# UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

FORM 8-K	

# CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event Reported): December 7, 2019

#### XBIOTECH INC.

(Exact Name of Registrant as Specified in Charter)

British Columbia Canada

(State of Incorporation)

001-37347

(Commission File Number)

N/A

(IRS Employer Identification No.)

5217 Winnebago Lane
Austin, Texas
(Address of Principal Executive Offices)

78744

(Zip Code)

(512) 386-2900

(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

	]	Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
[	]	Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
[	]	Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
[	]	Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, no par value	XBIT	NASDAQ Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). Emerging growth company [ X ]

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [ ]

#### Item 1.01. Entry into a Material Definitive Agreement.

Asset Purchase Agreement

On December 7, 2019, XBiotech Inc. (the "Company") entered into an Asset Purchase Agreement (the "Purchase Agreement") with Janssen Biotech, Inc. ("Janssen"), under which Janssen will acquire the Company's True Human Antibody bermekimab to target interleukin-1 alpha (IL- $1\alpha$ ). The Company will retain its True Human Antibody discovery program targeting IL- $1\alpha$  to treat all non-dermatological diseases. Upon closing of the transactions contemplated by the Purchase Agreement (the "Closing"), Janssen will pay \$750 million in cash to the Company, \$75 million of which will be held in an escrow account for 18 months to satisfy any indemnity claims. In addition, Janssen will be obligated to pay the Company up to four milestone payments of \$150 million each, or a maximum of \$600 million if it receives specified commercial authorizations within a specified timeframe for a pharmaceutical product that contains bermekimab and is for a non-dermatological indication.

The Purchase Agreement includes customary representations and warranties from each party to the other party, along with customary mutual indemnification obligations. Closing is subject to the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 and other customary closing conditions. The Company and Janssen have agreed to certain non-competition and exclusivity covenants and rights of first negotiation following the closing.

The Company plans to use the proceeds from the closing cash payment under the Purchase Agreement to fund discovery and development of its next generation True Human anti-IL- $1\alpha$  antibody program and to advance other antibody therapeutics in the Company's pipeline. The Company will also have sufficient cash to support a significant capital transaction, such as a stock repurchase, subject to board review and approval.

#### IP Non-Assertion and License Agreement

At the Closing, the Company and Janssen will enter into an IP Non-Assertion and License Agreement (the "License Agreement"), pursuant to which the Company will grant Janssen a non-exclusive license to certain patents and intellectual property of the Company. Janssen has agreed not to assert certain claims from the patents to be acquired from the Company in the transaction against the Company in connection with the Company's new antibodies targeting  $IL-1\alpha$  as described in the Purchase Agreement, to treat non-dermatological diseases.

#### Clinical Manufacturing Agreement

In addition, at the Closing, XBiotech USA, Inc., a subsidiary of the Company ("XBiotech USA), and Janssen Research & Development, LLC ("JRD") will enter into a Clinical Manufacturing Agreement (the "Manufacturing Agreement"). Pursuant to the Manufacturing Agreement, XBiotech USA will agree to manufacture bermekimab for use by Janssen in clinical trials, in exchange for payments, paid in quarterly installments.

#### Transition Services Agreement

Finally, at the Closing, XBiotech USA and JRD will enter into a Transition Services Agreement (the "Services Agreement" and, together with the Purchase Agreement, the License Agreement and the Manufacturing Agreement, the "Agreements"). Pursuant to the Services Agreement, XBiotech USA will agree to continue operational management, on a fee-for-service basis, of certain ongoing clinical trials related to bermekimab.

The foregoing description of the Agreements does not purport to be complete and is qualified in its entirety by reference to the terms of the Purchase Agreement, the form of License Agreement, the form of Manufacturing Agreement and the form of Services Agreement.

#### Item 8.01. Other Events.

On December 7, 2019, the Company issued a press release announcing the entry into the Purchase Agreement with Janssen. A copy of the press release issued in connection with the announcement is filed as Exhibit 99.1 to this Current Report on Form 8-K.

#### Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

### **Exhibit Number Description**

99.1 Press Release of XBiotech Inc., issued December 7, 2019

# SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: December 9, 2019

# XBIOTECH INC.

By: <u>/s/ John Simard</u> Name: John Simard

Title: Chief Executive Officer and President

# XBiotech Announces Agreement to Sell True Human Antibody Bermekimab Targeting IL-1a to Janssen

# XBiotech will continue its True Human anti IL-1α antibody discovery program outside of dermatology and use its manufacturing technology to produce clinical supplies of bermekimab for Janssen

AUSTIN, Texas, Dec. 07, 2019 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ: XBIT) announced today that it has entered into a definitive agreement with Janssen Biotech, Inc., a Janssen Pharmaceutical Company of Johnson & Johnson, to sell XBiotech's novel antibody (bermekimab) that neutralizes interleukin-1 alpha (IL-1 $\alpha$ ). IL-1 $\alpha$  promotes disease-causing inflammation in a wide range of medical conditions. Janssen will acquire all rights to bermekimab under the terms of the agreement, and XBiotech will be free to use its True Human Antibody discovery program to develop new antibody therapeutics that target IL-1 $\alpha$  to treat non-dermatological diseases. XBiotech plans to re-enter clinical development expeditiously with a next generation anti-IL-1 $\alpha$  therapeutic.

