

# Xenetic Biosciences Reports Third Quarter Financial Results and Provides Business Update

LEXINGTON, Mass.--(BUSINESS WIRE)-- <u>Xenetic Biosciences, Inc.</u> (NASDAQ: XBIO) ("Xenetic" or the "Company"), a biopharmaceutical company developing next-generation biologic drugs and novel orphan oncology therapeutics, announced today its financial results for the three months ended September 30, 2016.

Xenetic also provided an update to its corporate progress, clinical and regulatory status and anticipated milestones for the Company's lead product candidates, including ErepoXen®, a polysialylated form of erythropoietin for the treatment of anemia in pre-dialysis patients with chronic kidney disease, and FDA orphan designated oncology therapeutics Virexxa® and Oncohist™ for the treatment of progesterone receptor negative endometrial cancer and refractory Acute Myeloid Leukemia.

# **Recent Corporate Highlights**

- Announced uplisting and trading of its common stock on The Nasdaq Capital Market;
- Closed \$10 million public offering; OPKO Health, Inc. (Nasdaq: OPK) along with other healthcare institutional investors participated in the offering;
- Commenced <u>collaboration with Excivion Ltd.</u> to develop a vaccine against Zika and dengue viruses utilizing Xenetic's proprietary IMUXEN™ Technology; and
- Bolstered Board of Directors with appointment of <u>Jeffrey F. Eisenberg</u>; industry veteran with expertise in R&D, operations, manufacturing/quality, business development, strategic partnering, product development, commercialization, and talent management.

"The achievements we've made in 2016, including our recent uplist to Nasdaq and announcements of key partnerships and appointments, have enabled us to make substantial corporate progress and created a solid foundation on which we expect to build significant momentum in 2017," stated Scott Maguire, CEO. "Our programs continue to move forward and position Xenetic for success in developing biologic drugs and novel oncology therapeutics, that we believe have the potential to provide safe and well tolerated therapy options for patients with a variety of indications."

### **Program Updates**

Xenetic is working together with <u>Shire plc</u> (formerly Baxalta, Baxter Incorporated and Baxter Healthcare) to develop a novel series of polysialylated blood coagulation factors utilizing Xenetic's <u>PolyXen</u>™ technology, including a next generation Factor VIII. Shire is currently evaluating their product candidate <u>BAX826</u>, an investigational, extended half-life

recombinant Factor VIII treatment for hemophilia A, for the treatment of hemophilia in a Phase 2a clinical study. Shire expects to report topline data from this Phase 2a study in Q1 2017.

ErepoXen: polysialylated form of recombinant human erythropoietin (EPO), a hormone produced by the kidneys to maintain red blood cell production and prevent anemia.

## Recent ErepoXen Program Highlights

 Reported positive topline data from the third cohort of its Phase 2 dose-escalation study with its lead drug candidate ErepoXen® for the treatment of anemia in predialysis chronic kidney disease patients

ErepoXen is under investigation to reduce the required frequency of dosage and side effects and to be less immunogenic than existing treatments. Clinical results of ErepoXen suggest that the drug candidate can be administered once a month. ErepoXen is currently in Phase 2/3 clinical development in collaboration with the Serum Institute of India and SynBio of Russia.

## **Expected Near-Term Milestones**

- Complete patient recruitment in Phase 2 dose-escalation study of ErepoXen for the treatment of Anemia; and
- Report topline data from fourth and fifth cohorts of Phase 2 dose-escalation study for the treatment of anemia in pre-dialysis chronic kidney disease patients in 2017.

Virexxa®: (sodium cridanimod), a small-molecule immunomodulator and interferon inducer, currently being studied in an ongoing Phase 2 multi-national study for the treatment of progesterone receptor negative endometrial cancer. Virexxa is also in pre-clinical development for the treatment of triple negative breast cancer.

