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

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 unaudited financial results for the quarter ended June 30, 2017.

Xenetic also 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, and an update on its proprietary PolyXen™ platform technology.

"The second quarter was marked by the advancement of our flagship program, XBIO-101, into our Phase 2 program for the treatment of endometrial cancer, along with the important data we received from Shire's Phase 1/2 study of SHP656, which utilized our PolyXen platform technology. While this study did not meet its primary endpoint and Shire has subsequently stated the program has been discontinued, key findings from the study specific to our PolyXen platform technology, provide further validation that it has the potential to improve the clinical utility of protein and peptide drugs," stated [M. Scott Maguire, Xenetic's CEO](#).

## **XBIO-101 Program Update**

In the second quarter of 2017, the Company commenced patient enrollment for its Phase 2 clinical study of XBIO-101 in conjunction with progestin therapy for the treatment of endometrial cancer. The study targets a population of patients who have either failed progestin monotherapy or who have been identified as having progesterone receptor negative ("PrR-") tumors.

The primary objective of the open-label, multi-center, single-arm, two-period Phase 2 study is to assess the antitumor activity of XBIO-101 in conjunction with progestin therapy as measured by Overall Disease Control Rate in women with recurrent or persistent endometrial carcinoma not amenable to surgical treatment or radiotherapy who have either failed progestin monotherapy or who have been identified as PrR-. Secondary objectives include assessments of efficacy and safety/tolerability parameters.

The study is expected to enroll up to 72 women with recurrent or persistent endometrial cancer not amenable to surgical treatment or radiotherapy but suitable to be treated with

progestins. All subjects determined to be PrR- at screening, as well as those subjects who experience disease progression after at least 4 weeks of progestin monotherapy, will receive X BIO-101 in combination with continued progestin treatment. Subjects will receive treatment until disease progression as defined according to RECIST 1.1 criteria.

Xenetic has also filed a protocol under its existing Investigational New Drug application to expand the development of X BIO-101 into a biomarker study related to the treatment of triple negative breast cancer.

#### Expected Upcoming Milestones

- Commence patient dosing in the Phase 2 clinical study evaluating X BIO-101 in conjunction with progestin therapy for the treatment of progestin resistant endometrial cancer in Q3 2017; and
- Announce interim data from Phase 2 study before the end of 2018.

#### **PolyXen Platform Technology Update**

In May 2017, the Company, along with its strategic collaborator, Shire plc (LSE: SHP, NASDAQ: SHPG), announced data from Shire's Phase 1/2 program of SHP656, its PSA-Recombinant Factor VIII ("rFVIII"), which was being developed as a long-acting therapeutic for the treatment of hemophilia A, utilizing Xenetic's PolyXen platform technology to conjugate polysialic acid to therapeutic blood-clotting factors. Despite not achieving the principal objective of once-weekly dosing in this Phase 1/2 study, the Company's PolyXen technology demonstrated that it works as a platform to successfully extend the circulating half-life of rFVIII with no drug-related serious adverse events reported to date. Including the Company's own studies with a polysialylated erythropoietin ("PSA-EPO", "ErepoXen™") candidate, this is the second instance in which PolyXen platform technology has been demonstrated, in a human clinical trial setting, to confer extended half-life to a biotherapeutic, while maintaining pharmacological activity and a favorable safety and tolerability profile. Moving forward, Xenetic believes data from Shire's SHP656 program, although discontinued, continues to support the broad utility of its proprietary PolyXen technology platform, and expects the growing body of data from this platform will enable the Company to build a pipeline of partnerships utilizing this proven technology.

#### Expected Next Steps

- Pursue business development activities to identify target molecules to explore partnerships utilizing PolyXen delivery platform; and
- Explore other potential applications of the PolyXen platform technology within the Shire portfolio.

"We remain focused on driving forward with our strategy, including the continued advancement of our lead product candidate X BIO-101, as well as leveraging our proprietary PolyXen platform technology with the goal of building shareholder value in both the near and long-term," concluded Mr. Maguire.

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

Net loss for the three months ended June 30, 2017, was \$2.9 million compared to a net loss of approximately \$47.8 million for the same period in 2016. The decrease in net loss was primarily due to a decrease of in-process research and development expense, as well as a decrease in share-based compensation expense related to warrants previously issued in 2016. These decreases were offset by an increase in general operating costs and costs related to the initiation of our XBIO-101 Phase 2 clinical study.

The Company ended the quarter with approximately \$2.3 million of cash.

## **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 cridanimod) for the treatment of progesterone resistant endometrial cancer, and a polysialylated form of erythropoietin for the treatment of anemia in pre-dialysis patients with chronic kidney disease.

Xenetic is party to an agreement with Baxalta US Inc. and Baxalta AB (wholly owned subsidiaries of Shire plc) covering the development of a novel series of polysialylated blood coagulation factors. 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. The first program under this agreement was a next generation Factor VIII, and this program was terminated by Shire following a Phase 1/2 clinical trial. Xenetic and Shire are currently exploring whether to engage in further development of other blood coagulation factors. Additionally, Xenetic has previously received strategic investments from OPKO Health (Nasdaq: OPK), Serum Institute of India Limited and PJSC Pharmsynthez.