Following the acquisition, XBiotech will use its proprietary manufacturing technology to produce clinical supplies of bermekimab for Janssen under a supply agreement. In addition, XBiotech will contract with Janssen to provide clinical trial operation services to complete two ongoing Phase II clinical studies evaluating bermekimab in Hidradenitis Suppurativa and Atopic Dermatitis.

Upon closing, Janssen will make a cash payment of \$750 million to XBiotech. In addition, XBiotech may receive up to \$600 million in potential milestone payments. XBiotech expects to generate additional revenue from the manufacturing supply agreement and clinical services agreement with Janssen over the next two years.

XBiotech plans to use a portion of the proceeds from this transaction to fund discovery and development of its next generation True Human anti-IL- $1\alpha$  antibody program. Additionally, a portion of the revenue will be dedicated to advancing other antibody therapeutics in XBiotech's pipeline. The Company is also planning to use part of the proceeds in a capital transaction, such as a stock repurchase, subject to board review and approval.

John Simard, XBiotech's President & CEO, stated, "We are proud that Janssen has chosen bermekimab as an agent it believes could have an important impact. We believe their acquisition will enable recognition and increase awareness of the full potential of this first-in-class therapeutic. This transaction also provides us the opportunity to showcase our powerful True Human antibody discovery platform, which we are now utilizing to pursue next generation anti-Il- $1\alpha$  antibody therapeutics to treat multiple areas of unmet need outside of dermatology."

The acquisition of bermekimab provides further validation of the foundational science behind targeting IL-1a as a means to block disease-causing inflammation. Clinical and pre-clinical research suggests blocking IL-1a may be used to treat a number of chronic and acute inflammatory conditions, including skin disease, heart disease, heart attack, stroke, rheumatological disease, gastrointestinal diseases, and cancer.

Simard further stated, "The cash infusion from the bermekimab transaction will enable XBiotech to accelerate our True Human antibody pipeline. The Company will also have sufficient cash to support a significant capital transaction, which could provide for a non-dilutive liquidity event for our valued shareholders who have supported XBiotech's pioneering work."

The transaction is subject to customary closing conditions, including clearance under the Hart-Scott-Rodino Antitrust Improvements Act, and is expected to close shortly after HSR approval.

#### **About XBiotech**

XBiotech is a fully integrated, global biopharmaceutical company dedicated to pioneering the discovery, development and commercialization of therapeutic antibodies. XBiotech currently is advancing a pipeline of therapies by harnessing naturally occurring antibodies from patients with immunity to certain diseases. Utilizing natural human immunity as a source of new medicines offers the potential to redefine the standards of care for a wide range of diseases. The discovery and manufacturing techniques which enable this were designed by and are exclusive to XBiotech. Headquartered in Austin, Texas, XBiotech also leads the development of innovative, proprietary manufacturing technology to reduce the cost and complexity of biological drug production. For more information, visit <a href="https://www.xbiotech.com">www.xbiotech.com</a>.

# About True Human™ Therapeutic Antibodies

XBiotech's True Human<sup>TM</sup> antibodies are the only available antibodies derived without modification from humans who possess natural immunity to certain diseases. (Unlike all commercially available antibodies, which are called "Humanized" or "Fully Human," XBiotech's True Human<sup>TM</sup> antibodies are directly sourced from the natural human immune response for specific diseases without modification, and thereby have not been shown to cause immunogenicity.) 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 unprecedented safety, efficacy, and tolerability.

# **Cautionary Note on Forward-Looking Statements**

This press release contains forward-looking statements, including declarations regarding management's beliefs and expectations, including with respect to XBiotech's strategic ambitions, regarding the expected timing of closing of the transaction with Janssen, filings and approvals relating to the transaction, the amount and timing of potential future milestone payments by Janssen, the mechanism of action and potential safety and efficacy of bermekimab, the anticipated timing of clinical studies with bermekimab, the progression and results of such studies, statements regarding the regulatory pathway for bermekimab and the timing of

regulatory filings, and statements regarding any capital allocation decisions, including as to potential share repurchases. 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

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