

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): November 13, 2020

Xenetic Biosciences, Inc.

(Exact name of registrant as specified in charter)

Nevada
(State or other jurisdiction
of incorporation)

001-37937
(Commission File Number)

45-2952962
(IRS Employer
Identification No.)

40 Speen Street, Suite 102
Framingham, Massachusetts
(Address of principal executive offices)

01701
(Zip Code)

(781) 778-7720

(Registrant's telephone number, including area code)

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

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, \$0.001 par value per share	XBIO	The NASDAQ Stock Market LLC
Purchase Warrants	XBIOW	The NASDAQ Stock Market LLC

Check the appropriate box below if the Form 8-K is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- 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))

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

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 2.02. Results of Operations and Financial Condition.

On November 13, 2020, Xenetic Biosciences, Inc. (the “Company”) issued a press release announcing results for the quarter ended September 30, 2020 and providing a corporate update.

The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and hereby incorporated in this Item 2.02 by reference. The information in this Item 2.02, including Exhibit 99.1 attached hereto, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

FORWARD-LOOKING STATEMENTS

This Form 8-K, including the press release, contains forward-looking statements for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All statements contained in this Form 8-K, including the press release, other than statements of historical facts may constitute forward-looking statements within the meaning of the federal securities laws. These statements can be identified by words such as “expects,” “plans,” “projects,” “will,” “may,” “anticipates,” “believes,” “should,” “intends,” “estimates,” and other words of similar meaning. Any forward-looking statements contained herein are based on current expectations, and are subject to a number of risks and uncertainties. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These risks and uncertainties include those described in the “Risk Factors” section of the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2019 filed with the Securities and Exchange Commission (the “SEC”) on March 26, 2020, as amended on April 29, 2020, and subsequent reports that the Company may file with the SEC. In addition, forward-looking statements may also be adversely affected by general market factors, general economic and business conditions, including potential adverse effects of public health issues, such as the COVID-19 pandemic, on economic activity, competitive product development, product availability, federal and state regulations and legislation, the regulatory process for new product candidates and indications, manufacturing issues that may arise, patent positions and litigation, among other factors. The forward-looking statements contained in this Form 8-K, including the press release, speak only as of the date the statements were made, and the Company does not undertake any obligation to update forward-looking statements, except as required by law.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	<u>Press Release dated November 13, 2020 pertaining to the financial results of the Company for the quarter ended September 30, 2020.</u>

SIGNATURES

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.

XENETIC BIOSCIENCES, INC.

Date: November 13, 2020

By: /s/ James Parslow
Name: James Parslow
Title: Chief Financial Officer



Xenetic Biosciences, Inc. Reports Third Quarter 2020 Financial Results and Provides Corporate Update

– Continued advancement of XCART™ platform towards an IND filing and Phase 1 Study

– Leveraging partnerships with leading global academic institutions, including Scripps Research

FRAMINGHAM, MA – (November 13, 2020) – Xenetic Biosciences, Inc. (NASDAQ: XBIO) (“Xenetic” or the “Company”), a biopharmaceutical company focused on advancing XCART™, a personalized CAR T platform technology engineered to target patient- and tumor-specific neoantigens, today reported its financial results for the three and nine months ended September 30, 2020 and provided a corporate update.

“We continue to make progress as we work to advance XCART through preclinical development and into a Phase 1 study as quickly as possible. This includes finalizing the protocol of our upcoming exploratory study in Belarus which will be used to evaluate the XCART process in a clinical setting,” commented Jeffrey Eisenberg, Chief Executive Officer of Xenetic. “As we proceed through our preclinical development phase, we, along with our scientific advisors, continue to refine our analysis to identify which NHL patient populations would most benefit from XCART therapy, including those who can no longer be treated effectively with CD19 targeting therapeutics due to loss of the CD19 antigen.”

XCART Platform Technology Overview: Significantly differentiated, proprietary approach to personalized CAR T therapy for the treatment of multiple tumor types of B-cell Non-Hodgkin lymphomas, an area of significant unmet need, with the potential to address an initial global market opportunity of over \$5 billion annually.^[1] Xenetic believes XCART has the potential to transform CAR T therapy.

Program Highlights:

- Collaboration with Pharmsynthez and multiple academic institutions in Russia and Belarus to optimize the overall XCART workflow, including clinical manufacturing processes, and to ultimately dose B-cell non-Hodgkin lymphoma (NHL) patients.
- Research and development collaboration with Scripps Research covering design and implementation of the preclinical development program, as well as method development activities supporting process development for clinical manufacturing.

PolyXen® Platform Technology: Patent-protected platform technology designed for protein or peptide therapeutics, enabling next-generation biological drugs by prolonging a drug's circulating half-life and potentially improving other pharmacological properties.

Program Highlights:

- Exclusive License Agreement with Takeda Pharmaceuticals Co. Ltd. (“Takeda”) in the field of coagulation disorders. Takeda currently has one active development program underway utilizing the PolyXen platform technology.
- Royalty payments of approximately \$0.3 million received in the first nine months of 2020 as the relevant product has now launched worldwide and continues to be rolled out by Takeda’s sublicensee.

