



## XBiotech Provides Third Quarter 2015 Corporate and Clinical Update

November 12, 2015

**Conference Call and Audio Webcast Today at 8:30 a.m. ET**

Recent Highlights:

- Completed enrollment of Xilonix's Phase 3 European registration study in CRC
- Reported encouraging data from ongoing *S. aureus* Phase 1/2 clinical study
- Received FDA Fast Track designation for anti-*S. aureus* antibody
- Published positive Phase 2 results in cardiovascular therapy
- Enhanced intellectual property protection for True Human™ discovery engine
- Initiated discovery program in *C. difficile*
- Announced positive results for anti-Ebola candidates in collaboration with USAMRIID
- Identified positive donors for anti-*C. difficile* antibodies

AUSTIN, Texas, Nov. 12, 2015 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ:XBITE), the world's leading developer of next-generation True Human™ therapeutic antibodies, today provided a corporate and clinical update for the third quarter ended September 30, 2015. The Company's CEO and other key members of XBiotech's management team will provide updates on the company's clinical, R&D and manufacturing operations during this morning's conference call and audio webcast today at 8:30 a.m. ET.

John Simard, the Company's Chief Executive Officer, stated, "XBiotech has taken great strides to advance and build value across our entire business, including our lead clinical programs in oncology and infectious disease. We've also expanded our research and development pipeline and moved closer to significantly enhancing our manufacturing capabilities to support commercial production of our True Human antibody therapies. During the quarter, we completed patient enrollment for our European Phase 3 study of our lead candidate Xilonix™ for treating metastatic colorectal cancer and remain on track to report top line data from the pivotal trial by the end of this year. Additionally, we expanded our XCITE U.S. colorectal cancer study, which continues to ramp up to an anticipated 200 clinical sites across 30 countries worldwide by early next year. We remain on track to complete enrollment in this global FDA study, for which we also received Fast Track designation, by the end of 2016."

"At an investigators' meeting in October, we announced very encouraging early results from our ongoing Phase 1/2 clinical study of 514G3, an antibody therapy to treat *S. aureus* infections. The findings provided compelling evidence that 514G3 may enable elimination of *S. aureus* by the immune system, based on the ability of treated patients' blood to mediate *in vitro* clearance of *S. aureus*. We expect to begin enrolling the randomized, blinded Phase 2 stage of the study in February 2016 and complete the study by May 2016. Our program in *S. aureus* represents a potential franchise XBiotech can build around infectious disease. In addition to *S. aureus*, we began working to identify novel monoclonal antibodies against *Clostridium difficile* (*C. difficile*) using our True Human discovery platform. *C. difficile* infection can lead to a potentially devastating colitis. We were proud to announce that we successfully identified *C. difficile*-reactive blood donors just two weeks after beginning our initial screening. Confirmation of anti-*C. difficile* antibodies in the donor population is the first, crucial milestone in our discovery process. The presence of these antibodies provides the first empirical evidence that *C. difficile* antibodies exist in healthy individuals, suggesting that these antibodies work to clear *C. difficile* infection before it can become clinically relevant—thus providing a strong indicator we are on the right track to finding a *C. difficile* antibody therapeutic.

Similar to our successful Ebola program, the speed with which we identified donors harboring anti-*C. difficile* antibodies speaks to our unique ability to generate novel True Human antibodies in the face of urgent medical need. Contingent on donor availability, we can expect to have therapeutic candidates for anti-*C. difficile* as early as second quarter 2016."

Mr. Simard continued, "We continue to publish positive results for all of our key clinical programs and this quarter we announced a publication in the *Journal of Vascular Surgery* highlighting positive results from a Phase 2 study examining Xilonix in patients undergoing procedures to restore peripheral circulation, for which it also has FDA Fast Track designation. These data point towards Xilonix's potential as a safe and effective therapy to preserve vessel patency after endovascular intervention and builds upon the potential for targeting interleukin-1 alpha for a range of sterile inflammatory diseases."

