

May 16, 2017



## Xenetic Biosciences Reports 2017 First Quarter Financial Results and Provides Business Update

- Data from Shire expected in Q2 2017 could further validate proprietary PolyXen™ platform technology and provide cash milestone –*
- Company on track to commence patient recruitment for lead product candidate XBIO-101 for the treatment of progestin resistant endometrial cancer –*
- Management to host quarterly update conference call and webcast today at 8:30 AM ET –*

LEXINGTON, Mass.--(BUSINESS WIRE)-- [Xenetic Biosciences, Inc.](#) (NASDAQ: XBIO) (“Xenetic” or the “Company”), a clinical-stage biopharmaceutical company focused on the discovery, research and development of next-generation biologic drugs and novel orphan oncology therapeutics, announced today its financial results for the quarter ended March 31, 2017. As previously announced, the Company’s management team will host a quarterly update conference call with a live webcast today, May 16, 2017 at 8:30 AM ET for investors, analysts and other interested parties (details below).

Xenetic also provided an update on its license deal with Shire plc (LSE: SHP, NASDAQ: SHPG), a significant stockholder of the Company, along with the clinical status of the product candidate SHP656, or [PSA-Recombinant Factor VIII](#) (“rFVIII”) being developed as a long-acting therapeutic for the treatment of hemophilia utilizing Xenetic’s proprietary [PolyXen™ platform technology](#). The stated goal of Shire is to introduce an innovative, modified rFVIII protein with a significantly prolonged circulating half-life, with the objective of providing a once weekly treatment or reaching higher trough activity levels for greater efficacy. SHP656 is currently in a Phase 1/2 clinical study. Shire expects to report topline data from this Phase 1/2 study in the second quarter of 2017 and, if the outcome of the trial is successful, Xenetic expects Shire to launch a Phase 3 trial before the end of 2017. Xenetic has the potential to receive from Shire up to \$100 million in cash milestones plus royalties linked to sales.

Additionally, Xenetic provided an update to its corporate progress as well as clinical and regulatory status and anticipated milestones for the Company’s lead product candidate, XBIO-101 (sodium cridanimod), a small-molecule immunomodulator and interferon inducer which, in preliminary studies, has been shown to increase progesterone receptor (“PrR”) expression in endometrial tumor tissue. The Company is currently on track to commence patient recruitment in the second quarter of 2017 for a Phase 2 clinical study of XBIO-101 in conjunction with progestin therapy for the treatment of progestin resistant endometrial

cancer, and has filed a protocol under its existing Investigational New Drug application (“IND”) to expand the development of XBIO-101 into a biomarker study in triple negative breast cancer (“TNBC”) patients.

### **Recent Corporate Highlights**

- [Presented case study of PolyXen™ platform technology](#) at the 13<sup>th</sup> Annual Protein Engineering Summit (“PEGS”) Boston;
- [Rang Nasdaq Stock Market Opening Bell](#);
- [Appointed James F. Parslow, MBA, CPA as Chief Financial Officer](#);
- Filed a protocol under existing IND for a biomarker study of XBIO-101 in TNBC patients;
- Expanded its patent portfolio geographically into key markets including areas of Europe, Asia and North America and strengthened the patent portfolio in the US providing robust protection of its platform technology;
- [Received a \\$3 million milestone payment from Shire plc](#) related to Shire’s advancing the Phase 1/2 clinical study for SHP656 being developed as a long-acting therapeutic for the treatment of hemophilia; and
- [Appointed Curtis A. Lockshin, Ph.D. as Chief Scientific Officer](#).

“We have continued to lay a strong foundation for the Company in the first quarter of 2017, showcasing our commitment to operational excellence and importantly, further positioning ourselves for what we believe will be a truly transformational year. We’ve continued to make corporate advancements with key appointments to our management team, as well as clinical advancements with the preparatory work for our XBIO-101 Phase 2 trial and the filing of a protocol under our existing IND for TNBC. We look forward to the topline data from the Shire Phase 1/2 study of SHP656 in the second quarter, and our team remains focused on advancing our flagship product candidate, XBIO-101, with the launch of patient recruitment in our Phase 2 trial for the treatment of endometrial cancer, both of which are value-driving events for Xenetic,” stated [M. Scott Maguire, Xenetic’s CEO](#).