[1] Market Reports World GLOBAL NON-HODGKIN LYMPHOMA THERAPEUTICS MARKET - SEGMENTED BY TYPE OF TREATMENT - GROWTH, TRENDS AND FORECASTS (2018 - 2023); BioPharm Insight Surveillance, Epidemiology, and End Results (SEER) 9 registries, National Cancer Institute, 2017



Summary of Financial Results for Third Quarter 2020

Net loss for the nine months ended September 30, 2020 was approximately \$9.7 million compared to a net loss of approximately \$11.6 million for the same period in 2019. The results for the nine months ended September 30, 2020 included \$6.3 million of non-cash expenses representing the impairment of indefinite-lived intangibles of \$9.2 million less a \$2.9 million income tax benefit. The results for the nine months ended September 30, 2019 included \$6.3 million of non-cash expenses composed of in-process research and development expenses of \$3.0 million and Goodwill impairment of \$3.3 million, as well as \$1.1 million of transactions costs related to our acquisition of XCART. Excluding the non-cash charges of \$6.3 million for both the nine months ended September 30, 2020 and 2019, respectively, and the \$1.1 million of transaction costs in 2019, adjusted net loss was \$3.4 million and \$4.2 million for the nine months ended September 30, 2020 and 2019, respectively. As of September 30, 2020, working capital was \$7.2 million compared to \$9.7 million as of December 31, 2019. The decrease in working capital was primarily due to the Company's net loss for the nine months ended September 30, 2020. The Company ended the quarter with approximately \$7.1 million of cash.

Non-GAAP Measures

Adjusted net loss is a Non-GAAP financial measure, which is utilized by management in comparing our operating performance on a consistent basis. We present this non-GAAP financial measure because we believe such measure provides important supplemental information to management and investors regarding financial and business trends relating to the Company's financial condition and results of operations. Non-GAAP financial measures should not be considered in isolation from, or as a substitute for, financial information calculated in accordance with GAAP.

About Xenetic Biosciences

Xenetic Biosciences, Inc. is a biopharmaceutical company focused on progressing XCART™, a personalized CAR T platform technology engineered to target patient- and tumor-specific neoantigens. The Company is initially advancing cell-based therapeutics targeting the unique B-cell receptor on the surface of an individual patient's malignant tumor cells for the treatment of B-cell lymphomas. XCART™ has the potential to fuel a robust pipeline of therapeutic assets targeting high-value oncology indications.

Additionally, Xenetic is leveraging PolyXen®, its proprietary drug delivery platform, by partnering with biotechnology and pharmaceutical companies. PolyXen® has demonstrated its ability to improve the half-life and other pharmacological properties of next-generation biologic drugs. The Company has an exclusive license agreement with Takeda Pharmaceuticals Co. Ltd. in the field of coagulation disorders and receives royalty payments under this agreement.

For more information, please visit the Company's website at www.xeneticbio.com and connect on Twitter, LinkedIn, and Facebook.



Forward-Looking Statements

This press release contains forward-looking statements for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release other than statements of historical facts may constitute forward-looking statements within the meaning of the federal securities laws. These statements can be identified by words such as "expects," "plans," "projects," "will," "may," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning, including, but not limited to, statements regarding: our progress advancing XCART through preclinical development towards an IND filing and a Phase 1 study, including finalizing the exploratory study in Belarus; expectations regarding the collaboration with Pharmsynthez optimizing the overall XCART workflow and ultimately dosing NHL patients; our plans to initially apply the XCART technology to advance cell-based therapeutics by targeting the unique B-cell receptor on the surface of an individual patient's malignant tumor cells for the treatment of B-cell lymphomas; our expectations that XCART has the potential to fuel a robust pipeline of therapeutic assets targeting high-value oncology indications; our belief that our significantly differentiated, proprietary approach to personalized CAR T therapy for the treatment of multiple tumor types of B-cell Non-Hodgkin Lymphomas, an area of significant unmet need, has the potential to address an initial global market opportunity of over \$5 billion annually; our belief that XCART has the potential to transform CAR T therapy; our plans to leverage PolyXen® by partnering with biotechnology and pharmaceutical companies; and our expectation regarding receipt of royalty payments under the exclusive license agreement with Takeda Pharmaceuticals Co. Ltd. Any forward-looking statements contained herein are based on current expectations, and are subject to a number of risks and uncertainties. Many factors could cause our actual activities, performance, achievements, or results to differ materially from the activities and results anticipated in forward-looking statements. Important factors that could cause actual activities, performance, achievements, or results to differ materially from such plans, estimates or expectations include, among others, (1) unexpected costs, charges or expenses resulting from the acquisition of XCART; (2) uncertainty of the expected financial performance of the Company following completion of the acquisition of XCART; (3) failure to realize the anticipated potential of the XCART technology; (4) the ability of the Company to implement its business strategy; (5) failure of Scripps Research and/or Pharmsynthez or the other academic institutions in Belarus and Russia (as applicable) to perform their obligations under the respective agreements; (6) failure of the Company and Pharmsynthez to reach agreements with the contract sites on terms favorable to the Company, or at all; and (7) other risk factors as detailed from time to time in the Company's reports filed with the SEC, including its annual report on Form 10-K, periodic quarterly reports on Form 10-Q, periodic current reports on Form 8-K and other documents filed with the SEC. The foregoing list of important factors is not exclusive. In addition, forward-looking statements may also be adversely affected by general market factors, general economic and business conditions, including potential adverse effects of public health issues, such as the COVID-19 outbreak on economic activity, competitive product development, product availability, federal and state regulations and legislation, the regulatory process for new product candidates 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 the Company does not undertake any obligation to update forward-looking statements, except as required by law.

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