2017, all employees agreed to be paid 50% of their salaries in the form of unrestricted common stock of the Company. Starting with the month of September 2017, the salaries of all the employees of the Company were paid 50% in the form of unrestricted common stock of the Company. The total number of shares issued as of June 30, 2018 to the employees under this program was 2,010,534 shares at stock prices ranging from $0.31 to $0.55 per share. This program was suspended by the Board of Directors on June 30, 2018.

On March 24, 2018, the Company sold 1,250,000 shares of common stock. The Company realized net proceeds of $475,000 from this stock offering.

On April 20, 2018, the Company entered into Securities Purchase Agreements (the “Purchase Agreements”) with certain investors (the “Investors”) for the sale by the Company of an aggregate of 6,600,000 shares (the “Common Shares”) of the Company’s common stock, par value $0.001 per share (the “Common Stock”), at a purchase price of $0.39 per share. Concurrently with the sale of the Common Shares, pursuant to the Purchase Agreements the Company also sold 6,600,000 warrants, 50% of which are Class A Warrants and 50% of which are Class B Warrants (collectively, the “Warrants”). The Company will receive gross proceeds from the sale of the Warrants solely to the extent such Warrants

are exercised for cash. Both classes of Warrants will not be exercisable until six months after issuance and will have an exercise price of $0.39 per share, subject to adjustments as provided under the terms of the Warrants. The Class A Warrants and Class B Warrants will expire, respectively, two and five years after the date on which they are first exercisable. The closing of the sales of these securities under the Purchase Agreements took place on April 24, 2018.

The Company received net proceeds from the transactions of $2,343,820 after deducting certain fees due to the placement agent and the Company's transaction expenses. The net proceeds received by the Company from the transactions will be used for the production of Ampligen, to improve operations, and for working capital and general corporate purposes.

As of September 30, 2018, and December 31, 2017, there were 47,957,884 and 32,884,786 shares outstanding, respectively.

The 2009 Equity Incentive Plan, effective June 24, 2009, as amended, 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 2009 Equity Incentive Plan. Unless sooner terminated, the 2009 Equity Incentive Plan will continue in effect for a period of 10 years from its effective date. For the nine months ended September 30, 2018, there were 4,676,221 options granted by the Company under this Plan.

The 2018 Equity Incentive Plan, effective September 12, 2018, authorizes the grant of (i) Incentive Stock Options, (ii) Nonstatutory Stock Options, (iii) Stock Appreciation Rights, (iv) Restricted Stock Awards, (v) Restricted Stock Unit Awards, (vi) Performance Stock Awards, (vii) Performance Cash Awards, and (viii) Other Stock Awards.Initially, a maximum of 7,000,000 shares of common stock is reserved for potential issuance pursuant to awards under the 2018 Equity Incentive Plan. Unless sooner terminated, the 2018 Equity Incentive Plan will continue in effect for a period of 10 years from its effective date. For the nine months ended September 30, 2018, there were no options granted by the Company under this Plan.

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. Generally Accepted Accounting Standards (“U.S.GAAP”) and replace it with a principal-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. As of September 30, 2018, we have not identified any accounting changes that would materially impact the amount of reported revenues with respect to our product revenues. The Company applied the Full Retrospective Application to implement the new Accounting Standards Codification (“ASC”) 606. The Company, based on the nature of its Ampligen sales under its cost recovery programs, determined that there were no material differences between the new accounting standard and legacy GAAP and that difficulties will not arise for any “open” contract issues with its customers during the transition period. The Company also determined that the adoption of this standard had little or no impact to the Company’s opening balance of retained earnings.

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 will have no material impact on the Company’s financial statement presentation or disclosures.

In February 2016, the FASB issued ASU 2016-02, Leases, and has subsequently issued several supplemental and/or clarifying ASU's (collectively, "ASC 842"), which requires a dual approach for lease accounting under which a lessee would account for leases as finance leases or operating leases. Both finance leases and operating leases may result in the lessee recognizing a right-of use asset and a corresponding lease liability. For finance leases, the lessee would recognize interest expense and amortization of the right-of-use asset, and for operating leases, the lessee would recognize a straight-line total lease expense. The guidance also requires qualitative and specific quantitative disclosures to supplement the amounts recorded in the financial statements so that users can understand more about the nature of an entity’s leasing activities, including significant judgments and changes in judgments. This ASU will be effective for us beginning the first day of our 2019 fiscal year. Early adoption is permitted. A recent amendment to ASC 842 provides companies with the option to the transition provisions of the new lease standard upon the adoption date instead of at the earliest comparative period. We have begun a process to identify a complete population of our leases. Such process includes reviewing various contracts to identify whether such arrangements convey the right to control the use of an identified asset. We continue to evaluate the impact of the new accounting pronouncements, including enhanced disclosure requirements, on our business processes, controls and systems. We are currently evaluating the effects the adoption if this guidance will have on the consolidated financial statements.

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 will not have a material impact on the Company’s financial statement presentation or disclosures.

In 2018, the FASB also issued Accounting Standards Updates (“ASU”) 2018-01 through 2018-17. These updates did not have a significant impact on the financial statements.

Note 11: Note Payable

In May 2017, the Company entered into a mortgage and note payable agreement with a bridge funding company to obtain a two-year funding line of up to $4,000,000 secured by the property and assets located at 783 Jersey Avenue, New Brunswick, New Jersey. The Company borrowed $1,900,000 of the line in monthly advances including accrued interest as of December 31, 2017. The Company was able to request future advances in excess of $2,000,000 at the lender's discretion and be payable in full upon maturity. The Company paid interest on this note at a fixed rate of 12% per annum for the first 18 months and change to a rate equal to 800 basis points above the prime rate of interest during the remainder of the term; however, the interest rate was not to be less than 12% for the entire term. The note was interest only and payable monthly through the maturity. The Company was permitted to prepay the line without penalty commencing after six months. The balance on the note at December 31, 2017 was $1,835,000($1,900,000 less unamortized deferred finance costs of $65,000). The note was paid off on March 16, 2018 in conjunction with the sale leaseback of the Company's above property and assets at an amount of $1,956,803, which included all accrued interest and fees (See also Note 7 – Property and Equipment).

Note 12: Convertible Note Payable

On September 28, 2018, the Company entered into a $3,170,000 10% Secured Convertible Promissory Note (the "Note") with Iliad Research and Trading, L.P. (the "Holder"), which was issued to the Holder in conjunction with 500,000 shares of Common Stock (the "Origination Shares"). The Company collected $3,000,000 in cash from the Holder, during the period ended September 30, 2018 and the remainder $170,000 was retained by the Holder for the Holder's legal fees of $20,000 for the issuance of the Note and the Original Issue Discount of $150,000. The Company incurred $210,000 in third-party fees directly attributed to the issuance of the Note. The Company promised to pay the principal amount, together with guaranteed interest at the annual rate of 10%, with principal and accrued interest on the Note due and payable on September 28, 2019 (unless converted under terms and provisions as set forth within the Note). The Note provides the Holder with the right to convert, at any time, all or any part of the outstanding principal and accrued but unpaid interest into shares of the Company's common stock at a conversion price of $0.30 per share. In addition, beginning on March 28, 2019, the Note also provides the Holder with the right to redeem all or any portion of the Note ("Redemption Amount"). The payments of each Redemption Amount may be made, at the option of the Company, in cash, by converting such Redemption Amount into shares of common stock ("Redemption Conversion Shares"), or a combination thereof. The number of Redemption Conversion Shares equals the portion of the applicable Redemption Amount being converted divided by the lesser of $0.30 or 80% of the lowest Volume Weighted Average Price ("VWAP") during the ten (10) trading days immediately preceding the applicable measurement date (the "Market Price"). The Purchase Agreement requires the Company to reserve at least 8,900,000 shares of common stock from its authorized and unissued common stock to provide for all issuances of common stock under the Note. However, the Note provides that the aggregate number shares of common stock issued to the Holder under the Note and Purchase Agreement shall not exceed 19.99% of the total number of shares of common stock outstanding as of the closing date unless the Company has obtained stockholder approval of the issuance. The Origination Shares were to be returned to the Company in the event that the Company could provide within 30 days of the closing of the transaction certain requested assets as security for repayment of the Note. The security was not provided so the Origination Shares remained with the Holder.

The Company determined the Note should be recorded at fair value with subsequent changes in fair value recorded in earnings. This conclusion is based on the redemption conversion feature, which allows the Holder to trigger the redemption of the Note for cash or conversion of the Note for common shares prior to its maturity date at a price of the lesser of $0.30 per share or the Market Price as defined within the Note. The choice of cash redemption or conversion of the Note for common shares is at the option of the Company. This feature may require the Company to issue a variable number of common shares to settle the Note which was determined to have a predominantly fixed monetary value at inception. In connection with the Note, the Company recorded a loss in the Company's Consolidated Statements of Comprehensive Income (Loss) equal to $678,000 for the three and nine months ended September 30, 2018.

Interest expense associated with the Note was approximately $4,300 for the three and nine months ended September 30, 2018, which included approximately $2,500 associated with the amortization of applicable discounts to the Note.

