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): May 12, 2021

Xenetic Biosciences, Inc.

(Exact name of registrant as specified in charter)

Nevada	**001-37937**	**45-2952962**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

40 Speen Street, Suite 102 **Framingham, Massachusetts**	**01701**
(Address of principal executive offices)	(Zip Code)

(781) 778-7720
(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 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:

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

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 May 12, 2021, Xenetic Biosciences, Inc. (the "Company") issued a press release announcing results for the quarter ended March 31, 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 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 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 May 12, 2021 pertaining to the financial results of the Company for the quarter ended March 31, 2021.

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.

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

Date: May 12, 2021

Exhibit 99.1

Xenetic Biosciences, Inc. Reports First Quarter 2021 Financial Results

– Continued execution on XCART™ development plan with commencement of exploratory patient biopsy trial expected to position the Company to conduct IND-enabling studies in the United States

– Licensing partners leveraging PolyXen® platform technology continue to make clinical, regulatory and commercial advancements

FRAMINGHAM, MA – (May 12, 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 first quarter of 2021 and provided a corporate update.

"During the first quarter our focus remained on advancing the development of our XCART™ platform, which we believe has the potential to provide a personalized CAR T therapy targeting cancers with a patient-and tumor-specific approach. The commencement of our exploratory patient biopsy trial is a key component of our preclinical development strategy and an important step forward toward advancing into a Phase 1 study," commented Jeffrey Eisenberg, Chief Executive Officer of Xenetic.

XCART™ Platform Technology Overview*: Significantly differentiated, proprietary approach to personalized CAR T lymphoma therapy targeting tumor-specific antigens 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 to optimize the overall XCART™ workflow, including clinical manufacturing processes, and ultimately to conduct a first in human study in 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.
- Recently commenced exploratory patient biopsy study in Eastern Europe. When sufficient experience is gained through this exploratory study, the collaborations being leveraged in the XCART™ development program may be expanded to include development and qualification of manufacturing processes for producing XCART™-designed, tumor-specific autologous CAR T cells. The work being performed under these collaborations is expected to position the Company to conduct IND-enabling studies in the United States.

Upcoming Potential Milestones

- Seeking U.S. FDA INTERACT meeting.
- Initiating process development for clinical CAR T manufacturing.

[1] Triangle Insights: Company Commissioned Market Report

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 blood coagulation disorders.
  - Takeda currently has one active development program underway.
  - Royalty payments of approximately $0.2 million were received in the quarter ended March 31, 2021, as Takeda's sublicensee has now launched the relevant product in multiple global markets.
- Company's partner, Pharmsynthez, announced positive Phase 3 trial results and 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 First Quarter 2021

Net loss for the quarter ended March 31, 2021 was approximately $1.3 million. Research & development expenses for the three months ended March 31, 2021 increased by approximately $0.3 million, or 75.1%, to $0.6 million from $0.4 million in the comparable quarter in 2020. The increase was due to the Company's increase on spending for the XCART™ platform technology. General and administrative expenses for the three months ended March 31, 2021 and 2020 were approximately $0.9 million. Increases in consulting and employee related costs during the three months ended March 31, 2021 compared to the same period in 2020 were substantially offset by lower share-based expense and legal and accounting costs. At March 31, 2021, the Company reported working capital was approximately $10.2 million. Working capital decreased by $1.2 million from December 31, 2020 due to the Company's net loss for the three months ended March 31, 2021. The Company ended the quarter with approximately $10.0 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 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, and expectations regarding timing of, a recently commenced exploratory patient biopsy study in Eastern Europe and any subsequent expansion of the XCART™ development program to include development and qualification of manufacturing processes for producing XCART-designed, tumor-specific autologous CAR T cells; efforts to seek, and timing of, an INTERACT meeting with the U.S. FDA; efforts and expectations regarding initiating 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 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 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) 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™ or PolyXen® 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 Eastern Europe, including 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; (7) failure of Pharmsynthez to receive approval for its registration for Epolong in Russia or, if approved, to successfully commercialize and market Epolong; and (8) 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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