### **Expected Near-Term Milestones**

- Commence patient recruitment in Q2 2017 for a Phase 2 clinical study of XBIO-101 in conjunction with progestin therapy for the treatment of endometrial cancer in women with recurrent or persistent disease who have failed progestin monotherapy;
- Announce topline data from the Shire Phase 1/2 study of SHP656 in Q2 2017;
- Receive milestone payment from Shire if endpoints are achieved in Phase 1/2 study of SHP656; and
- Leverage Shire SHP656 program to enter into more industry collaborations involving the PolyXen technology.

### **Summary of Financial Results for First Quarter 2017**

Net loss for the three months ended March 31, 2017, was \$2.9 million compared to a net loss of approximately \$3.6 million for the same period in 2016. The net loss in the first quarter of 2016 included a net charge of approximately \$1.7 million associated with hybrid debt instruments including changes in derivative fair value, issuance losses as well as interest expense associated with the instruments. All hybrid debt instruments were settled in 2016 and none were issued or outstanding during the three months ended March 31, 2017.

The Company ended the quarter with approximately \$4.3 million of cash.

### **Conference Call and Webcast Information**

Xenetic management will host a conference call for investors, analysts and other interested parties on Tuesday, May 16, 2017 at 8:30 a.m. ET. The conference call and live webcast will be accompanied by presentation slides.

To participate in the call, please dial (877) 407-6914 (domestic) or (201) 493-6709 (international). The live [webcast](#) and accompanying slides will be available by accessing the [IR Calendar](#) in the [Investors](#) section of Xenetic's website ([www.xeneticbio.com](http://www.xeneticbio.com)). A replay of the webcast will be available for 90 days, starting approximately two hours after the presentation ends.

### **About Xenetic Biosciences**

Xenetic Biosciences, Inc. is a clinical-stage biopharmaceutical company focused on the discovery, research and development of next-generation biologic drugs and novel orphan oncology therapeutics. Xenetic's proprietary drug development platforms include PolyXen™, which enables next generation biologic drugs by improving their half-life and other pharmacological properties. Xenetic's lead investigational product candidates include oncology therapeutic XBIO-101 (sodium cridanmod) for the treatment of progesterone resistant endometrial cancer (EC), and a polysialylated form of erythropoietin for the treatment of anemia in pre-dialysis patients with chronic kidney disease.

Xenetic is also working together with Shire plc (formerly Baxalta, Baxter Incorporated and Baxter Healthcare) to develop a novel series of polysialylated blood coagulation factors, including a next generation Factor VIII. This collaboration relies on Xenetic's PolyXen technology to conjugate polysialic acid ("PSA") to therapeutic blood-clotting factors, with the goal of improving the pharmacokinetic profile and extending the active life of these biologic molecules. Shire is a significant stockholder of the Company, having invested \$10 million in the Company during 2014. The agreement is an exclusive research, development and license agreement which grants Shire a worldwide, exclusive, royalty-bearing license to Xenetic's PSA patented and proprietary technology in combination with Shire's proprietary molecules designed for the treatment of blood and bleeding disorders. Under the agreement, Xenetic may receive regulatory and sales target payments for total potential milestone receipts of up to \$100 million plus royalties on sales. Additionally, Xenetic has previously received strategic investments from OPKO Health (Nasdaq: OPK), Serum Institute of India Limited and Pharmsynthez.

Xenetic is also developing a broad pipeline of clinical candidates for breakthrough

biologics and novel oncology therapeutics in a number of orphan disease indications. For more information, please visit the company's website at [www.xeneticbio.com](http://www.xeneticbio.com) and connect on [Twitter](#), [LinkedIn](#), [Facebook](#) and [Google+](#).

## Forward-Looking Statements

This press release contains "forward-looking statements," as that term is defined under the Private Securities Litigation Reform Act of 1995 (PSLRA), which statements may be identified by words such as "expects," "plans," "projects," "will," "may," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning, including statements regarding expected benefits of NGS cancer panels, the ability to accurately determine the heritable factors increasing the risk of cancer, permitting tailored treatment, screening and prevention of cancer in patients, as well as other non-historical statements about our expectations, beliefs or intentions regarding our business, technologies and products, financial condition, strategies or prospects. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include those described in our filings with the Securities and Exchange Commission, as well as the risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments. In addition, forward-looking statements may also be adversely affected by general market factors, competitive product development, product availability, federal and state regulations and legislation, the regulatory process for new products and indications, manufacturing issues that may arise, patent positions and litigation, among other factors. The forward-looking statements contained in this press release speak only as of the date the statements were made, and we do not undertake any obligation to update forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the PSLRA.