Note 13: Fair Value

The Company is required under U.S.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, namely (1) a merger or consolidation with another person; (2) sale of substantially all of its assets; (3) holders of common stock sell 50% or more of outstanding shares; (4) the Company effects an exchange of all its securities for other securities, cash or property, and (5) the Company effects a stock purchase agreement or business combination for more than 50% of outstanding shares. The fair value of the redeemable warrants ("Warrants") related to the Company's August 2016, February 2017, June 2017, August 2017 and April 2018 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:

	September 30, 2018		December 31, 2017	
Underlying price per share	$ 0.23		$ 0.35	
Exercise price per share	$ 1.88		$ 1.88	
Risk-free interest rate	2.87	%	2.05	%
Expected holding period	2.92		3.70	
Expected volatility	70	%	65	%
Expected dividend yield	-		-	

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

	September 30, 2018		December 31, 2017	
Underlying price per share	$0.23		$0.35	
Exercise price per share	$0.69-0.75		$0.69-$0.75	
Risk-free interest rate	2.91	%	2.10	%
Expected holding period	3.84-3.85		4.10	
Expected volatility	70	%	65	%
Expected dividend yield	-		-	

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

	September 30, 2018		December 31, 2017	
Underlying price per share	$ 0.23		$ 0.35	
Exercise price per share	$ 0.63		$ 0.63	
Risk-free interest rate	2.90	%	2.14	%
Expected holding period	3.67		4.4	
Expected volatility	70	%	65	%
Expected dividend yield	-		-	

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

	September 30, 2018	December 31, 2017
Underlying price per share	$ 0.23	$0.35
Exercise price per share	$ 0.45	$0.45
Risk-free interest rate	2.89 %	1.33%-2.11%
Expected holding period	3.43	0.2-4.2
Expected volatility	70 %	65 %
Expected dividend yield	-	-

The Company utilized the following assumptions to estimate the fair value of the April 2018 Warrants:

	September 30, 2018	April 24, 2018
Underlying price per share	$0.23	$0.34
Exercise price per share	$0.39	$0.39
Risk-free interest rate	2.80%-2.94%	2.56%-2.86%
Expected holding period	2.07-5.07	2.5-5.5
Expected volatility	70 %	70 %
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 $0.00 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 18 months at the earliest;
b. The Company flagship product is approved in Argentina for Severely Debilitated CFS patients;
c. The Company may have to perform additional clinical trials for FDA approval of its flagship product;
d. Industry and market conditions continue to include a global market recession, adding risk to any transaction;
e. Available capital for a potential buyer in a cash transaction continues to be limited;
f. The nature of a life science company is heavily dependent on future funding and high costs, including research & development;
g. 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
h. 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 stated above, the Company used a discrete uniform probability distribution over the Expected Holding Period to model 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., using 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 $1,400,000 at September 30, 2018and $962,000 at December 31, 2017.

The Company applies FASB ASC 820 that defines fair value, establishes a framework for measuring fair value in U.S. GAAP, 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 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. As of September 30, 2018, 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 September 30, 2018			
	Total	Level 1	Level 2	Level 3
Assets:				
Marketable securities	$20	$ 20	$ -	$-
Liabilities:				
Redeemable warrants	$1,400	$ -	$ -	$1,400
Convertible note payable	$3,387	$ -	$ -	$3,387

	(in thousands)			
	As of December 31, 2017			
	Total	Level 1	Level 2	Level 3
Assets:				
Marketable securities	$695	$695	$ -	$-
Liabilities:				
Redeemable warrants	$962	$-	$ -	$962
Convertible note payable	$-	$-	$ -	$-

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

Balance at December 31, 2017	$962
Warrants exercised and cancelled	(222)
Warrants issued	1,486
Fair value adjustments	(826)
Balance at September 30, 2018	$1,400

Note 14: Financing Obligation Arising from Sale Leaseback Transaction

On March 16, 2018, the Company sold land and a building for $4,080,000 and concurrently entered into an agreement to lease the property back for ten years at $408,000 per year for two years through March 31, 2020. The lease payments will increase 2.5% per year for the next three years through March 31, 2023 and the lease payments will

increase 3% for the remaining five years through March 31, 2028. The sale of the property includes an option to repurchase the property at fair value which does not permanently transfer all the risks and rewards of ownership to the buyer. The option to repurchase the property also would be at a higher price than the sales price and is considered likely based upon the Company's plans going forward. Because the sale of the property includes the option to repurchase the property and includes the above attributes, the transaction was accounted for as a financing transaction whereby the Company debited cash for the amount of cash received and credit financing obligation. The Company will continue to report the property as an asset and the property will continue to be depreciated. The fair value repurchase option is accounted for similar to a share appreciation mortgage. Accordingly, the guidance in ASC 470-30 related to participating mortgage loans would be applied to the liability. If the option expires unused, the sale is recognized at that time. The gain on the sale would be the excess of the liability (current fair value of the property) over its carrying amount.If the option is exercised, the cash payment by the seller-lessee is to pay off the financing obligation.As part of the sale of this building, warrants were provided to the buyer for the purchase of up to 3,225,806 shares of Company common stock for a period of five years at an exercise price of $0.3875 per share, 125% of the closing price of the common stock on the NYSE American on the date of execution of the letter of intent for the purchase. The warrants cannot be exercised to the extent that any exercise would result in the purchaser owning in excess of 4.99% of our issued and outstanding shares of common stock.

The Property and equipment in Note 7 above are the property and equipment involved in this transaction. Depreciation on the building will continue until a sale has been recognized.

Future minimum payments required under the Financing Obligation and the balance of the Finance Obligation as of September 30, 2018, are as follows:

During the year:

	(in thousands)
2018	$ 102
2019	408
2020	417
2021	427
2022	438
Thereafter	2,475
Total of payments	4,267
Less deferred issuance costs	(252)
Less discount on debt instrument	(1,082)
Less imputed interest	(367)
Total balance	2,566
Less current portion	197
Long term portion	$ 2,369

Interest expense relating to this financing agreement was $43,000 for the nine months ended September 30, 2018.

Note 15: Subsequent Events

The Company evaluated subsequent events through the date on which these financial statements were issued and determined that no subsequent event, other than the above, constituted a matter that required adjustment to the financial statements for the three months ended September 30, 2018.

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. We cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Any statements in this Report about our expectations, beliefs, plans, objectives, assumptions or future events or performance that are not historical facts are forward-looking statements. You can identify these forward-looking statements by the use of words or phrases such as "believe", "may", "could", "will", "estimate", "continue", "anticipate", "inte "seek", "plan", "expect", "should", or "would," and similar expressions intended to identify forward-looking statements.

Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties inherent in our business including, without limitation: our ability to adequately fund our projects as we will need additional funding to proceed with our objectives, the potential therapeutic effect of our products, the possibility of obtaining regulatory approval, our ability to find senior co-development partners with the capital and expertise needed to commercialize our products and to enter into arrangements with them on commercially reasonable terms, our ability to manufacture and sell any products, our ability to enter into arrangements with third party vendors, market acceptance of our products, our ability to earn a profit from sales or licenses of any drugs, our ability to discover new drugs in the future, changing market conditions, changes in laws and regulations affecting our industry, and issues related to our New Brunswick, New Jersey facility. In February 2013, we received a Complete Response Letter (“CRL”) from the Food and Drug Administration (“FDA”) for our Ampligen New Drug Application (“NDA”) for the treatment of CFS. The FDA communicated that we should conduct at least one additional clinical trial, complete various nonclinical studies and perform a number of data analysis. Please see the discussion in "Our Products - Ampligen®" below for more detail. Accordingly, the remaining steps to potentially gain FDA approval of the Ampligen NDA, the final results of these and other ongoing activities could vary materially from our expectations and could adversely affect the chances for approval of the Ampligen NDA. These activities and the ultimate outcomes are subject to a variety of risks and uncertainties, including but not limited to risks that (i) the FDA may ask for additional data, information or studies to be completed or provided; and (ii) the FDA may require additional work related to the commercial manufacturing process to be completed or may, in the course of the inspection of manufacturing facilities, identify issues to be resolved.

In August 2016, we received approval of our NDA from Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica (“ANMAT”) for commercial sale of rintatolimod (U.S. tradename: Ampligen®) in the Argentine Republic for the treatment of severe CFS. The product will be marketed by GP Pharm, our commercial partner in Latin America. We believe, but cannot assure, that this approval provides a platform for potential sales in certain countries within the European Union under regulations that support cross-border pharmaceutical sales of licensed drugs. In Europe, approval in a country with a stringent regulatory process in place, such as Argentina, should add further validation for the product as the Early Access Program (“EAP”) as discussed below and underway in Europe in pancreatic cancer. ANMAT approval is only an initial, but important, step in the overall successful commercialization of our product. There are a number of actions that must occur before we could be able to commence commercial sales in Argentina. Commercialization in Argentina will require, among other things, an appropriate reimbursement level, appropriate marketing strategies, completion of manufacturing preparations for launch. Approval of rintatolimod for severe CFS in the Argentine Republic does not in any way suggest that the Ampligen NDA in the United States or any comparable application filed in the European Union or elsewhere will obtain commercial approval.

In May 2016, we entered into a five-year agreement with myTomorrows, a Netherlands based company, for the commencement and management of an EAP in Europe and Turkey (the “Territory”) related to CFS. Pursuant to the agreement, myTomorrows, as our exclusive service provider and distributor in the Territory, is performing EAP activities. In January 2017, the EAP was extended to pancreatic cancer patients beginning in the Netherlands. In February 2018, we signed an amendment to extend the territory to cover Canada to treat pancreatic cancer patients, pending government approval. In March 2018, we signed an amendment to which myTomorrows will be our exclusive service provider for special access activities in Canada for the supply of Ampligen for the treatment of CFS. No assurance can be given that we can sufficiently supply product should we experience an unexpected demand for Ampligen in our clinical studies, the commercial launch in Argentina or pursuant to the EAPs. No assurance can be given that Ampligen will prove effective in the treatment of pancreatic cancer.

