

# Xenetic Biosciences CEO Delivers "2014 – The Year in Review" Update to Investors and Stakeholders

LEXINGTON, Mass.-- **Xenetic Biosciences, Inc. (OTCBB:XBIO**), a biopharmaceutical company focused on developing next-generation biologic drugs and novel oncology therapeutics, announces that CEO M. Scott Maguire has written a Letter to Shareholders, the full text of which appears below:

### To Our Shareholders:

The year 2014 at Xenetic Biosciences has been defined by a number of significant achievements. As I review all the activities of the past year I am, quite frankly, extremely excited and proud to share with you our considerable accomplishments and to review our plans to build upon that momentum in 2015. Key highlights of 2014 included:

- We completed a complex merger transaction between the former UK public company Xenetic Biosciences plc and the U.S. public company General Sales and Leasing Inc. in January, and the company's common stock began trading in the U.S. on the OTCBB under the symbol XBIO.
- Within days of our listing in the U.S., Baxter International made a \$10 million equity investment in our company at a price of \$0.935 per share.
- Accompanying this Baxter investment was an amendment to our license agreement with them for their next-generation PSA-rFactorVIII product. Our agreement with Baxter now calls for potential cash milestones of up to \$100 million, plus substantial sales royalties should the product meet its clinical objectives and, ultimately, be approved for market launch.
- We opened our new corporate headquarters and research and development facility in Lexington, Massachusetts. Like other UK- and European-based companies, Xenetic has come to greater Boston to be at the heart of the U.S. biotech industry. We hired several senior industry personnel including MIT-educated Dr. Curt Lockshin as VP of Research and Operations to work alongside Dr. Henry Hoppe, VP of Drug Development and a former senior member of Genzyme. We now believe we have a team with talent that would rival any of our larger peers.
- We added healthcare industry veterans to our Board of Directors, including Mark Leuchtenberger as Non-Executive Chairman and Timothy Cote, M.D., MPH, the Former Head of the U.S. Food and Drug Administration (FDA) Office of Orphan Products Development.
- We made excellent clinical progress with our ErepoXen®, PSA-Oxyntomodulin, PulmoXen™ and OncoHist™ programs, reporting the successful clinical data over the course of the year.
- We now have six drug candidates that have reported positive clinical news across eight

- therapeutic areas.
- A world-leading key opinion leader in blood cancers, presented data on OncoHist at the American Society of Hematology (ASH) Annual Meeting last week.

# PolyXen technology

As you know, PolyXen® is our proprietary enabling platform technology for protein drug delivery. It uses the natural polymer polysialic acid (PSA) to prolong a drug's half-life and potentially improve the stability of therapeutic peptides and proteins. Multiple therapeutics incorporating this technology are currently being studied for several different indications.

We call these therapeutics "biobetters" as they represent an improvement over current biologic drugs. PolyXen is a next-generation approach to the widely marketed PEGylation delivery technology. We believe that PolyXen offers many advantages including greater versatility, biogradeability and broader patent coverage.

During 2014 we made excellent progress in developing EropoXen,® a polysialylated form of recombinant human erythropoietin (EPO), which is a hormone produced by the kidneys to maintain red blood cell production and prevent anemia. Chronic renal failure or chemotherapy can cause anemia. ErepoXen is a polysialylated form of EPO designed to reduce the frequency of dosage and side effects compared with existing treatments, and to be less immunogenic. The annual worldwide market for anemia therapies is estimated to be \$7.2 billion.

EropoXen is the subject of several ongoing safety, efficacy and tolerability studies.

- We are currently conducting a Phase 2a dose-escalation study in pre-dialysis chronic kidney disease patients in Australia and New Zealand, and expect to report information on the second cohort by the end of the year having already released positive data on the first cohort this past summer.
- Our partner in India, Serum Institute of India, has dosed 20 patients in an open-label, single-escalating-dose study to assess the efficacy, safety and tolerability of IV ErepoXen in patients with chronic kidney disease who are on dialysis. To date there have been no drug-related adverse events. With this trial we now have data on subcutaneous and intravenous modes of administration utilizing PSA.
- In addition our partner in Russia, SynBio LLC, is studying ErepoXen in a head-to-head comparison against Aranesp®, the leading anemia drug marketed by Amgen, also in pre-dialysis patients. Results from this study also are expected in early 2015.

In a Phase 1 clinical trial in 12 healthy volunteers of PulmoXen<sup>™</sup> for the treatment of cystic fibrosis (CF) conducted by OJSC Pharmsynthez, our license partner in Russia, the compound was found to be well tolerated. Subjects were administered PulmoXen via inhalation daily for seven days, in doses of 2500 IU and 5000 IU. PulmoXen is a novel, modified form of recombinant human DNase I (rhDNase I) designed to be a next-generation version of the commercial drug Pulmozyme, the standard of care for CF. Pulmozyme is sold by the Genentech division of Roche, and has annual worldwide sales of approximately \$700 million.

We announced positive results from a Phase 1 clinical trial of PSA-Oxyntomodulin for the treatment of type 2 diabetes and obesity, which also was conducted in Russia by OJSC

Pharmsynthez. In this single-center, randomized, placebo-controlled trial PSA-Oxyntomodulin was administered once to 12 healthy volunteers subcutaneously at one of three different dose levels (0.25, 0.75 and 1.5 mg/kg) with a placebo administration in each cohort. PSA-Oxyntomodulin was found to be well tolerated in all patients at all doses tested.