Xenetic is also developing a broad pipeline of clinical candidates for next-generation 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 for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release other than statements of historical facts may constitute forward-looking statements within the meaning of the federal securities laws. These statements can 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 the Company's ability to develop and customize the Company's

PolyXen™ platform technology to improve the clinical utility of protein and peptide drugs; the Company's anticipated corporate development strategies and pursuit of current and future collaborations to co-develop new product candidates; its ability to add new programs to its pipeline and expand the development of its current product candidates into new indications; the initiation, timing, progress, enrollment and reporting of results of its preclinical programs and clinical trials; the Company's potential for future growth and creation of shareholder value; and the Company's liquidity and ability to fund its future operations;. Any forward-looking statements contained herein are based on current expectations, and are subject to a number of risks and uncertainties. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These risks and uncertainties include those described in the "Risk Factors" section of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and filed with the Securities and Exchange Commission on March 31, 2017, and subsequent reports that it may file with the Securities and Exchange Commission. 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 product candidates 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 the Company does not undertake any obligation to update forward-looking statements, except as required by law.

**XENETIC BIOSCIENCES, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**

	June 30, 2017	December 31, 2016
	(Unaudited)	
<b>ASSETS</b>		
Current assets:		
Cash	\$ 2,331,950	\$ 4,048,131
Restricted cash	66,510	66,510
Accounts receivable	—	3,000,000
Prepaid expenses and other	1,432,512	1,224,009
Total current assets	<u>3,830,972</u>	<u>8,338,650</u>
Property and equipment, net	37,610	42,366
Goodwill	3,283,379	3,283,379
Indefinite-lived intangible assets	9,243,128	9,243,128
Other assets	<u>43,380</u>	<u>66,342</u>
Total assets	<u>\$ 16,438,469</u>	<u>\$ 20,973,865</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,013,316	\$ 1,006,903

Accrued expenses	920,313	838,888
Deferred revenue and other current liabilities	67,495	20,205
Total current liabilities	2,001,124	1,865,996
Deferred tax liability	2,918,518	2,918,518
Other liabilities	10,016	19,876
Total liabilities	4,929,658	4,804,390
Commitments and contingent liabilities (Note 10)		
Stockholders' equity:		
Preferred stock, 10,000,000 shares authorized		
Series B, \$0.001 par value: 2,120,742 and 2,305,742		
issued and outstanding as of June 30, 2017 and		
December 31, 2016, respectively	2,120	2,305
Series A, \$0.001 par value: 970,000 shares issued and		
outstanding as of June 30, 2017 and December 31, 2016	970	970
Common stock, \$0.001 par value; 45,454,546 shares		
authorized as of June 30, 2017 and December 31, 2016;		
9,041,426 and 8,731,029 shares issued as of June 30,		
2017 and December 31, 2016, respectively; 8,717,541		
and 8,407,144 shares outstanding as of June 30, 2017		
and December 31, 2016, respectively	9,040	8,730
Additional paid in capital	164,646,683	163,522,921
Accumulated deficit	(148,122,556)	(142,338,005)
Accumulated other comprehensive income	253,734	253,734
Treasury stock	(5,281,180)	(5,281,180)
Total stockholders' equity	11,508,811	16,169,475
Total liabilities and stockholders' equity	\$ 16,438,469	\$ 20,973,865

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

	THREE MONTHS ENDED JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	2017	2016	2017	2016
Operating costs and expenses:				
Cost of research and development revenue	\$ (59,091)	\$ —	\$ (59,091)	\$ —
Research and development	(873,837)	(2,205,213)	(2,094,981)	(2,634,494)
In-process research and development expense	—	(39,500,000)	—	(39,500,000)

General and administrative	(1,970,471)	(1,557,677)	(3,605,004)	(2,980,043)
Loss from operations	<u>(2,903,399)</u>	<u>(43,262,890)</u>	<u>(5,759,076)</u>	<u>(45,114,537)</u>
Other non-operating income (expense):				
Change in fair value of derivative liability	–	1,769,275	–	1,905,289
Loss on issuance of hybrid debt instruments	–	–	–	(1,584,218)
Loss on conversion of debt	–	(6,187,337)	–	(6,187,337)
Other income (expense)	(25,276)	12,863	(34,632)	(13,551)
Interest income	10,201	13	10,201	27
Interest expense	(456)	(103,086)	(1,044)	(348,470)
Total other non-operating expense	<u>(15,531)</u>	<u>(4,508,272)</u>	<u>(25,475)</u>	<u>(6,228,260)</u>
Net loss	<u>\$(2,918,930)</u>	<u>\$(47,771,162)</u>	<u>\$(5,784,551)</u>	<u>\$(51,342,797)</u>
Basic and diluted loss per share	<u>\$ (0.34)</u>	<u>\$ (6.12)</u>	<u>\$ (0.67)</u>	<u>\$ (8.28)</u>
Weighted-average shares of common stock outstanding, basic and diluted	<u>8,706,387</u>	<u>7,804,187</u>	<u>8,613,127</u>	<u>6,197,776</u>

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