Currently, two Ampligen clinical trials are under way at university cancer centers testing whether tumor microenvironments can be reprogrammed to increase the effectiveness of cancer immunotherapy, including checkpoint blockade. One is at Roswell Park Comprehensive Cancer Center and the other is at the University of Pittsburgh Medical Center. No assurance can be given as to the results of these two trials. We anticipate that six additional cancer trials will be initiated in collaboration with University Medical/Cancer Research Centers using Ampligen plus checkpoint blockade. In addition, no assurance can be given as to whether some or all of the planned additional six oncology clinical trials will occur and they are subject to many factors including lack of regulatory approval(s), lack of study drug, or a change in priorities at the sponsoring Universities or Cancer Centers. Even if these additional clinical trials are initiated, we cannot assure that these clinical studies or the two studies underway will be successful or yield any useful data.

Our overall objectives include plans to continue seeking approval for commercialization of Ampligen in the United States and abroad as well as seeking to broaden commercial therapeutic indications for Alferon N Injection presently approved in the United States and Argentina. We continue to pursue senior co-development partners with the capital and expertise needed to commercialize our products and to enter into arrangements with them on commercially reasonable terms. Our ability to commercialize our products, widen commercial therapeutic indications of Alferon N Injection and/or capitalize on our collaborations with research laboratories to examine our products are subject to a number of significant risks and uncertainties including, but not limited to our ability to enter into more definitive agreements with some of the research laboratories and others that we are collaborating with, to fund and conduct additional testing and studies, whether or not such testing is successful or requires additional testing and meets the requirements of the FDA and comparable foreign regulatory agencies. We do not know when, if ever, our products will be generally available for commercial sale for any indication.

We outsource certain components of our manufacturing, quality control, marketing and distribution while maintaining control over the entire process through our quality assurance and regulatory groups. We cannot provide any guarantee that the facility or our contract manufacturer will necessarily pass an FDA pre-approval inspection for Alferon manufacture.

The production of new Alferon Active Pharmaceutical Ingredient ("API") inventory will begin once the validation phase is complete. While the facility has already been approved by the FDA under the Biological License Application ("BLA") for Alferon, this status will need to be reaffirmed by a successful Pre-Approval Inspection by the FDA prior to commercial sale of newly produced inventory product. If and when the Company obtains a reaffirmation of FDA BLA status and has begun production of new Alferon API, it will need FDA approval as to the quality and stability of the final product before commercial sales can resume. We will need additional funds to finance the revalidation process in our facility to initiate commercial manufacturing, thereby readying ourselves for an FDA Pre-Approval Inspection. If we are unable to gain the necessary FDA approvals related to the manufacturing process and/or final product of new Alferon inventory, our operations most likely will be materially and/or adversely affected. In light of these contingencies, there can be no assurances that the approved Alferon N Injection product will be returned to production on a timely basis, if at all, or that if and when it is again made commercially available, it will return to prior sales levels.In addition, we are currently readying the New Brunswick facility to start manufacturing polymers used for the production of Ampligen to satisfy our future needs. While we anticipate that we will be able to commence manufacturing polymers at the New Brunswick facility, we may need additional funding to continue manufacturing. There cannot be any guarantee that we will obtain adequate funds to sustain manufacturing at the New Brunswick facility or that the facility will be able to manufacture sufficient lots for the commercial launch of Ampligen.

We believe, and are investigating, Ampligen's potential role in enhancing the activity of influenza vaccines. While certain studies involving rodents, non-human primates (monkeys) and healthy human subjects indicate that Ampligen may enhance the activity of influenza vaccines by conferring increased cross-reactivity or cross-protection, further studies will be required and no assurance can be given that Ampligen will assist in the development of a universal vaccine for influenza or other viruses.

We do not undertake and specifically decline any obligation to publicly release the results of any revisions which may be made to any forward-looking statement to reflect events or circumstances after the date of such statements or to reflect the occurrence of anticipated or unanticipated events.

Overview

General

Hemispherx Biopharma, Inc. and its subsidiaries (collectively, "Hemispherx", "Company", "we" or "us") are an immuno-pharma research and development ("R&D") and commercial growth company focused on unmet medical needs in immunology, especially immuno-oncology. We have established a strong foundation of laboratory, pre-clinical and clinical data with respect to the development of natural interferon and nucleic acids to enhance the natural antiviral defense system of the human body and to aid the development of therapeutic products for the treatment of cancers, viral infections, and chronic diseases.

Our flagship products include Argentinean approved, Ampligen® and Argentinean and FDA approved, Alferon N Injection®. Ampligen represents an experimental Ribonucleic Acid ("RNA") in the U.S. being developed for globally important viral diseases and disorders of the immune system. Hemispherx' platform technology includes components for the potential treatment of various severely debilitating and life-threatening diseases. Alferon N Injection is approved for a category of Sexually Transmitted Disease ("STD") infection in the US and Argentina, and for the treatment of refractory patients that failed or were intolerant to treatment with recombinant interferons in Argentina.

We operate a 30,000 sq. ft. facility in New Brunswick, N.J. with the objective of producing Ampligen polymers and Alferon.

In February 2013, we received a Complete Response Letter ("CRL") from the FDA for our Ampligen NDA for the treatment of CFS. The FDA communicated that we should conduct at least one additional clinical trial, complete various nonclinical studies and perform a number of data analysis. Please see the discussion in "Our Products - Ampligen®" below for more detail.

In August 2016, we received approval of our NDA from Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica ("ANMAT") for commercial sale of Ampligen in the Argentine Republic for the treatment of severe CFS.

We are 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 Argentinean approved drug, Ampligen, and our FDA approved drug, Alferon N Injection.

Our principal executive office is located at 2117 SW Highway 484, Ocala FL 34473.

OUR PRODUCTS

Our primary pharmaceutical product platform consists of our Argentinean approved drug, Ampligen, and our Argentinean and FDA approved natural interferon product, Alferon N Injection.

Ampligen®

Ampligen is approved for sale in Argentina and is an experimental drug currently undergoing clinical development for the treatment of certain cancers and CFS in the United States of America. Over its developmental history, Ampligen has received various designations, including Orphan Drug Product Designation (FDA and European Medicines Agency ("EMA"), Treatment protocol (e.g., "Expanded Access" or "Compassionate" use authorization) with Cost Recovery Authorization (FDA) and "promising" clinical outcome recognition based on the evaluation of certain summary clinical reports ("AHRQ" or Agency for Healthcare Research and Quality). Ampligen represents the first drug in the class of large (macromolecular) RNA (nucleic acid) molecules to apply for NDA review. Based on the results of published, peer reviewed pre-clinical studies and clinical trials, we believe that Ampligen may have broad-spectrum anti-viral and anti-cancer properties.

We believe that nucleic acid compounds represent a potential new class of pharmaceutical products as they are designed to act at the molecular level for treatment of human diseases. There are two forms of nucleic acids, deoxyribonucleic acid ("DNA") and ribonucleic acid ("RNA"). DNA is a group of naturally occurring molecules found in chromosomes, the cell's genetic machinery. RNA is a group of naturally occurring informational molecules which orchestrate a cell's behavior which, in turn, regulates the action of groups of cells, including the cells which compromise the body's immune system. RNA directs the production of proteins and regulates certain cell activities including the activation of an otherwise dormant cellular defense against viruses and tumors. Our drug technology utilizes specifically-configured RNA. Our double-stranded RNA drug product, trademarked Ampligen, is an experimental, unapproved drug in the United States, that is administered intravenously. Ampligen has been assigned the generic name rintatolimod by the United States Adopted Names Council (USANC) and has the chemical designation poly(I):poly(C_{12}U).

Clinical trials of Ampligen already conducted by us include studies of the potential treatment of cancer patients with renal cell carcinoma and malignant melanoma, CFS, Hepatitis B and HIV. All of these potential uses will require additional clinical trials to generate the safety and effectiveness data necessary to support regulatory approval.

In February 2013, we received a CRL from the FDA for Ampligen for CFS. In its CRL, the FDA communicated that Hemispherx should conduct at least one additional clinical trial, complete various nonclinical studies and perform a number of data analyses. We are actively engaged with the FDA and have had several meetings in order to reach an

agreement on the path forward. Until we reach an agreement with the FDA regarding the design of a study, we are unable to reasonably estimate the nature or costs necessary to obtain FDA clearance or anticipated completion dates of any additional clinical study or studies. The FDA authorized an open-label expanded access treatment protocol, ("AMP-511"), allowing patient access to Ampligen for treatment in an open-label safety study under which severely debilitated CFS patients have the opportunity to be on Ampligen to treat this very serious and chronic condition. The data collected from the AMP-511 protocol through a consortium group of clinical sites provide safety information regarding the use of Ampligen in patients with CFS. We are establishing an enlarged data base of clinical safety information which we believe will provide further documentation regarding the absence of autoimmune disease associated with Ampligen treatment. We believe that continued efforts to understand existing data, and to advance the development of new data and information, will ultimately support our future filings for Ampligen and/or the design of future clinical studies. In 2015, we engaged an independent certified public accountant to recalculate the cost per dose consistent with the current guidelines, utilizing the costs to produce a vial. In October 2016, the FDA granted our request to implement the new cost which was initiated during the quarter ended March 31, 2017. As of September 30, 2018, there are 11 patients being treated in this open-label expanded access treatment protocol.

In August 2016, we received approval of our NDA from ANMAT for commercial sale of rintatolimod (U.S. tradename: Ampligen®) in the Argentine Republic for the treatment of severe CFS. The product will be marketed by GP Pharm, our commercial partner in Latin America. Commercialization in Argentina will require, among other things, GP Pharm to establish disease awareness, medical education, creation of an appropriate reimbursement level, design of marketing strategies and completion of manufacturing preparations for launch.

