

April 3, 2017



# Xenetic Biosciences Reports 2016 Year End Financial Results and Provides Business Update

- Significant corporate and clinical developments in 2016 build solid foundation and position company for a transformational 2017 -
- Data in Q2 2017 from Shire could further validate proprietary PolyXen™ platform technology and provide cash milestone -
- Company advancing XBIO-101 in two indications during 2017 -
- Management to host quarterly update conference call and webcast on April 4<sup>th</sup> at 8:30 AM ET -

LEXINGTON, Mass.--(BUSINESS WIRE)-- [Xenetic Biosciences, Inc.](http://www.xeneticbiosciences.com) (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 year ended December 31, 2016. The Company's management team will host a quarterly update conference call with a live webcast on Tuesday, April 4, 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 FVIII 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 in 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 preparing 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. Xenetic also recently filed a protocol under its existing investigational new drug application (“IND”) for a biomarker study of XBIO-101 in triple negative breast cancer (“TNBC”).

### **Recent Corporate Highlights**

- Uplisted to the Nasdaq Capital Market;
- [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;
- Filed a protocol under its existing IND for a biomarker study of XBIO-101 for the treatment of TNBC;
- 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;
- [Appointed Jeffrey Eisenberg as Chief Operating Officer](#);
- [Appointed Curtis A. Lockshin, Ph.D. as Chief Scientific Officer](#); and
- [Appointed Edward J. Benz, Jr., M.D.](#), former CEO of the Dana-Farber Cancer Institute, to its Board of Directors.

“Over the course of 2016 and the beginning of 2017, we have worked diligently to lay a solid foundation for the Company and as such, have positioned ourselves for what we believe will be a transformational year. The corporate achievements we’ve made, including our uplist to Nasdaq, the bolstering of both our management team with two C-level appointments as well as our board of directors and notable progress with our clinical and regulatory strategies, have enabled us to build momentum which we believe has the potential to propel Xenetic to its next stage of growth,” 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.

“Moving forward, we are excited for the year ahead and remain committed to executing our strategy. We believe that our expected near term corporate and clinical advancements

will unlock significant shareholder value, in both the short-term and long-term,” concluded Mr. Maguire.

### **Summary of Financial Results for Fiscal Year 2016**

Net loss for the three months ended December 31, 2016, was \$0.4 million, or a net loss applicable to common stockholders of \$4.4 million after accretion of beneficial conversion feature on convertible preferred stock of \$4.0 million, compared to a net loss of approximately \$3.6 million for the same period in 2015. The decrease in net loss was primarily related to \$3.0 million of milestone revenue earned in December 2016.

Net loss for the year ended December 31, 2016, was \$54.2 million, or a net loss applicable to common stockholders of \$58.2 million after accretion of beneficial conversion feature on convertible preferred stock of \$4.0 million, resulting in a loss per share applicable to common stockholders of \$7.84, compared to a net loss of \$12.5 million resulting in a loss per share applicable to common stockholders of \$2.96 for the year ended December 31, 2015. The increase in net loss was primarily related to the immediate expensing of in-process research and development acquired in 2016.

The Company ended the year with approximately \$4.0 million of cash.

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

Xenetic management will host a conference call for investors, analysts and other interested parties on Tuesday, April 4, 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™, a transformative delivery technology enabling extended half-life and improved pharmacological properties of biologic drugs. Xenetic's lead investigational product candidates include oncology therapeutic XBIO-101 (sodium cridanimod) 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 an innovative 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.**  
**CONSOLIDATED BALANCE SHEETS**

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**December 31, 2016    December 31, 2015**

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**ASSETS**

Current assets:

Cash	\$	4,048,131	\$	132,229
Restricted cash		66,510		66,510
Accounts receivable		3,000,000		—
Prepayment on acquisition		—		3,744,517
Prepaid expenses and other		1,224,009		247,298
Total current assets		<u>8,338,650</u>		<u>4,190,554</u>
Property and equipment, net		42,366		62,021
Goodwill		3,283,379		3,283,379
Indefinite-lived intangible assets		9,243,128		9,243,128
Other assets		<u>66,342</u>		<u>129,306</u>
Total assets	\$	<u>20,973,865</u>	\$	<u>16,908,388</u>

#### LIABILITIES AND STOCKHOLDERS' EQUITY

##### Current liabilities:

Accounts payable	\$	1,006,903	\$	1,788,521
Accrued expenses		838,888		1,487,046
Hybrid debt instruments, net of accumulated amortization of \$0 and \$108,527 at December 31, 2016 and 2015, respectively		—		3,652,749
Other current liabilities		20,205		19,098
Loans due to related parties		—		395,000
Total current liabilities		<u>1,865,996</u>		<u>7,342,414</u>
Deferred tax liability		2,918,518		2,918,518
Other liabilities		<u>19,876</u>		<u>38,791</u>
Total liabilities		<u>4,804,390</u>		<u>10,299,723</u>

##### Commitments and contingent liabilities

##### Stockholders' equity:

Preferred stock, 10,000,000 shares authorized

Series B, \$0.001 par value: 2,305,742 and no shares issued and outstanding as of December 31, 2016, and December 31, 2015, respectively

2,305 —

Series A, \$0.001 par value: 970,000 and no shares issued and outstanding as of December 31, 2016, and December 31,

2015, respectively 970 –

Common stock, \$0.001 par value;  
45,454,546 shares authorized as of  
December 31, 2016 and 2015; 8,731,029  
and 4,909,685 shares issued as of  
December 31, 2016 and December 31,  
2015, respectively; 8,407,144 and  
4,585,800 shares outstanding as of  
December 31, 2016 and December 31,  
2015, respectively

	8,730	4,909
Additional paid in capital	163,522,921	99,763,101
Accumulated deficit	(142,338,005)	(88,131,899)
Accumulated other comprehensive income	253,734	253,734
Treasury stock	(5,281,180)	(5,281,180)
Total stockholders' equity	<u>16,169,475</u>	<u>6,608,665</u>
Total liabilities and stockholders' equity	<u>\$ 20,973,865</u>	<u>\$ 16,908,388</u>

**XENETIC BIOSCIENCES, INC.**  
**CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

	<b>YEAR ENDED DECEMBER 31,</b>	
	<b>2016</b>	<b>2015</b>
Revenue		
Milestones	\$ 3,000,000	\$ –
Total revenues	<u>3,000,000</u>	<u>–</u>
Operating costs and expenses:		
Research and development	(43,737,814)	(3,434,016)
General and administrative	(6,692,786)	(6,388,000)
Loss from operations	<u>(47,430,600)</u>	<u>(9,822,016)</u>
Other income (expense):		
Change in fair value of derivative liability	2,125,113	(2,125,117)
Loss on issuance of hybrid debt instruments	(1,690,784)	(59,612)
Loss on conversion of debt	(6,394,921)	–
Other expense	(85,374)	(235,421)
Interest income	32	1,694
Interest expense	(729,572)	(266,999)
Total other expense	<u>(6,775,506)</u>	<u>(2,685,455)</u>
Net loss	(54,206,106)	(12,507,471)

Accretion of beneficial conversion feature on convertible preferred stock	<u>(4,035,260)</u>	<u>—</u>
Net loss applicable to common stockholders	(58,241,366)	(12,507,471)
Other comprehensive loss from foreign currency translation adjustment	<u>—</u>	<u>(321,942)</u>
Total comprehensive loss	<u>\$ (54,206,106)</u>	<u>\$ (12,829,413)</u>
Basic and diluted loss per share applicable to common stockholders	<u>\$ (7.84)</u>	<u>\$ (2.96)</u>
Weighted-average shares of common stock outstanding, basic and diluted	<u>7,430,574</u>	<u>4,223,905</u>

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