



XBiotech Highlights Quarterly Developments

August 10, 2018

Company Provides Updated Overview on its Clinical, Discovery and Financial Position

AUSTIN, Texas, Aug. 10, 2018 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ: XBIT) provided an update on recent corporate and other developments in its Form 10-Q filing with the SEC. The Company reported, among other things, an approximately 50% reduction in operating expenses compared to the same time last year, and also provided key updates and forecasts related to its clinical and discovery pipeline.

John Simard, XBiotech's President & CEO, commented, "I am pleased to report that after set-backs in the clinic, XBiotech has reorganized, reduced costs, enhanced operations and is once again on a strong trajectory as it relates to both research and clinical development. I believe that our operational capability and assets are second-to-none in the healthcare sector considering our cash burn and market capitalization."

Further information with respect to the Company's recent developments and other items is set forth in the Form 10-Q filed yesterday. In particular, the Management's Discussion and Analysis section of the Form 10-Q contains the following overview of XBiotech's recent clinical activities and certain related operational matters:

Clinical Programs

XBiotech recently announced launch of a Phase 2, open label clinical trial to evaluate the Company's True Human™ monoclonal antibody, MABp1 (bermekimab), in patients with moderate to severe Atopic Dermatitis (AD). The Company will be introducing its new pre-filled syringes to deliver bermekimab by subcutaneous injection. The Company has just released its first production lot of pre-filled syringes which contain a highly concentrated formulation of bermekimab, allowing dosing of 400mg in a single, convenient injection. The study will test the subcutaneous bermekimab therapy in AD patients after only 4 or 8 weeks of treatment, compared with the 16 week treatment regimen currently used for the only approved antibody therapy for AD. Longer treatment durations may be needed to achieve optimal clinical activity with bermekimab, particularly when there are severe skin lesions. Evaluating the subcutaneous dose, rapidity, and extent of response is the purpose of the study. Findings from the AD study could establish the basis for further randomized studies that would be necessary for the purpose of product registration.

During the present quarter XBiotech also announced launch of a Phase 2, open label clinical study to evaluate bermekimab in patients with moderate to severe Hidradenitis Suppurativa (HS). The HS study will evaluate subcutaneous administered of bermekimab in a 13 week open label treatment regimen, treating both patients having failed anti-TNF treatments and those with no prior anti-TNF treatment history. There is currently an antibody therapy to block TNF. However, it is estimated that approximately 75% of patients will either fail to respond to the anti-TNF therapy or relapse after an initial response. The Company has already demonstrated in a double-blind, placebo controlled study that bermekimab, when administered as an intravenous therapy, is effective in treating patients that have failed anti-TNF therapy. The current study will evaluate whether subcutaneous administration, using pre-filled syringes, is similarly effective as bermekimab intravenous therapy. If so, the pre-filled syringe product candidate will have a beneficial impact on the convenience of the candidate therapy. If the subcutaneous therapy is found to be similarly effective, additional studies will need to be conducted to obtain marketing approval.

XBiotech is currently supporting a physician-sponsored clinical research study headed by Dr. Andrew Hendifar, MD, at Cedars-Sinai Medical Center. The study is being conducted to examine the safety of bermekimab in combination with Onivyde (nanoliposomal irinotecan) and 5- fluorouracil (5FU)/folinic acid (leucovorin) for pancreatic cancer patients suffering from cachexia. In a large randomized study in advanced cancer patients treated with bermekimab, patients experienced increased lean body mass after treatment. This increase could lead to improved weight maintenance and quality of life in pancreatic cancer patients. The study will therefore evaluate whether a correlation between cachexia, activity, and quality of life exists for patients receiving the bermekimab therapy. To date, more than half of the number of patients targeted for the study have been enrolled. Clinical results are expected to be reported later in 2018.