In May 2016, we entered into a five-year agreement with myTomorrows, a Netherlands based company, for the commencement and management of an Early Access Program ("EAP") in Europe and Turkey (the "Territory") related to CFS. Pursuant to the agreement, as amended, myTomorrow's also will manage all Early Access Programs and Special Access Programs in Europe, Canada and Turkey to treat pancreatic cancer and ME/CFS patients.

In April 2018, we completed data analysis of an intranasal human safety study of Ampligen plus FluMist known as AMP-600. The study was previously closed after the US Centers for Disease Control and Prevention (“CDC”) recommended against the use of FluMist®. Intranasal Ampligen in combination with FluMist® was generally well-tolerated in the study.

On June 1, 2018 Ampligen was cited as outperforming two other TLR3 agonists, poly IC and natural double stranded RNA, in creating an enhanced tumor microenvironment for checkpoint blockage therapy in the journal of Cancer Research (http://cancerres.aacrjournals.org/content/early/2018/05/31/0008-5472.CAN-17-3985).In a head-to-head study in explant culture models, Ampligen activated the TLR3 pathway and promoted an accumulation of killer T cells but, unlike the other two TLR3 agonists, it did so without causing regulatory T cell (Treg) attraction. These findings were considered important because they indicate that Ampligen selectively reprograms the tumor microenvironment by inducing the beneficial aspects of tumor inflammation (attracting killer T cells), without amplifying immune suppressive elements such as regulatory T cells. The study was conducted at the University of Pittsburgh and Roswell Park Comprehensive Cancer Center, as a part of the NIH-funded P01 CA132714 and Ovarian Cancer Specialized Program of Research Excellence (SPORE). Based upon these findings Hemispherx and Roswell Park Comprehensive Cancer Center expanded their existing scientific collaboration to advance the clinical development of Ampligen - an investigational immune-enhancing TLR3 agonist - which has shown promise in preclinical studies when combined with checkpoint inhibitors (CPIs). The parties executed a Memorandum of Understanding (“MOU”) designed to further assess the clinical potential of Ampligen in treating certain cancers. This phase I/II study will evaluate the potential of Ampligen to enhance the immune mediated effects of CPIs in patients with advanced solid tumors and validate prior research that demonstrated synergy with this combination in preclinical models.

On June 15, 2018 we completed production of a commercial-size batch of more than 8,500 vials of Ampligen® and, following its “Fill & Finish” at the Contract Manufacturing Organization, this lot passed all required testing for regulatory release for human use. Approximately 2,100 of these vials will be shipped to myTomorrows pursuant to a standing stock order for its EAPs. We will receive payment for these vials as it is dispensed in the EAP. We anticipate that the remaining vials, and additional planned batches, may be used for our projected initial needs for clinical trials of Ampligen in the United States, including the FDA-approved open-label expanded access treatment protocol in ME/CFS, and clinical trials involving various cancers with Ampligen as a stand-alone therapy as well as in combination with checkpoint blockade technology.This lot may also be used for certain testing and validation required for the commercial launch of Ampligen in Argentina.

In September 2018, we reported that we successfully filled and finished a second commercial-size batch production run of roughly 8,000 vials of Ampligen. In September 2018 our regulatory inspection and clearance for distribution of our second commercial scale lot of Ampligen, slated for multiple uses including product launch in Argentina for the treatment of ME/CFS, our ME/CFS EAP in the U.S. and Europe and the pancreatic cancer EAP in the Netherlands.

In October 2018, we signed a clinical trial agreement with Roswell Park Comprehensive Cancer Center to evaluate Ampligen in combination with checkpoint inhibitors (CPIs). The Phase IIa clinical trial will evaluate the immune-mediated effects of cytokine modulation in combination with CPIs in patients with primary resistance to CPI therapy. The protocol will seek to evaluate the combination of Ampligen and CPIs in patients with advanced urothelial carcinoma, renal cell carcinoma and melanoma. Ampligen is the Company's investigational immune-enhancing TLR3 agonist that has demonstrated a robust anti-cancer effect in preclinical models when combined with CPIs. This new agreement expands the extensive prior clinical and preclinical work into the clinical checkpoint blockade arena and offers the opportunity to begin evaluation of this combination therapy in patients with a variety of solid tumors where large numbers of patients do not respond or progress following treatment with standard CPI-based therapy.

Alferon N Injection®

Alferon N Injection is the registered trademark for our injectable formulation of natural alpha interferon, which was approved by the FDA for the treatment of certain categories of genital warts. Alferon is the only natural-source, multi-species alpha interferon currently approved for sale in the U.S. and Argentina for the intralesional (within lesions) treatment of refractory (resistant to other treatment) or recurring external genital warts in patients 18 years of age or older. Alferon is also approved in Argentina for the treatment of refractory patients that failed or were intolerant to treatment with recombinant interferons. Certain types of human papilloma viruses ("HPV") cause genital warts, a sexually transmitted disease ("STD"). The CDC estimates that "approximately twenty million Americans are currently infected with HPV with another six million becoming newly infected each year. HPV is so common that at least 50% of sexually active men and women get it at some point in their lives." Although they do not usually result in death, genital warts commonly recur, causing significant morbidity and entail substantial health care costs.

Interferons are a group of proteins produced and secreted by cells to combat diseases. Researchers have identified four major classes of human interferon: alpha, beta, gamma and omega. Alferon N Injection contains a multi-species form of alpha interferon. The world-wide market for injectable alpha interferon-based products has experienced rapid growth and various alpha interferon injectable products are approved for many major medical uses worldwide. Alpha interferons are manufactured commercially in three ways: by genetic engineering, by cell culture, and from human white blood cells. All three of these types of alpha interferon are or were approved for commercial sale in the U.S. Our natural alpha interferon is produced from human white blood cells.

The potential advantages of natural alpha interferon over recombinant (synthetic) interferon produced and marketed by other pharmaceutical firms may be based upon their respective molecular compositions. Natural alpha interferon is composed of a family of proteins containing many molecular species of interferon. In contrast, commercial recombinant alpha interferon products each contain only a single species. Researchers have reported that the various species of interferons may have differing antiviral activity depending upon the type of virus. Natural alpha interferon presents a broad complement of species, which we believe may account for its higher activity in laboratory studies. Natural alpha interferon is also glycosylated (partially covered with sugar molecules). Such glycosylation is not present on the currently U.S. marketed recombinant alpha interferons. We believe that the absence of glycosylation may be, in part, responsible for the production of interferon-neutralizing antibodies seen in patients treated with recombinant alpha interferon. Although cell culture-derived interferon is also composed of multiple glycosylated alpha interferon species, the types and relative quantity of these species are different from our natural alpha interferon.

Alferon N Injection [Interferon alfa-n3 (human leukocyte derived)] is a highly purified, natural-source, glycosylated, multi-species alpha interferon product. There are essentially no neutralizing antibodies observed against Alferon N Injection to date and the product has a relatively low side-effect profile. The recombinant DNA derived alpha interferon formulations have been reported to have decreased effectiveness after one year of treatment, probably due to neutralizing antibody formation.

See “Manufacturing” and “Marketing/Distribution” sections below for more details on the manufacture and marketing/distribution of Alferon N Injection.

Other Diseases

In December 2013, we began supporting the University of Pittsburgh’s chemokine modulation research initiative which includes Ampligen as an adjuvant. As part of this collaboration, Hemispherx has supplied clinical grade Ampligen (rintatolimod) to the University. The study, under the leadership of Professor of Surgery Pawel Kalinski, M.D., Ph.D., involved the chemokine modulatory regimen developed by Dr. Kalinski’s group and successfully completed the Phase 1 dose escalation in patients with resectable colorectal cancer. In the 1st quarter of 2017, Dr. Kalinski relocated to Roswell Park Comprehensive Cancer Center (“RPCCC”) in Buffalo, NY. Dr. Kalinski has been working to establish a cancer program at RPCCC which will continue to require a supply of Ampligen.

Currently, two Ampligen clinical trials are under way at university cancer centers testing whether tumor microenvironments can be reprogrammed to increase the effectiveness of cancer immunotherapy, including checkpoint blockade. The first, a Phase 2A study evaluating a chemokine modulatory regimen in patients with colorectal cancer metastatic to the liver is on-going at Roswell Park Comprehensive Cancer Center with Dr. P. Boland as the Principal Investigator. Four of the 12 planned patients have been enrolled. The second, a Phase 1/2 study of autologous DC1 vaccines and intraperitoneal chemo-immunotherapy for patients with recurrent ovarian cancer is on-going at the University of Pittsburgh Medical Center with Dr. R. Edwards as the Principal Investigator. Ten of the 12 planned patients have been enrolled. An interim report is expected in the 1st Q of 2019.

An overview of six additional cancer trials plan to be initiated in collaboration with University Medical/Cancer Research Centers using Ampligen plus checkpoint blockade follows below:

Advanced ovarian carcinoma using cisplatin, pembrolizumab (anti-PD-1) plus Ampligen: Dr. R. Edwards, Principal Investigator (PI), University of Pittsburgh Medical Center plans on enrolling up to 45 subjects in this single arm Phase II study.

Refractory metastatic colorectal carcinoma using pembrolizumab (anti-PD-1) plus Ampligen: Dr. P. Boland, PI, Roswell Park Comprehensive Cancer Center plans to enroll up to 22 patients into this single arm Phase II study.

Metastatic triple negative breast cancer using chemokine modulation therapy including Ampligen and pembrolizumab (anti-PD-1): Dr. M. Opyrchal, PI, Roswell Park Comprehensive Cancer Center with IRB approval pending.