We continue to work with Baxter International to develop novel, longer-acting forms of polysialylated blood coagulation factors using Xenetic's technology to conjugate PSA to therapeutic blood-clotting factors. This work includes Factor VIII, a multibillion-dollar drug for treating hemophilia. The goal of the program is to improve the pharmacokinetic profile and extend the active life of these factors to once-a-week administration as opposed to the drugs currently on the market that are delivered two to five times a week.

As noted above, we were very pleased to receive a direct investment of \$10 million from Baxter in conjunction with an amended license agreement, which included increased contingent milestone payments totaling potentially up to \$100 million, as well as higher royalties on sales.

### OncoHist™

One of the world's most prominent leaders in hematological cancers, Richard M. Stone, M.D., presented an abstract at ASH on preclinical work with OncoHist in acute myeloid leukemia (AML) cells. The abstract concluded that the research supported the development of OncoHist alone and in combination with chemotherapy for the treatment of AML.

We are very excited about this research and with our affiliation with Dr. Stone, who is Director of the Adult Acute Leukemia Program at Dana-Farber Cancer Institute and Professor, Department of Medicine, Harvard Medical School. He also serves on the Medical Oncology Board of the American Board of Internal Medicine and is Chair, Alliance Leukemia Committee.

We are preparing to enter human clinical trials in the U.S. with OncoHist in 2015 for the treatment of refractory AML, based on research by Dr. Stone and his colleagues through our agreement with Dana-Farber. Notably, AML has the lowest survival rate of all leukemias.

## ImuXen® technology

ImuXen<sup>®</sup> is our patented platform technology based on the concept of simultaneous delivery of multiple active pharmaceutical ingredients (APIs) as antigens within the same liposome. MyeloXen<sup>™</sup> uses this vaccine technology. We announced that our license partner Pharmsynthez completed dosing in its Phase 2 clinical study with MyeloXen in patients with relapsing remitting and secondary progressive multiple sclerosis. MyeloXen was well tolerated by patients completing the study. We look forward to receiving further results of the trial with this promising drug candidate during 2015.

Importantly, proof-of-concept data in humans generated by our partners in Russia and India reduce Xenetic's development costs as well as our development risk.

# Looking ahead

We are excited about the many milestones we look to achieve during 2015. Among these

are further results from the Phase 2 ErepoXen clinical trial being conducted in Australia and New Zealand. In addition, we plan to complete enabling studies for OncoHist in order to file an Investigational New Drug application with the FDA in AML, to initiate a Phase 2a study in 2015 in AML and possibly to initiate an additional Phase 2a study in another leukemia indication. We also plan to submit an orphan drug application in the U.S. and the EU for OncoHist in an additional hematology indication.

One of our goals in 2014 was to list our common stock on the NASDAQ market. While we were not able to do so this past year, we remain committed to that goal as a priority for the Company; however, we cannot predict at this time when this may occur.

Lastly, we invite you to view our updated corporate Fact Sheet, which contains further information on our milestones and growth strategy. You may access it by clicking <a href="here">here</a>. We look forward to keeping you abreast of our progress and plans via periodic public conference calls, and plan to hold the next one in the first months of 2015. We will announce details of the call approximately one week prior.

I would like to thank our employees, business partners and shareholders for their support throughout the year. We have great technologies, great IP, great programs, great partners and a robust management team that will leave no stone unturned to leverage our assets to deliver shareholder value.

Sincerely,

M. Scott Maguire
Chief Executive Officer

### **About Xenetic Biosciences**

Xenetic Biosciences is a biopharmaceutical company developing next-generation biologic drugs and novel oncology therapeutics. Xenetic's proprietary drug technology platforms include PolyXen® for creating next-generation biologic drugs by extending the efficacy, safety and half-life of biologic drugs, and OncoHist® for the development of novel oncology drugs focused on orphan indications. Xenetic's lead product candidates include ErepoXen®, an improved, polysialylated form of erythropoietin (EPO) for the treatment of anemia in predialysis patients with chronic kidney disease, and OncoHist®, a recombinant human histone H1.3 molecule which Xenetic is developing for the treatment of refractory acute myeloid leukemia (AML). Xenetic is developing a novel series of polysialylated blood coagulation factors through its license agreement with Baxter International Inc. 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 <a href="https://www.xeneticbio.com">www.xeneticbio.com</a>.

### **Forward-Looking Statements**

This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including but not limited to, the potential safety, tolerability and efficacy of our product candidates and the advancement of our clinical trials. Forward-looking statements can be identified by terminology such as "anticipate," "believe," "could," "could increase the likelihood," "estimate," "expect," "intend," "is planned," "may,"

"should," "will," "will enable," "would be expected," "look forward," "may provide," "would" or similar terms, variations of such terms or the negative of those terms. Any forward-looking statements in this press release are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to, the risk of cessation or delay of any of the ongoing or planned clinical trials and/or our development of our product candidates, the risk that the results of previously conducted studies involving similar product candidates will not be repeated or observed in ongoing or future studies involving current product candidates, the risk that our collaboration with Baxter will not continue or will not be successful, and the risk that any one or more of our product candidates will not be successfully developed and commercialized. For a discussion of other risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in our Annual Report on Form 10-K, as well as discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and Xenetic undertakes no duty to update this information unless required by law.

### Xenetic Biosciences Inc.

M. Scott Maguire, Chief Executive Officer 781-778-7720

j.mccusker@xeneticbio.com

or

### U.S. Contact:

LHA
Kim Sutton Golodetz, 212-838-3777
kgolodetz@lhai.com

or

# **UK/European Contact:**

Walbrook PR
Mike Wort, +44 (0)20 7933 8780
mike.wort@walbrookpr.com

Source: Xenetic Biosciences, Inc.