In 2017, XBiotech completed a double-blind, placebo controlled study using its True Human™ antibody, 514G3 to treat patients with *Staphylococcus aureus* (*S. aureus*) bacteremia. The results of this study showed that patients with life-threatening *S. aureus* infections treated with a single dose of the 514G3 experienced shorter hospital stays, fewer *S. aureus* related serious adverse events, and fewer serious adverse events of any kind compared to those who received placebo. The Company is now planning further clinical development of the 514G3 antibody. XBiotech plans to evaluate 514G3 as a prophylaxis to reduce the risk of *S. aureus* infections in patients being treated with hemodialysis for kidney failure. Patients undergoing hemodialysis are at significant risk for life-threatening *S. aureus* bacteremia. About one-half million patients currently receive over 50 million dialysis treatments annually in the U.S. Patients on hemodialysis have about a 20% one-year mortality risk while being treated. Infections are the second leading cause of death in these patients, and *S. aureus* infections are the main cause of infectious morbidity and mortality. The Company is currently planning to use 514G3 as a prophylaxis to reduce *S. aureus* risk in hemodialysis patients, with a clinical study launch in 2019.

Research & Development

During the present quarter a collaborative research project between XBiotech and a leading academic researcher yielded groundbreaking results on the role of interleukin-1alpha (IL-1 α) in disease (IL-1 α is the target of bermekimab). The published findings centered around the discovery that IL-1 α produced from white blood cells may be a cause of blood clots that could lead to heart attacks or strokes. The research was headed by a world-leading cardiovascular researcher, Dr. Peter Libby, Mallinckrodt Professor of Medicine at Harvard Medical School and clinical cardiologist at Brigham and Women's and Massachusetts General Hospital. Dr. Libby reported that white blood cells, known as neutrophils, can release blood clotting IL-1 α , thus offering the potential for new treatment approach using XBiotech's anti-IL-1 α antibody, bermekimab. The findings describe an intriguing mechanism whereby so called neutrophil extracellular traps (NETs), released from neutrophils, are laden with IL-1 α that is capable of activating cells of the artery wall in a way that in turn activates the blood clotting cells known as platelets. NETs have been implicated in a wide range of disease pathologies, from chronic obstructive pulmonary disease to cancer. While Dr. Libby's findings specifically describe the role of NETs in forming blood clots, the clinical

implications of the findings in human disease are thus considered far reaching.

XBiotech has been developing a candidate True Human™ antibody therapy to treat or prevent shingles. Shingles, also known as herpes zoster, is a viral disease caused by varicella zoster virus (VZV). It occurs frequently in elderly persons, causing extremely painful skin rashes and blisters, which can occur on the body or face. The disease can be self-limiting with skin lesions healing and pain resolving within one month. Alternatively, the disease may be chronic, with debilitating nerve pain that can last for years or eye infections that can result in vision loss. The Company's R&D program for herpes zoster began by screening the healthy human population for antibodies that neutralize VZV and then isolating the genetic information encoding individual anti-VZV antibodies. Using this proprietary discovery technology, the Company succeeded in identifying high affinity antibodies against VZV. Since XBiotech does not presently have the capability to perform infectious disease research using the VZV virus in-house, the Company recently contracted an outside research organization to assess the ability of these antibodies to block VZV infectivity. Data has recently been provided by the contractor demonstrating that several of its anti-VZV antibodies do in fact block the ability of the VZV virus to infect cells. The Company plans to contract additional studies. There are no relevant animal models for shingles and the Company therefore expects to advance an antibody therapy for clinical trials based on these or similar cellular-based VZV infectivity studies. These antibodies against VZV are now being developed in our manufacturing production system, which could enable adequate quantities of antibody product for potential use in clinical trials and commercial development. If necessary, manufacturing of VZV antibodies will be done at the Company's facility and headquarters in Austin, Texas.