Ampligen in combination with checkpoint inhibitors in three advanced solid tumors, urothelial (bladder), melanoma, and renal cell carcinoma, resistant to checkpoint blockade: Dr. M. Opyrchal, PI, Roswell Park Comprehensive Cancer Center is currently working on the study design details.

First line therapy for non-small cell lung cancer ("NSCLC") with standard of care including pembrolizumab (anti-PD-1) plus Ampligen: Dr. V. Ernani, PI, University of Nebraska Medical Center is currently working on the study design and budget details.

Advanced pancreatic carcinoma using atezolizumab (anti-PD-L1) plus Ampligen: Dr. K. Klute, PI, University of Nebraska Medical Center is currently working on the study design and budget details.

Some of the statements included in this document may be forward-looking statements that involve a number of risks and uncertainties. For example, planned initiation of these 6 oncology clinical trials may not occur secondary to many factors including lack of regulatory approval(s), lack of study drug, or a change in priorities at the sponsoring Universities or Cancer Centers. Even if the clinical trials are initiated, we cannot assure that the clinical studies will be successful or yield any useful data.

In November 2014, we submitted an application for orphan drug designation to the European Medicines Agency ("EMA") for rintatolimod (Ampligen) to treat Ebola virus disease ("Ebola") and in March 2015, the EMA forwarded to us both its Public Summary of Opinion and its record designation approving the Orphan Medicinal Products Designation for rintatolimod as a potential treatment of Ebola virus disease. In July 2015, we submitted an application for orphan drug designation to the EMA for Alferon N to treat Middle East Respiratory Syndrome ("MERS") and in January 2016, the EMA forwarded to us both its Public Summary of Opinion and its record designation approving the Orphan Medicinal Products Designation for Alferon N Injection, also known as interferon alfa-n3, as a potential treatment of MERS. In addition, we concluded our series of collaborations designed to determine the potential effectiveness of Alferon N and Ampligen as potential preventative and/or therapeutic treatments for Ebola related disorders. Although we believe that the threat of both MERS and Ebola globally may reemerge in the future, it appears that the spread of these disorders has somewhat diminished. As a result, we have elected to focus our research and development efforts on other areas at this time.

In January 2017, the EAP through our agreement with myTomorrows designed to enable access of Ampligen to ME/CFS patients had been extended to pancreatic cancer patients beginning in the Netherlands. myTomorrows is our exclusive service provider in Europe and Turkey and will manage all EAP activities relating to the pancreatic cancer extension of the program. In February 2018, the agreement with myTomorrows was extended to cover Canada to treat pancreatic cancer patients, pending government approval.

In July 2017, we entered into a Material Transfer Agreement with RPCCC in Buffalo, N.Y. to continue the colorectal cancer studies (previously conducted at University of Pittsburgh) with Dr. Pawel Kalinski and his associates with the initiation of a phase 2 study which has treated four patients as of September 30, 2018.

As of September 30, 2018, 40 pancreatic patients have received treatment with Ampligen immuno-oncology therapy in an EAP managed by Amsterdam-based myTomorrows, an international leader in providing physician access to experimental medicines.

Laboratory experiments do not necessarily indicate clinical benefit. Some of the research both past and present has been, and may in the future be, sponsored in part by contracts or grants from us to various independent research entities.

Manufacturing

In January 2017, we entered into a purchase order commitment with Jubilant Hollister-Stier LLC ("Jubilant") pursuant to which Jubilant will manufacture commercial size batches of Ampligen for us. The first lot was manufactured in April 2018, and released for human use in June 2018 for reimbursement and clinical use. The second lot was successfully filled and finished and released for human use in September 2018 for reimbursement and clinical use.

Commercial sales of Alferon in the US will not resume until new batches of commercial filled and finished product are produced and released by the FDA. While the facility is approved by the FDA under the BLA for Alferon, this status will need to be reaffirmed by an FDA pre-approval inspection. We will also need the FDA's approval to release commercial product once we have submitted satisfactory stability and quality release data. Currently, the manufacturing process is on hold and there is no definitive timetable to have the facility back online. We estimate we will need approximately $10,000,000 to commence the manufacturing process. Due to the Company extending the timeline of Alferon production to an excess of one year, we reclassified Alferon work-in-process inventory of $1,115,000 to other assets within our balance sheet as of September 30, 2018 and due to the high cost estimates to bring the facility back online.The above estimated cost includes additional funds needed for the revalidation process in our facility to initiate commercial manufacturing, thereby readying ourselves for an FDA Pre-Approval Inspection. If we are unable to gain the necessary FDA approvals related to the manufacturing process and/or final product of new Alferon inventory, our operations most likely will be materially and/or adversely affected. In light of these contingencies, there can be no assurances that the approved Alferon N Injection product will be returned to production on a timely basis, if at all, or that if and when it is again made commercially available, it will return to prior sales levels.

Marketing/Distribution

If we are unable to achieve licensing, collaboration and/or joint ventures, our marketing strategy for Ampligen will be part of the differing health care systems around the world along with the different marketing and distribution systems that are used to supply pharmaceutical products to those systems. We expect that, subject to receipt of FDA, and/or other regulatory approval, along with the current ANMAT approval, Ampligen may be utilized in four medical arenas: physicians' offices, clinics, hospitals, and the home treatment setting. In preparation for the FDA's consideration of our Ampligen NDA, we undertook early stage development of pre-launch and launch driven marketing plans focusing on audience development, medical support and payer reimbursement initiatives which could facilitate product acceptance and utilization at the time of regulatory approval, if obtained. Similarly, we continued to consider distribution scenarios for the Specialty Pharmacy/Infusion channel which could provide market access, offer 3PL (third party logistics) capabilities and provide the requisite risk management control mechanisms. It is our intent to utilize third party service providers to execute elements of both the marketing/sales and distribution plans. As a possible option, we considered a plan to utilize a small group of Managed Market account managers to introduce the product to payor, employer and government account audiences. We believe that this approach could establish a market presence and facilitate the generation of revenue without incurring the substantial costs associated with a traditional sales force. Furthermore, Management believes that any approach considered should enable us to retain multiple options for future marketing strategies.

In May 2016, we entered into a five-year exclusive Renewed Sales, Marketing, Distribution and Supply Agreement (the "Agreement") with GP Pharm. Under this Agreement, GP Pharm was responsible for gaining regulatory approval in Argentina for Ampligen to treat severe CFS in Argentina and for commercializing Ampligen for this indication in Argentina. We granted GP Pharm the right to expand rights to sell this experimental therapeutic into other Latin America countries based upon GP Pharm achieving certain performance milestones. We also granted GP Pharm an option to market Alferon N Injection in Argentina and other Latin America countries.

In January 2017, the ANMAT granted a five-year extension to a previous approval to sell and distribute Alferon N Injection (under the brand name "Naturaferon") in Argentina. This extends the approval until 2022. In February 2013, we received the ANMAT approval for the treatment of refractory patients that failed or were intolerant to treatment with recombinant interferon, with Naturaferon® in Argentina.

In June 2017, we signed an amendment to the EAP with myTomorrows. This amendment is for myTomorrows to provide support services to Hemispherx with respect to the execution of the 511-Program ("511-Services"). The 511-Services shall be rendered for a period of six months to be renewed with additional six month periods with written mutual consent, or until termination of the 511-Program. The 511-Services were rendered free of charge and the contract has since expired.

In August 2017, we extended our agreement with Asembia, formerly Armada Healthcare, LLC, to undertake the marketing, education and sales of Alferon N Injection throughout the United States.

In August 2017, we extended our agreement with specialty distributor, BioRidgePharma, LLC ("BioRidge") to warehouse, ship, and distribute Alferon N Injection on an exclusive basis in support of U.S. sales.

In May 2016, we entered into an amended and restated five-year agreement (the "Impatients Agreement") with Impatients, N.V. ("myTomorrows"), a Netherlands based company, for the commencement and management of an EAP in Europe and Turkey (the "Territory") related to ME/CFS. Pursuant to the agreement, myTomorrows, as our exclusive service provider and distributor in the Territory, is performing 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. We are supporting these efforts and supplying Ampligen to myTomorrows at a predetermined transfer price. In the event that we receive Marketing Authorization in any country in the Territory, we will pay myTomorrows a royalty on products sold. Pursuant to the Impatients Agreement, the royalty would be a percentage of Net Sales (as defined in the Impatients Agreement) of Ampligen sold in the Territory where Marketing Authorization was obtained, and the maximum royalty would be a percentage of Net Sales. The formula to determine the percentage of Net Sales will be based on the number of patients that are entered into the EAP. The Company believes that disclosure of the exact maximum royalty rate and royalty termination date could cause competitive harm. However, to assist the public in gauging these terms, the actual maximum royalty rate is somewhere between 2% and 10% and the royalty termination date is somewhere between five and fifteen years from the First Commercial Sale of a product within a specific country. The parties established a Joint Steering Committee comprised of representatives of both parties to oversee the EAP. No assurance can be given that activities under the EAP will result in Marketing Authorization or the sale of substantial amounts of Ampligen in the Territory. In 2017, the Company commenced sales of recently manufactured Ampligen in international programs.

In January 2017, the EAP through our agreement with myTomorrows designed to enable access of Ampligen to ME/CFS patients has been extended to pancreatic cancer patients beginning in the Netherlands. myTomorrows is our exclusive service provider in the Territory and will manage all EAP activities relating to the pancreatic cancer extension of the program.

In February 2018, we signed an amendment to the EAP with myTomorrows. This amendment extended the territory to cover Canada to treat pancreatic cancer patients, pending government approval.