Mr. Simard concluded, "We are building infrastructure to support future growth in our pipeline and to accommodate commercial-scale manufacturing. We are now nearing completion on a new manufacturing facility, which we expect to begin operations in 2016 and will produce several hundred thousand doses of antibody per year. The construction progress to expand our manufacturing capabilities, strengthened intellectual property surrounding True Human discovery technology, FDA Fast Track designation along with all the significant advances with R&D and clinical programs made for a very positive third quarter."

### Significant Upcoming Milestones

- Report top-line data for Pivotal European Phase 3 colorectal cancer study by year end 2015
- Complete construction of new manufacturing facility in March 2016
- Complete Phase 1/2 study of 514G3 therapeutic antibody against *S. aureus* by May 2016
- Complete enrollment and report interim data for global XCITE Phase 3 Xilonix study in late 2016

## Financial Summary

On April 14, 2015, XBiotech priced its initial public offering of 4,000,000 shares of its common stock at \$19.00 per share, for gross proceeds of \$76,000,000 before the underwriting discount. The shares began trading on The NASDAQ Global Select Market under the ticker symbol "XBIT" on April 15, 2015.

As of September 30, 2015, XBiotech had cash and cash equivalents of approximately \$105 million. XBiotech continues to have no debt. XBiotech believes their current cash and cash equivalents on-hand will be sufficient to fund operations through calendar year 2017.

The conference call can be accessed by dialing:

- U.S. toll free: 877-242-7960
- International: 330-863-3267
- Conference ID: 73120913
- The live audio webcast can be accessed on the Investor Relations section of the XBiotech website at [investors.xbiotech.com](http://investors.xbiotech.com). The webcast will be archived for 90 days.

## About XBiotech

XBiotech is pioneering the discovery and development of targeted antibodies based on its True Human™ technology. The company's mission is to rethink the way antibody medicines are discovered and commercialized by advancing its robust pipeline of human antibodies for treating serious diseases such as cancer, inflammatory conditions and infectious diseases. XBiotech's lead product, Xilonix™, is a potential breakthrough antibody therapy that is currently the subject of two pivotal clinical studies for treating patients with advanced colorectal cancer. Xilonix specifically targets and neutralizes interleukin-1 alpha (IL-1a), a molecule known to promote angiogenesis, growth and spread of tumors, as well as mediate symptoms such as metabolic dysregulation, fatigue and anxiety associated with advanced cancer. XBiotech's True Human antibodies are cloned directly from individual donors who possess natural immunity against certain diseases. For more information, visit [www.xbiotech.com](http://www.xbiotech.com).

## Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements, including declarations regarding management's beliefs and expectations that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "would," "could," "expects," "plans," "contemplate," "anticipates," "believes," "estimates," "predicts," "projects," "intend" or "continue" or the negative of such terms or other comparable terminology, although not all forward-looking statements contain these identifying words. Forward-looking statements are subject to inherent risks and uncertainties in predicting future results and conditions that could cause the actual results to differ materially from those projected in these forward-looking statements. These risks and uncertainties are subject to the disclosures set forth in the "Risk Factors" section of certain of our SEC filings. Forward-looking statements are not guarantees of future performance, and our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate, may differ materially from the forward-looking statements contained in this press release. Any forward-looking statements that we make in this press release speak only as of the date of this press release. We assume no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

CONTACT: Ashley Otero  
XBiotech  
[aotero@xbiotech.com](mailto:aotero@xbiotech.com)  
512.386.2930

Tiberend Strategic Advisors, Inc.:

Joshua Drumm, Ph.D. (investors)  
[jdrumm@tiberend.com](mailto:jdrumm@tiberend.com)  
212.375.2664

Janine McCargo (media)  
[jmccargo@tiberend.com](mailto:jmccargo@tiberend.com)  
646.604.5150

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