#### Recent Virexxa Program Highlights

 Announced the U.S. Food and Drug Administration (<u>FDA</u>) acceptance of <u>Investigational New Drug application</u> (IND) to initiate Phase 2 clinical trial of Virexxa® in endometrial cancer.

Xenetic is preparing to commence a 78-patient, Phase 2 clinical study of Virexxa in conjunction with progestin therapy for the treatment of endometrial cancer in women with recurrent or persistent disease who have failed progestin monotherapy. In addition, Virexxa is currently being evaluated in an ongoing Phase 2 multi-national study enrolling 58 subjects with documented evidence of progesterone receptor negative (PrR-negative) endometrial cancer as determined by tumor biopsy. The latter study is being conducted in conjunction with Pharmsynthez PJSC (St. Petersburg Russia) and its subsidiary AS Kevelt (Tallinn, Estonia). For more information on this Phase 2 study, please visit <a href="https://www.clinicaltrials.gov">www.clinicaltrials.gov</a> and reference Identifier NCT02064725.

## Expected Near-Term Milestones

• Initiate Phase 2 clinical study of Virexxa in conjunction with progestin therapy for the

treatment of endometrial cancer in women with recurrent or persistent disease who have failed progestin monotherapy in Q2 2017; and

• Submit IND for biomarker study of Virexxa for the treatment of triple negative breast cancer in Q1 2017.

Oncohist<sup>™</sup>: a novel recombinant human histone H1.3 molecule for the treatment of refractory Acute Myeloid Leukemia (AML) with potential to treat numerous other cancer indications.

Oncohist is currently being evaluated in a Phase 1/2 trial for the treatment of Acute Myeloid Leukemia (AML) in refractory patients. This Phase 1/2 trial is designed to evaluate Oncohist as a combination therapy, together with Cytarabine and is being developed with the Company's Russian partner, Pharmsynthez.

"Moving forward, we remain committed to aggressively advancing the development of our pipeline. We believe that our expected near term corporate and clinical advancements will continue to unlock and build shareholder value, in both the short-term and long-term," concluded Mr. Maguire.

# **Summary of Financial Results for Third Quarter 2016**

For the three months ended September 30, 2016, the Company reported a net loss of \$2,471,981, or a net loss per diluted share of \$0.28, compared to a net loss of \$5,323,699, or a net loss per diluted share of \$1.26 for the three months ended September 30, 2015.

For the nine months ended September 30, 2016, the Company reported a net loss of \$53,814,778, or a net loss per diluted share of \$7.54, compared to a net loss of \$8,880,086, or a net loss per diluted share of \$2.10 for the nine months ended September 30, 2015.

The Company ended the quarter with approximately \$0.2 million of cash and cash equivalents.

On November 7, 2016, the Company closed on a \$10 million public offering and commenced trading of its common stock on The Nasdaq Capital Market.

#### **About Xenetic Biosciences**

Xenetic Biosciences, Inc. is a clinical-stage biopharmaceutical company focused on discovery, research and development of next-generation biologic drugs and novel oncology therapeutics. Xenetic's proprietary drug technology platforms include PolyXen®, designed to develop next generation biologic drugs by extending the efficacy, safety and half-life of biologic drugs.

Xenetic's lead product candidates include ErepoXen<sup>™</sup>, a polysialylated form of erythropoietin for the treatment of anemia in pre-dialysis patients with chronic kidney disease, and FDA orphan designated oncology therapeutics Virexxa<sup>™</sup> and Oncohist<sup>™</sup> for the treatment of progesterone receptor negative endometrial cancer and refractory Acute Myeloid Leukemia.

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 one of the Company's largest shareholders having invested \$10M in the common stock of 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.

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 <a href="https://www.xeneticbio.com">www.xeneticbio.com</a> and connect on <a href="https://www.xeneticbio.com">Twitter</a>, <a href="https://www.xeneticbio.com">LinkedIn</a>, <a href="https://www.xeneticbio.com">Facebook</a> and <a href="https://www.xeneticbio.com">Google+</a>.

#### **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 forwardlooking 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.

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