In March 2018, we signed an amendment to the EAP with myTomorrows, pursuant to which myTomorrows will be our exclusive service provider for special access activities in Canada for the supply of Ampligen for the treatment of ME/CFS.

401(k) Plan

Each participant immediately vests in his or her deferred salary contributions, while Company contributions will vest over one year. The 6% Company matching contribution was terminated effective January 1, 2016. For the nine months ended September 30, 2018, the Company did not make any contributions towards the 401(k) Plan.

New Accounting Pronouncements

See **"**Note 10: Recent Accounting Pronouncements".

Disclosure About Off-Balance Sheet Arrangements

None.

Critical Accounting Policies

There have been no material changes in our critical accounting policies and estimates from those disclosed in Part II; Item 7: “Management’s Discussion and Analysis of Financial Condition and Results of Operations; Critical Accounting Policies” contained in our Annual Report on Form 10-K for the year ended December 31, 2017.

RESULTS OF OPERATIONS

Three months ended September 30, 2018 versus three months ended September 30, 2017

Net Loss

Our net loss was approximately $3,078,000 and $1,252,000 for the three months ended September 30, 2018 and 2017, respectively, representing an increase in loss of approximately $1,826,000 or 146% when compared to the same period in 2017. This increase in loss for these three months was primarily due to the following:

1) an increase in manufacturing related research and development expense of $808,000 or 103%;

2) the quarterly revaluation of certain redeemable warrants resulted in a non-cash gain of $696,000 in the September 30, 2018 quarter compared to a gain of $1,438,000 in the September 30, 2017 quarter, a decrease of $742,000;and

3) the fair value adjustment for the convertible note resulted in a loss of $678,000 in the quarter ended September 30, 2018, which did not occur in 2017; offset by

4) a decrease in legal fees due to a favorable settlement of legal fees of $342,000; and by a decrease in production costs of $191,000

Net loss per share was $(0.07) and $(0.04) for the three months ended September 30, 2018 and 2017, respectively. The weighted average number of shares of our common stock outstanding as of September 30, 2018 was 47,184,338 as compared to 30,096,500 as of September 30, 2017.

Revenues

Revenues from our Ampligen Cost Recovery Program were $11,000 and $4,000 for the three months ended September 30, 2018 and 2017, respectively.

The primary reason for the decrease in revenues of $52,000 or 58% between periods was due to the unavailability of Ampligen for our EAP through our agreement with MyTomorrows designed to enable access of Ampligen to pancreatic cancer patients in the Netherlands. In September 2018 an additional 7,907 vials of Ampligen were completed.

For the three months ended September 30, 2018 and 2017, we had no Alferon N Injection Finished Good product to commercially sell and all revenue was generated from the EAP and our FDA-approved open-label expanded access treatment protocol, ("AMP-511"), that allows patient access to Ampligen for treatment in an open-label safety study.

Production Costs

Production costs were approximately $208,000 and $399,000, respectively, for the three months ended September 30, 2018 and 2017, representing a decrease of $191,000 or 48% in production costs in the current period. These costs primarily represent stability testing and pre-production expenses related to Alferon. The reduction in costs was primarily due to a write off of $210,000 for expired Alferon fill and finish costs in the prior year.

Research and Development Costs

Overall Research and Development ("R&D") costs for the three months ended September 30, 2018 were approximately $1,595,000 as compared to $787,000 for the same period a year ago, reflecting an increase of approximately $808,000 or 103%. The primary reasons for the increase in research and development costs was due to an increase of $386,000 due to the manufacture and completion of 7,907 Ampligen vials in September 2018; an increase of $263,000 for the production of polymers; and a reduction of Alferon related costs of $127,000 incurred in the prior year.

General and Administrative Expenses

General and Administrative ("G&A") expenses for the three months ended September 30, 2018 and 2017, were approximately $1,273,000 and $1,556,000, respectively, reflecting a decrease of approximately $283,000 or 18%. The decrease in G&A expenses during the current period was mainly due to a favorable settlement of legal fees of $342,000.

Redeemable Warrants

The quarterly revaluation of certain redeemable warrants resulted in a non-cash adjustment to the redeemable warrants liability for the three months ended September 30, 2018 amounted to a loss of approximately $696,000, compared to a gain of $1,438,000 for June 30, 2017, representing a decrease of $742,000 or 52% (see Note 12: Fair Value - for the various factors considered in the valuation of redeemable warrants).

Convertible Note Payable

The quarterly valuation of the convertible note payable resulted in a non-cash loss of $678,000 in the quarter ended September 30, 2018 which did not occur in 2017.

Nine months ended September 30, 2018 versus nine months ended September 30, 2017

Net Loss

Our net loss was approximately $8,206,000 and $6,266,000 for the nine months ended September 30, 2018 and 2017, respectively, representing an increase in loss of approximately $1,940,000 or 31% when compared to the same period in 2017. This increase in loss for these nine months was primarily due to the following:

1) a decrease in revenues of $260,000 or 67%;

2) an increase in interest and finance costs of $182,000;

3) the quarterly revaluation of certain redeemable warrants resulted in a non-cash gain of $826,000 in the nine months ended September 30, 2018 compared to a gain of $2,361,000 in the nine months ended September30, 2017, a decrease of $1,535,000;

4) the fair value adjustment for the convertible note resulted in a loss of $678,000 in the quarter ended September 30, 2018, which did not occur in 2017;

5) an increase in research and development expense of $507,000 or 15%; offset by

6) a decrease in production costs of $285,000;

7) a gain resulting from a settlement of litigation with a vendor of $474,000;

8) a gain from the sale of the underutilized building in New Brunswick of $223,000; and

9) a decrease in legal fees due to a favorable settlement of legal fees of $342,000.

Net loss per share was $(0.19) and $(0.23) for the nine months ended September 30, 2018 and 2017, respectively. The weighted average number of shares of our common stock outstanding as of September 30, 2018 was 42,749,070 as compared to 27,598,715 as of September 30, 2017.

Revenues

Revenues from our Ampligen Cost Recovery Program were $35,000 and $101,000 for the nine months ended September 30, 2018 and 2017, respectively, a decrease of $66,000 or 65%.

The primary reason for the decrease in revenues of $260,000 or 67% between periods was due to the unavailability of Ampligen for our EAP through our agreement with MyTomorrows designed to enable access of Ampligen to pancreatic cancer patients in the Netherlands. Ampligen has been manufactured and 8,484 Ampligen vials were completed in June 2018 and 7,907 in September 2018.

For the nine months ended September 30, 2018 and 2017, we had no Alferon N Injection Finished Good product to commercially sell and all revenue was generated from the EAP and our FDA approved open-label expanded access treatment protocol, (“AMP-511”), that allows patient access to Ampligen for treatment in an open-label safety study.

Production Costs

Production costs were approximately $602,000 and $887,000, respectively, for the nine months ended September 30, 2018 and 2017, representing a decrease of $285,000 or 32% in production costs in the current period. These costs primarily represent stability testing and pre-production expenses related to Alferon. The reduction in costs was primarily due to a write-off of $210,000 for expired Alferon fill and finish costs in the prior year and a decrease in other Alferon production costs of $41,000.

Research and Development Costs

Overall Research and Development (“R&D”) costs for the nine months ended September 30, 2018 were approximately $3,791,000 as compared to $3,284,000 for the same period a year ago, reflecting an increase of approximately $507,000 or 15%. The primary reason for the increase in research and development costs was due to an increase of $850,000 for the completion of the manufacture of 8,484 vials and 7,907 vials in June and September 2018,

respectively, an increase of $418,000 for the production of polymers and a reduction of U.S. clinical costs of $715,000 as a result of reduction in amounts due to clinical investigators resulting from renegotiated terms with the investigators.

General and Administrative Expenses

General and Administrative ("G&A") expenses for the nine months ended September 30, 2018 and 2017, were approximately $4,569,000 and $4,839,000, respectively, reflecting a decrease of approximately $270,000 or 6%. The decrease in G&A expenses during the current period was mainly due to a favorable settlement of legal fees of $342,000.

Interest Expense and Finance Costs

Interest and finance costs for the nine months ended September 30, 2018 was $252,000 compared to $70,000 in the prior year, an increase of $182,000 or 260%. The increase is mainly due to a note/mortgage payable incurred in May 2017 which was paid off in March 2018 with the resulting write off of the balance of the unamortized mortgage settlement costs in addition to the interest expense on the mortgage plus the interest settlement costs on the Finance Obligation from the sale leaseback of the main New Brunswick building. None of these were incurred in the 9 months ended September 30, 2019.

Interest and Other Income

Interest and other income for the nine months ended September 30, 2018 and 2017 were approximately $45,000 and $60,000, respectively, representing a decrease of approximately $15,000 or 25%. The primary cause for the decrease in investment income during the current quarter was primarily due to lower balances available to invest in the current period as compared to the prior period.

Redeemable Warrants

The quarterly revaluation of certain redeemable warrants resulted in a non-cash adjustment to the redeemable warrants liability for the nine months ended September 30, 2018 amounted to a gain of approximately $826,000, compared to a gain of $2,361,000 for September 30, 2017, which represents a decrease of $1,535,000 or 65% (see Note 13: Fair Value - for the various factors considered in the valuation of redeemable warrants).

Convertible Note Payable

The quarterly valuation of the convertible note payable resulted in a non-cash loss of $678,000 in the period ended September 30, 2018 which did not occur in 2017.

Other Transactions

In the nine months ended September 30, 2018 there was a gain of $474,000 resulting from the settlement of litigation with Nitto Avecia Pharma Services, Inc. (“NAPS”).

