

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): August 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 August 13, 2020, Xenetic Biosciences, Inc. (the “Company”) issued a press release announcing results for the quarter ended June 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 August 13, 2020 pertaining to the financial results of the Company for the quarter ended June 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: August 13, 2020

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



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

- Successfully established two strategic academic collaborations in Q2 2020 to advance development of XCART™, its differentiated CAR T therapy platform –
- Strengthened panel of experts on the Scientific Advisory Board, bringing valuable expertise across all phases of preclinical and clinical development –

FRAMINGHAM, MA – (August 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 second quarter ended June 30, 2020 and provided a corporate update.

“The second quarter was marked by the achievement of important milestones for the Company. We previously announced that we would seek to utilize academic collaborators, which we believe provides many significant advantages to our overall XCART program, including access to leading CAR T experts as well as manufacturing facilities with the ability to carry out our early development activities,” commented Jeffrey Eisenberg, Chief Executive Officer of Xenetic. “Now that we have entered into strategic collaboration agreements with Scripps Research and Pharmsynthez, we believe we are well-positioned to efficiently advance our XCART program through preclinical development and into the clinic. We will be working closely with both institutions to develop the manufacturing methods for XCART and generate key preclinical data to support a potential Phase I dosing study.”

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 doubled during the second quarter 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 Second Quarter 2020

Net loss for the six months ended June 30, 2020 was approximately \$2.1 million compared to a net loss of approximately \$2.7 million for the same period in 2019. As of June 30, 2020, working capital was \$8.3 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 six months ended June 30, 2020. The Company ended the quarter with approximately \$8.1 million of cash.

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 belief that academic collaborators provide many significant advantages to our overall XCART program, including access to leading CAR T experts as well as manufacturing facilities with the ability to carry out our early development activities; our belief that we are well-positioned to efficiently advance our XCART program through preclinical development and into the clinic; our expectations regarding working closely with our academic collaborators to develop the manufacturing methods for XCART and generate key preclinical data to support a potential Phase 1 dosing study; 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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Source: Xenetic Biosciences, Inc.