## XENETIC BIOSCIENCES, INC. CONDENSED CONSOLIDATED BALANCE SHEETS

	<b>March 31, 2017</b>	<b>December 31, 2016</b>
	<b>(Unaudited)</b>	
<b>ASSETS</b>		
Current assets:		
Cash	\$ 4,323,511	\$ 4,048,131
Restricted cash	66,510	66,510
Accounts receivable	–	3,000,000
Prepaid expenses and other	1,820,023	1,224,009
Total current assets	<u>6,210,044</u>	<u>8,338,650</u>
Property and equipment, net	40,083	42,366
Goodwill	3,283,379	3,283,379
Indefinite-lived intangible assets	9,243,128	9,243,128

Other assets	<u>54,884</u>	<u>66,342</u>
Total assets	<u>\$ 18,831,518</u>	<u>\$ 20,973,865</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,368,529	\$ 1,006,903
Accrued expenses	605,094	838,888
Other current liabilities	<u>20,483</u>	<u>20,205</u>
Total current liabilities	1,994,106	1,865,996
Deferred tax liability	2,918,518	2,918,518
Other liabilities	<u>15,020</u>	<u>19,876</u>
Total liabilities	<u>4,927,644</u>	<u>4,804,390</u>
Commitments and contingent liabilities		
Stockholders' equity:		
Preferred stock, 10,000,000 shares authorized		
Series B, \$0.001 par value: 2,185,742 and 2,305,742		
issued and outstanding as of March 31, 2017, and		
December 31, 2016, respectively	2,185	2,305
Series A, \$0.001 par value: 970,000 shares issued and		
outstanding as of March 31, 2017, and December 31,		
2016	970	970
Common stock, \$0.001 par value; 45,454,546 shares		
authorized as of March 31, 2017, and December 31,		
2016; 8,976,426 and 8,731,029 shares issued as of		
March 31, 2017 and December 31, 2016, respectively;		
8,652,541 and 8,407,144 shares outstanding as of		
March 31, 2017 and December 31, 2016, respectively	8,975	8,730
Additional paid in capital	164,122,816	163,522,921
Accumulated deficit	(145,203,626)	(142,338,005)
Accumulated other comprehensive income	253,734	253,734
Treasury stock	<u>(5,281,180)</u>	<u>(5,281,180)</u>
Total stockholders' equity	<u>13,903,874</u>	<u>16,169,475</u>
Total liabilities and stockholders' equity	<u>\$ 18,831,518</u>	<u>\$ 20,973,865</u>

**XENETIC BIOSCIENCES, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(Unaudited)

	THREE MONTHS ENDED MARCH 31,	
	2017	2016
Operating costs and expenses:		
Research and development	\$ (1,221,144)	\$ (429,281)
General and administrative	(1,634,533)	(1,422,366)
Loss from operations	<u>(2,855,677)</u>	<u>(1,851,647)</u>
Other non-operating income (expense):		
Change in fair value of derivative liability	–	136,014
Loss on issuance of hybrid debt instruments	–	(1,584,218)
Other expense	(9,356)	(26,414)
Interest income	–	14
Interest expense	(588)	(245,384)
Total other non-operating expense	<u>(9,944)</u>	<u>(1,719,988)</u>
Net loss	<u>\$ (2,865,621)</u>	<u>\$ (3,571,635)</u>
Basic and diluted loss per share	<u>\$ (0.34)</u>	<u>\$ (0.78)</u>
Weighted-average shares of common stock outstanding, basic and diluted	<u>8,518,830</u>	<u>4,591,364</u>

View source version on businesswire.com:

<http://www.businesswire.com/news/home/20170516005503/en/>

Jenene Thomas Communications, LLC.

Jenene Thomas, 908-938-1475

[jenene@jenenethomascommunications.com](mailto:jenene@jenenethomascommunications.com)

Source: Xenetic Biosciences, Inc.