In the nine months ended September 30, 2018 there was also a gain of $223,000 resulting from the sale of the second building in New Brunswick, New Jersey.

Liquidity and Capital Resources

As of September 30, 2018, we had approximately $4,075,000 in cash, cash equivalents and marketable securities inclusive of approximately $20,000 in marketable securities, representing an increase of approximately $1,968,000 from December 31, 2017. Cash used in operating activities for the nine months ended September 30, 2018 was approximately $8,451,000 compared to approximately $7,181,000 for the same period in 2017, an increase of $1,270,000 or 18%. The primary reason for this increase was the overall reductions in accrued expenses.

Cash provided in investing activities for the nine months ended September 30, 2018 was approximately $1,610,000 compared to cash provided by investing activities of approximately $1,643,000 for the same period in 2017, representing a decrease of $33,000. The primary reason for the decrease during the current period is the receipt of $963,000 from the sale of the underutilized second building in New Brunswick, New Jersey in 2018 compared to lower sales of marketable securities of $1,024,000 in 2018 compared to 2017.

Cash provided by financing activities for the nine months ended September 30, 2018 was approximately $9,484,000 compared to approximately $3,633,000 for the same period in 2017, an increase of $5,851,000. The primary reasons for the increase in the nine months ended September 30, 2018 can be attributable to our receipt of net proceeds of approximately $4,904,000 from the sale common stock pursuant to our Equity Distribution Agreement (“EDA”) with Maxim Group, the exercise of warrants and the sale of shares through a stock offering (see “Note 8: Stockholders’ Equity”). Also, we received $1,678,000 from the sale leaseback of the main building located in New Brunswick, New Jersey.

If we are unable to commercialize and sell Ampligen and/or recommence material sales of Alferon N Injection, our operations, financial position and liquidity may be adversely impacted, and additional financing may be required. In this regard, due to the high cost estimates to bring the facility back online, we will need additional funds to finance the revalidation process in our facility and to initiate commercial manufacturing, thereby readying ourselves for an FDA Pre-Approval Inspection and to commercialize our products. However, there is no assurance that such financing will be available.

As of September 1, 2017, the directors agreed to defer 100% of their fees until cash is available. In consideration of this deferral, 226,023 options were issued to each of the two independent directors in February 2018 with an exercise price of $0.37 for a period of 10 years with a vesting period of 3 years. As of September 1, 2017, certain officers agreed to defer 40% of their salaries until cash is available and all employees agreed to be paid 50% of their salaries in the form of unrestricted common stock of the Company. In April 2018, the Board of Directors approved a payment of 50% of the deferred Board fees and the deferred officer salaries. As of July 15, 2018, these programs were suspended and all deferred fees and salaries were paid in July 2018. This Program was reactivated as of August 16, 2018 with the understanding that options would not be issued on the deferred amounts until the 2018 Equity Incentive Plan was approved by the stockholders and the securities issuable thereunder were registered with the SEC. The 2018 Equity Incentive Plan was approved by the stockholders and the securities issuable thereunder were registered with the SEC and, on October 17, 2018, 172,786 options were issued to each of the two independent directors with an exercise price of $0.22.

We are 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 FDA-approved drug Alferon.

We reactivated our Equity Distribution Agreement with Maxim under our universal shelf registration statement in December 2017. Since December 5, 2017 through September 30, 2018, we have sold an aggregate of 2,143,388 shares under the EDA for proceeds of $907,053 net of $27,211 in commissions. The actual number of shares that we can sell pursuant to the EDA and the proceeds to be received therefrom are dependent upon the market price of our common stock.

In January and February 2018, we realized net proceeds of approximately $1,260,000 from the exercise of 2,800,000 warrants with an exercise price on $0.45.

On March 16, 2018, we sold our property located at 783 Jersey Ave, New Brunswick, NJ for $4,080,000 and the purchasers received 3,225,806 warrants to purchase common stock. Simultaneously therewith, we leased the facility back.

On March 24, 2018, we sold 1,250,000 shares of common stock for net proceeds of approximately $475,000 from this stock offering.

In February 2018, we sold our unencumbered, unutilized, and wholly owned property located at 5 Jules Lane, New Brunswick, New Jersey to Acellories, NJ LLC, a New Jersey limited liability company, pursuant to a sale agreement dated September, 11, 2017. The sale price was $1,050,000.

On April 20, 2018 the Company entered into Securities Purchase Agreements for the sale by the Company of an aggregate of 6,600,000 shares at a purchase price of $0.39 per share. Concurrently with the sale of the shares, the Company also sold 6,600,000 warrants, 50% of which are Class A Warrants and 50% of which are Class B Warrants. The Company realized $2,343,820 from this sale.

There can be no assurances that, if needed, we will be able to raise adequate funds from these or other sources or enter into licensing, partnering or other arrangements to advance our business goals. Our inability to raise such funds or enter into such arrangements, if needed, could have a material adverse effect on our ability to develop our products. Also, we have the ability to curtail discretionary spending, including some research and development activities, if required to conserve cash. Because of our long-term capital requirements, we may seek to access the public equity

market whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time. We are unable to estimate the amount, timing or nature of future sales of outstanding common stock or instruments convertible into or exercisable for our common stock. Any additional funding may result in significant dilution and could involve the issuance of securities with rights, which are senior to those of existing stockholders. We may also need additional funding earlier than anticipated, and our cash requirements, in general, may vary materially from those now planned, for reasons including, but not limited to, changes in our research and development programs, clinical trials, acquisitions of intellectual property or assets, enhancements to the manufacturing process, competitive and technological advances, the regulatory processes including the commercializing of Ampligen products or new utilization of Alferon products.

The proceeds from our financings have been used to fund infrastructure growth including manufacturing, regulatory compliance and market development along with our efforts regarding the Ampligen manufacturing, Ampligen NDA and preparedness for the FDA pre-approval inspections of the New Brunswick manufacturing facility. There can be no assurances that, if needed, we will raise adequate funds from these or other sources, which may have a material adverse effect on our ability to develop our products. Also, we have the ability to curtail discretionary spending, including some research and development activities, if required to conserve cash.

ITEM 3: Quantitative and Qualitative Disclosures About Market Risk

We had approximately $4,075,000 in cash, cash equivalents and marketable securities at September 30, 2018 as compared to $2,107,000 at December 31, 2017.

To the extent that our cash and cash equivalents exceed our near term funding needs, we intend to invest the excess cash in money market accounts, high-grade corporate bonds or fixed-income type bond funds. We employ established conservative policies and procedures to manage any risks with respect to investment exposure.

ITEM 4: Controls and Procedures

Our Chief Executive Officer ("CEO") and the Chief Financial Officer ("CFO") performed an evaluation of the effectiveness of our disclosure controls and procedures, which have been designed to permit us to effectively identify and timely disclose important information. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on that evaluation, our CEO and CFO concluded that the controls and procedures were effective as of September 30, 2018, to ensure that material information was accumulated and communicated to our management, including our CEO and CFO, is appropriate to allow timely decisions regarding required disclosure.

During the nine months ended September 30, 2018, we have made no change in our internal controls over financial reporting that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

Part II – OTHER INFORMATION

ITEM 1: Legal Proceedings

In December 2017, Hemispherx commenced suit against Biolife Plasma Services, LP. formerly d/b/a Pennsylvania Plasma, a Shire Company (Biolife) asserting breach by Biolife of a contract which Hemispherx pursuant to which Biolife was obligated to supply Hemispherx with leukocytes. In addition to lost profits from the breach, the Complaint also seeks damages arising from the breach of the implied covenant of good faith and fair dealing. BioLife, the defendant, has filed its Answer, Affirmative Defenses and a Counterclaim in the amount of $96,676 representing the invoices withheld after BioLife indicated that they were not intending to fulfill the balance of the contract. Hemispherx has denied the allegations of the counterclaim. We are currently in the initial stages of discovery.

ITEM 1A: Risk Factors

The following cautionary statements identify important factors that could cause our actual results to differ materially from those projected in the forward-looking statements made in this Form 10-Q. Among the key factors that have a direct bearing on our results of operations are.

Risks Associated with Our Business:

We may continue to incur substantial losses and our future profitability is uncertain.

As of September 30, 2018, our accumulated deficit was approximately $316,966,000. We have not yet generated significant revenues from our products and may incur substantial and increased losses in the future. We cannot assure that we will ever achieve significant revenues from product sales or become profitable. We require, and will continue to require, the commitment of substantial resources to develop our products. We cannot assure that our product development efforts will be successfully completed or that required regulatory approvals will be obtained or that any products will be manufactured and marketed successfully, or be profitable.

We will require additional financing which may not be available.

The development of our products requires the commitment of substantial resources to conduct the time consuming research, preclinical development, and clinical trials that are necessary to bring pharmaceutical products to market. As of September 30, 2018, we had approximately $4,075,000 in cash, cash equivalents and marketable securities (inclusive of approximately $20,000 in Marketable Securities). However, if we are unable to commercialize and sell Ampligen and/or recommence material sales of Alferon N Injection, our operations, financial position and liquidity may be adversely impacted.

The FDA communicated in its Complete Response Letter (“CRL”), that the Company should conduct at least one additional clinical trial, complete various nonclinical studies and perform a number of data analyses. Until we undertake the end-of-review conference(s) with the FDA or otherwise reach an agreement with the FDA regarding the design of a confirmatory study, we are unable to reasonably estimate the nature, costs, necessary efforts to obtain FDA clearance or anticipated completion dates of any additional clinical study or studies. Utilizing the industry norms for undertaking a Phase III clinical study, we estimate upon acceptance of the study’s design that it would take approximately 18 months to three years to complete a new well-controlled Ampligen clinical study for resubmission to the FDA. It can be reasonably anticipated that the time and cost to undertake clinical trial(s), studies and data analysis are beyond our current financial resources without gaining access to additional funding. The actual duration to complete the clinical study may be different based on the length of time it takes to design the study and obtain FDA’s acceptance of the design, the final design of an acceptable Phase III clinical study design, availability of suitable participants and clinical sites along with other factors that could impact the implementation of the study, analysis of results or requirements of the FDA and/or other governmental organizations.

