#### HEMISPHERX BIOPHARMA INC

Form 10-Q May 15, 2017

## **UNITED STATES**

#### SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, D.C. 20549** 

## **FORM 10-Q**

Quarterly Report Pursuant to Section 13 or 15(d)

of the Securities Exchange Act of 1934

For the Quarterly Period Ended March 31, 2017

Commission File Number: 1-13441

## **HEMISPHERX BIOPHARMA, INC.**

(Exact name of registrant as specified in its charter)

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

## 1617 JFK Boulevard, Suite 500, Philadelphia, PA 19103

(Address of principal executive offices) (Zip Code)

<u>(215) 988-0080</u>
(Registrant's telephone number, including area code)
(Former name, former address and former fiscal year, if changed since last report)
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
[X] Yes [ ] No
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or such shorter period that the registrant was required to submit and post such files).
[X] Yes [ ] No
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):
[ ]Large accelerated filer [ ] Accelerated filer [ ]Non-accelerated filer [X]Smaller reporting company [ ] Emerging growth company
If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards pursuant to Section 13(a) of the Exchange Act. [ ]
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). [ ] Yes [X] No

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

## **PART I - FINANCIAL INFORMATION**

## **ITEM 1: Financial Statements**

## HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES

## **Consolidated Balance Sheets**

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

	March 31,2017 (Unaudited)	December 31,2016 (Audited)
ASSETS		
Current assets:	<b>4.77</b> (	ΦΦ 400
Cash and cash equivalents	\$776	\$2,408
Marketable securities	2,973	3,460
Accounts receivable	41	
Assets held for sale	764	764
Prepaid expenses and other current assets	636	309
Total current assets	5,190	6,941
Property and equipment, net	9,257	9,514
Patent and trademark rights, net	870	872
Other assets	1,546	1,546
Total assets	\$16,863	\$18,873
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$927	\$887
Accrued expenses	1,709	1,548
Total current liabilities	2,636	2,435
Redeemable warrants	1,279	940
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, par value \$0.01 per share, authorized 5,000,000; issued and outstanding;	_	_
none		
Common stock, par value \$0.001 per share, authorized 350,000,000 shares; issued and outstanding 26,186,998 and 24,202,921, respectively	26	24

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

See accompanying notes to consolidated financial statements.

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## **Consolidated Statements of Comprehensive Loss**

(in thousands, except share and per share data)

(Unaudited)

	Three months ended March 31,			ch
	2017		2016	
Revenues:	Φ.2.2		Φ20	
Clinical treatment programs - US	\$23		\$39	
Clinical treatment programs - Europe	61		-	
Total revenues	84		39	
Costs and expenses:				
Production costs	270		268	
Research and development	1,391		1,002	
General and administrative	1,664		2,448	
Total costs and expenses	3,325		3,718	
Operating loss	(3,241	)	(3,679	)
Interest and other income	26		61	
Redeemable warrants valuation adjustment	393		_	
Gain (loss) on sales of short term marketable securities	1		(107	)
Gain from sale of income tax net operating losses and research credits	-		1,561	
1 0			•	
Net loss	(2,821	)	(2,164	)
Other comprehensive income:				
Reclassification adjustments for loss on sales of short term marketable securities	(1	)	107	
included in net loss	•		40	
Unrealized gain on marketable securities	12	`	40	`
Net comprehensive loss	\$(2,810	)	\$(2,017	)
Basic and diluted loss per share	\$(0.11	)	\$(0.10	)
Weighted average shares outstanding, basic and diluted	25,341,06	58	20,630,3	28

See accompanying notes to consolidated financial statements.

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## Consolidated Statement of Changes in Stockholders' Equity

## For the Three Months Ended March 31, 2017

(in thousands except share data)

(Unaudited)

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

See accompanying notes to consolidated financial statements.

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## **Consolidated Statements of Cash Flows**

## For the Three Months Ended March 31, 2017 and 2016

(in thousands)

Cash flows from investing activities:

(Unaudited)

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

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

See accompanying notes to consolidated financial statements.

#### NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

#### **Note 1: Basis of Presentation**

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

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

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

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

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

#### **Note 2: Net Loss Per Share**

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

#### **Note 3: Equity-Based Compensation**

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

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

Stock option activity for employees:

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

Unvested stock option activity for employees:

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

Stock option activity for non-employees:

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

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	(Years)		
271,500 \$ 10.41	4.66	\$	_
(5,590 ) 15.08			
265,910 \$ 10.31	4.41	\$	
265,910 \$ 10.31	4.41	\$	
254,104 \$ 10.69	4.11	\$	
		271,500 \$ 10.41	271,500 \$ 10.41

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Unvested stock option activity for non-employees:

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

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

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

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

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

#### **Note 4: Inventories**

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

Inventories consist of the following:

(in thousands)

March
31, December
31, 31, 2016

2017

Inventory work-in-process, January 1

Froduction

Transfer to other assets

Spoilage

Inventory work-in-process, end of period

(in thousands)

March
31, 2016
2017

— (1,326)
— —

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

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### **Note 5: Marketable Securities**

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

Securities classified as available for sale consisted of:

March 31, 2017

(in thousands)

Securities	Amortized Cost	Gros Unre Gain		Gross Unrealized Losses	Fair Value	Short-Term Investments	_	
Mutual Funds	\$ 2,967	\$	6	\$ -	- \$2,973	\$ 2,973	\$	
Totals	\$ 2,967	\$	6	\$ -	- \$2,973	\$ 2,973	\$	

December 31, 2016

(in thousands)

Securities Amortized Cost	Gross Unrealized	Gross Unrealized	Fair Value	Short-Term Investments	Long
	Gains	Losses			