

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, 2021

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)

Registrant's telephone number, including area code: **(781) 778-7720**

Not applicable

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

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))

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, \$0.001 par value per share	XBIO	The Nasdaq Stock Market LLC
Purchase Warrants	XBIOW	The Nasdaq Stock Market LLC

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, 2021, Xenetic Biosciences, Inc. (the "Company") issued a press release announcing results for the quarter ended June 30, 2021 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 that we intend to be subject to 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, performance, achievements 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 as detailed from time to time in the Company's reports filed with the Securities and Exchange Commission ("SEC"), including the Company's annual report on Form 10-K, periodic quarterly reports on Form 10-Q, current reports on Form 8-K and other documents filed 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 outbreak (including any new variant strains of the underlying virus) 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 [Press Release dated August 13, 2021 pertaining to the financial results of the Company for the quarter ended June 30, 2021.](#)
104 Cover Page Interactive Data File (formatted as inline XBRL).

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, 2021

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



Xenetic Biosciences, Inc. Reports Second Quarter 2021 Financial Results and Provides Business Update

– Continued execution on XCART™ pre-clinical development plan and progress toward IND-enabling studies

– Strong royalty growth with PolyXen® platform technology

– Bolstered cash position with recently completed \$12.5 million private placement

FRAMINGHAM, MA – (August 13, 2021) – 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 of 2021 and provided a corporate update.

“Over the course of the second quarter, we continued to execute our innovative and differentiated XCART program, and the technical progress we’ve accomplished brings us closer to the critical milestone of conducting IND-enabling studies in the United States. In light of that progress, we are taking important steps to validate the key workflow and manufacturing components that we believe will maximize the XCART opportunity,” commented Jeffrey Eisenberg, Chief Executive Officer of Xenetic. “Additionally, with our recently completed \$12.5 million private placement and the royalty growth we have seen through our PolyXen license agreement, I believe we are in a strong position moving forward to maintain optionality and execute on advancing our development program.”

XCART Platform Technology Overview: Significantly differentiated, proprietary approach to personalized CAR T lymphoma therapy targeting tumor-specific neoantigens that target independently of CD19 or other surface antigens that are common to both normal and malignant B-cells. Lead program for Non-Hodgkin lymphoma, an area of significant unmet need, with the potential to address an initial global market opportunity of over \$7 billion annually.^[1]

Program Highlights:

- Collaboration with Pharmsynthez and multiple academic institutions in Eastern Europe which provides access to methods and materials, including clinical samples, for optimizing the overall XCART workflow.
- Ongoing research and development collaboration with Scripps Research covering design and implementation of the pre-clinical development program, as well as activities supporting process development for clinical manufacturing.
- Ongoing exploratory patient biopsy study in Eastern Europe. The work being performed under this collaboration has achieved its initial objective of supporting further XCART platform development, including that of downstream XCART processes.

[1] Triangle Insights: Company Commissioned Market Report

“Through the experience gained in Eastern Europe, the ongoing work at Scripps, and the enthusiasm of our expanding network of subject matter experts and contract development partners, we’ve made considerable progress in advancing toward conducting IND-enabling studies for XCART,” added Curtis Lockshin, Ph.D., Chief Scientific Officer of Xenetic. “We look forward to building on that momentum as we continue to advance XCART beyond its academic foundation toward a commercially viable platform, including a clinical manufacturing process for generating patient-specific CAR T products.”

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:

- Royalty payments of approximately \$0.3 million were received in the quarter ended June 30, 2021 from the sublicense of the Company’s partner, Takeda. Takeda’s sublicensee has now launched the relevant product in multiple global markets.
- Company’s partner, Pharmsynthez, has filed a registration dossier in Russia to obtain approval of Epolong, a polysialylated form of human erythropoietin as a treatment for anemia in patients with chronic kidney disease.

Summary of Financial Results for Second Quarter 2021

Net loss for the quarter ended June 30, 2021 was approximately \$1.1 million. Research and development expenses for the three months ended June 30, 2021 increased by approximately \$0.2 million, or 70.4%, to \$0.5 million from \$0.3 million in the comparable quarter in 2020. The increase was due to the Company’s increased spending on the XCART platform technology. General and administrative expenses for the three months ended June 30, 2021 was \$0.9 million, increasing \$0.1 million, or 13.1%, compared to the same period in the prior year. The increase was primarily due to reduced general and administrative expenses by \$0.1 million during the three months ended June 30, 2020 due to a gain on settlement of certain vendor amounts to close out our XBIO-101 trial during such period. At June 30, 2021, the Company reported working capital was approximately \$9.2 million. The Company ended the quarter with approximately \$9.3 million of cash. Subsequent to quarter end, the Company completed a \$12.5 million private placement of common stock and warrants to purchase common stock resulting in approximately \$11.4 million of net proceeds to the Company.

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 that we intend to be subject to 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 with respect to our exploratory patient biopsy study in Eastern Europe and any subsequent expansion of the XCART™ development program; efforts and expectations regarding process development for clinical CAR T manufacturing; our belief that the XCART™ platform has the potential to provide a personalized CAR T therapy targeting cancers with a patient-and tumor-specific approach; our belief that we are taking the steps necessary to validate the key workflow and manufacturing components that we believe will maximize the XCART opportunity; our belief that we are in a strong position to maintain optionality and execute on advancing our development program; our expectation that the work being performed under the collaborations being leveraged in the XCART™ development program will position the Company to conduct IND-enabling studies in the United States; our expectations that the Company is advancing a commercially viable platform, including a clinical manufacturing process for generating patient-specific CAR T products; 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 lymphoma therapy for the treatment of multiple tumor types of B-cell Non-Hodgkin lymphoma, an area of significant unmet need, has the potential to address an initial global market opportunity of over \$7 billion annually; and our expectations 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) failure to realize the anticipated potential of the XCART™ or PolyXen® technology; (2) the ability of the Company to implement its business strategy; (3) failure of Scripps Research and/or Pharmsynthez or the other academic institutions in Eastern Europe, including Belarus and Russia (as applicable) to perform their obligations under the respective agreements; (4) failure of the Company and Pharmsynthez to reach agreements with the contract sites on terms favorable to the Company, or at all; (5) failure of Pharmsynthez to receive approval for its registration for Epolong in Russia or, if approved, to successfully commercialize and market Epolong; and (6) 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, 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.