Given the challenging economic conditions, we continue to review every aspect of our operations for cost and spending reductions to assure our long-term financial stability while maintaining the resources necessary to achieve our primary objectives of obtaining NDA approval of Ampligen along with the manufacturing, marketing and distribution of our products, including Alferon N Injection. We will need additional funds to finance the revalidation process in our facility to initiate commercial manufacturing, thereby readying ourselves for an FDA Pre-Approval Inspection. We may also need additional capital to eventually commercialize and sell Ampligen and/or recommence and increase sales of Alferon N Injection or our other products. We anticipate considering multiple options in an attempt to secure funding, including but not limited to such methods as the sales of additional equity, licensing agreements, partnering with other organizations, debt financing or other sources of capital.

We reactivated our EDA in December 2017. In addition, in 2018, we sold our property located at 783 Jersey Ave, New Brunswick, NJ for $4,080,000, simultaneously leasing the facility back, and sold the unencumbered, unutilized, and wholly owned property located at 5 Jules Lane, New Brunswick, NJ for $1,050,000. However, if we are unable to obtain additional funding or other sales of securities and/or otherwise, our ability to develop our products, commercially produce inventory or continue our operations may be materially adversely affected.

On September 28, 2018, we issued a Secured Convertible Promissory Note (the “Convertible Note”) to a Lender with an original principal amount of $3,170,000 that bears interest at a rate of 10% per annum and matures on September 28, 2019, unless earlier paid, redeemed or converted in accordance with its terms. The Company also issued to the Lender 500,000 shares of its Common Stock. The Company received proceeds of $3,000,000 after an original issue discount and payment of Lender’s legal fees.

Risks Associated with an Investment in Our Common Stock:

The market price of our stock may be adversely affected by market volatility.

The market price of our common stock has been and is likely to be volatile. This is especially true given the current significant instability in the financial markets. In addition to general economic, political and market conditions, the price and trading volume of our stock could fluctuate widely in response to many factors, including:

- announcements of the results of clinical trials by us or our competitors;
- announcements of availability or projections of our products for commercial sale;
- announcements of legal actions against us and/or settlements or verdicts adverse to us;
- adverse reactions to products;
- governmental approvals, delays in expected governmental approvals or withdrawals of any prior governmental approvals or public or regulatory agency comments regarding the safety or effectiveness of our products, or the

- adequacy of the procedures, facilities or controls employed in the manufacture of our products;
- changes in U.S. or foreign regulatory policy during the period of product development;
- developments in patent or other proprietary rights, including any third party challenges of our intellectual property rights;
- announcements of technological innovations by us or our competitors;
- announcements of new products or new contracts by us or our competitors;
- actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- changes in financial estimates by securities analysts and whether our earnings meet or exceed the estimates;
- conditions and trends in the pharmaceutical and other industries;
- new accounting standards;
- overall investment market fluctuation;
- restatement of prior financial results;
- notice of NYSE American non-compliance with requirements; and
- occurrence of any of the risks described in these “Risk Factors”.

Our common stock is listed for quotation on the NYSE American. For the nine months ended September 30, 2018, the trading price of our common stock has ranged from $0.65 to $0.21 per share. We expect the price of our common stock to remain volatile. The average daily trading volume of our common stock varies significantly.

Our stock price may be adversely affected if a significant amount of shares are sold in the public market.

We may issue shares to be used to meet our capital requirements or use shares to compensate employees, consultants and/or Directors. In this regard, we have registered securities for public sale pursuant to a universal shelf registration statement and we had been selling shares under this shelf registration statement. Since December 5, 2017 through September 30, 2018, we have sold an aggregate of 2,203,077 shares under our EDA with Maxim Group. In April 2018, we sold 6,600,000 shares at a purchase price of $0.39 per share and issued 6,600,000 warrants with an exercise price of $0.39. In February 2017, we sold 1,818,185 shares of our common stock and issued warrants. These warrants were subsequently exchanged for warrants to purchase an aggregate of 5,300,000 shares of common stock at an exercise price of $0.45 per share, most exercisable commencing December 1, 2017. In September 2016, we sold 3,333,334 shares of our common stock and issued warrants to purchase 2,500,000 shares of common stock. The warrants were exercised in June and July 2017. We have registered and/or will register the shares issuable upon exercise of all of the above mentioned warrants for public sale and, should the market price of our common stock exceed the exercise price of these warrants, some or all of these warrants may be exercised. In addition, in September 2018, we issued a secured convertible promissory note (the "Convertible Note") to a lender with an original principal amount of $3,170,000. We also issued to the lender 500,000 shares of Common Stock. Commencing March 28, 2019, the Lender has the right to redeem all or any portion of the Convertible Note in the form of cash and/or shares of Common Stock, and the conversion rate is linked to the market price at such time. If the Lender redeems and we are unable to pay in cash, we will be required to issued additional shares of Common Stock and such issuance most likely will have an adverse effect on our share price.

We are unable to estimate the amount, timing or nature of future sales of outstanding common stock or instruments convertible into or exercisable for our common stock. Sales of substantial amounts of our common stock in the public market, including additional sale of securities pursuant to our EDA with Maxim Group or otherwise under the universal shelf registration statement or upon exercise of outstanding options and warrants, could cause the market price for our common stock to decrease. Furthermore, a decline in the price of our common stock would likely impede our ability to raise capital through the issuance of additional shares of common stock or other equity securities. Please see Item 2-Management's Discussion and Analysis of Financial Condition and Result of Operations; Liquidity and Capital Resources" in PART I.

Please also see Part I, Item IA – "Risk Factors" for more information concerning risks associated with our business and risks associated with an investment in our common stock contained within our 2017 Form 10-K filed with the SEC on March 29, 2018 and our Forms 10-Q for the quarters ended March 31, 2018 and June 30, 2018 filed with the SEC on May 15, 2018 and August 14, 2018, respectively.

The trading price of our common stock has decreased significantly over the past year. If it decreases further or does not increase, we run the risk of our stock being delisted from the NYSE American. If our stock is so delisted, the market for our common stock most likely will be adversely affected.

Our stock price has fallen during 2018 from a closing price of $0.35 on January 2, 2018 to a closing price of $0.21 on October 30, 2018. On March 16, 2016, when our stock price was selling at a low price per share, we received written notice from the NYSE MKT LLC (the "NYSE MKT") that we are not in compliance with the continued listing standards because our common stock has been selling for a low price per share for a substantial period of time. To rectify this, we effected a 12-to-1 reverse stock split in August 2016 and, in September 2016, we received written notice from the NYSE MKT LLC that we were back in compliance with the continued listing standards.If the market price for our common stock decreases further or does not increase, we run the risk of our stock being delisted from the NYSE American. The market for our common stock most likely would be adversely affected if such a delisting were to occur.

Special Note Regarding Forward Looking Statements

Because the risk factors referred to above 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, 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. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Our research in clinical efforts may continue for the next several years and we may continue to incur losses due to clinical costs incurred in the development of Ampligen for commercial application. Possible losses may fluctuate from quarter to quarter as a result of differences in the timing of significant expenses incurred and receipt of licensing fees and/or cost recovery treatment revenue. Please see "Cautionary Statement Regarding Forward-Looking Statements" set forth before Part I of this report.

ITEM 2: Unregistered Sales of Equity Securities and Use of Proceeds

On April 20, 2018 the Company entered into Securities Purchase Agreements for the sale by the Company of an aggregate of 6,600,000 shares at a purchase price of $0.39 per share. Concurrently with the sale of the shares, the Company also sold 6,600,000 warrants, 50% of which are Class A Warrants and 50% of which are Class B Warrants. The Company realized $2,343,820 from this sale.

ITEM 3: Defaults upon Senior Securities

None.

ITEM 4: Mine Safety Disclosures

Not Applicable.

ITEM 5: Other Information

In October 2018, the agreement for the sale leaseback of the building was restated to correct the language so that it excludes certain equipment from the sale and to include the corrected list of equipment not sold in the transaction.

ITEM 6: Exhibits

(a) Exhibits

10.1 October 9, 2018, Clinical Trial Agreement with Roswell Park Comprehensive Cancer Center.

10.2 October 8, 2018, Restated First Amendment to Purchase and Sale Agreement.

10.3 October 9, 2018, Restated Bill of Sale for the Restated First Amendment and Sale Agreement.

31.1	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Executive Officer.
31.2	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Financial Officer.
32.1	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Executive Officer.
32.2	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Financial Officer.
101	The following materials from Hemispherx' Quarterly Report on Form 10-Q for the period ended September 30, 2018 formatted in eXtensible Business Reporting Language ("XBRL"): (i) Condensed Balance Sheets; (ii) Condensed Consolidated Statements of Comprehensive Loss; (iii) Changes in Stockholders' Equity; (iv) Condensed Consolidated Statements of Cash Flows; and (v) Notes to Condensed Consolidated Financial Statements.

SIGNATURES

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

HEMISPHERX BIOPHARMA, INC.

/s/ Thomas K. Equels
Thomas K. Equels, Esq.
Chief Executive Officer & President

/s/ Adam Pascale
Adam Pascale
Chief Financial Officer

Date: November 14, 2018

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