XBiotech is developing an oral antibody therapy to treat *Clostridium difficile* (CD) infections. The antibody therapy is aimed at treating a very serious form of diarrhea and intestinal inflammation caused by CD. CD infections may be transient or may progress to be life-threatening and are a leading cause of morbidity and mortality in hospital-acquired infections in the U.S. The incidence of CD infections has risen sharply over the last two decades with nearly 500,000 infections occurring in 2011 which resulted in 29,000 deaths, with mortality often occurring within 30 days of diagnosis. The R&D program began with screening more than 500 healthy human volunteers for antibodies that neutralize the causative agent of the disease and isolating the genetic information encoding these antibodies in individuals. The Company searched for antibodies that could be expected, when taken orally, to be particularly effective at blocking both the motility of the bacteria and its ability to bind to the intestine. Using this proprietary discovery technology, the Company succeeded in identifying high affinity antibodies. Recently, the Company completed preliminary animal studies that showed that some of these antibodies are capable of reducing the severity of infection and injury to the intestine in CD infected animals. Antibody combinations (blocking both CD binding and motility) will now be evaluated to further improve effectiveness of a therapy to prevent CD. Based on these results, antibodies are now being developed in our manufacturing production system, which could enable adequate quantities of antibody product for potential use in clinical trials and commercial development. If necessary, manufacturing of CD antibodies will be done at the Company's facility and headquarters in Austin, Texas.

In 2015, XBiotech undertook an effort to isolate and characterize anti-Ebola antibodies from an individual who had survived and fully recovered from a life-threatening infection with the Ebola virus. The discovery program was thus focused in this case on the antibody repertoire from a single individual who had developed a life-saving immune response against the virus. Using its proprietary approach, the Company isolated the genetic information encoding individual anti-Ebola antibodies from this individual that were further used to produce small quantities of antibodies for research purposes. Later in 2015, the Company established a research and development agreement with the United States Army Medical Research Institute for Infectious Diseases (USAMRIID) to aid in the evaluation of the effectiveness of the antibodies to block Ebola infections. The USAMRIID later reported that 8 out of 10 of the antibodies that it had been provided were effective at neutralizing a deadly strain of the Ebola virus. The Ebola outbreak appeared to subside in 2016 and the project by XBiotech was not advanced further. With the new outbreak in 2018, the Company sees the humanitarian need for an effective therapy to treat Ebola infections. During this quarter, the Company has begun adapting its manufacturing process for the anti-Ebola virus to prepare for limited production. The Company expects to be able to produce significant quantities of a candidate Ebola therapeutic product later this year. The Company will continue to seek to avail its therapeutic Ebola antibodies to areas where Ebola outbreaks occur.

Other

During the past quarter XBiotech has all but completed consolidation of its operations in its new headquarters facility in Austin, Texas. The Company previously occupied three building locations totaling almost 90,000 square feet of space. Operations will now be exclusively housed in a custom-built 33,000 square foot facility that includes a new large scale manufacturing operation, R&D laboratories and administrative space. The move has enabled significant reduction in operating costs while maintaining all R&D and operational capabilities in an improved GMP environment. The new facility is built on a 48 acre property, which is wholly owned by the Company. XBiotech remains 100% debt-free, further reducing go-forward fixed operating costs.

About True Human™ Therapeutic Antibodies

XBiotech's True Human™ antibodies are derived without modification from individuals who possess natural immunity to certain diseases. With discovery and clinical programs across multiple disease areas, XBiotech's True Human antibodies have the potential to harness the body's natural immunity to fight disease with increased safety, efficacy and tolerability.

About XBiotech

XBiotech is a fully integrated global biosciences company dedicated to pioneering the discovery, development and commercialization of therapeutic antibodies based on its True Human™ proprietary technology. XBiotech currently is advancing a robust pipeline of antibody therapies to redefine the standards of care in oncology, inflammatory conditions and infectious diseases. Headquartered in Austin, Texas, XBiotech also is leading the development of innovative biotech manufacturing technologies designed to more rapidly, cost-effectively and flexibly produce new therapies urgently needed by patients worldwide. For more information, visit 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.

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