

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): March 17, 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)

(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 March 17, 2021, Xenetic Biosciences, Inc. (the "Company") issued a press release announcing results for the fourth quarter and year ended December 31, 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 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, periodic 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 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	Press Release dated March 17, 2021 pertaining to the financial results of the Company for the fourth quarter and year ended December 31, 2020.

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: March 17, 2021

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



Xenetic Biosciences, Inc. Reports Fourth Quarter and Full Year 2020 Financial Results

– Driving development of XCART™ platform and leveraging academic collaborations through preclinical development

– Recent clinical, regulatory and commercial advancements from licensing partners leveraging PolyXen® platform technology

FRAMINGHAM, MA – (March 17, 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 fourth quarter and full year 2020, and provided a corporate update.

“Notwithstanding the challenges presented by the COVID-19 pandemic, 2020 was a year of significant progress for the Company, including the establishment of partnerships and academic collaborations and advancement in our development efforts, in particular with respect to CAR design and model cell line development, as well as the strengthening of our financial position. Our focus remains on advancing the XCART™ platform, and we look forward to further evaluation of our XCART™ process in a clinical setting during our upcoming exploratory study in Eastern Europe,” commented Jeffrey Eisenberg, Chief Executive Officer of Xenetic. “Our goal remains to complete our preclinical development phase and advance into a Phase 1 study as quickly as possible.”

XCART Platform Technology Overview: Significantly differentiated, proprietary approach to personalized CAR T therapy targeting tumor specific antigens that are independent of CD19 or other antigens common to all B-Cells. Lead program for 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

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.

Upcoming Potential Milestones

- Initiation of exploratory patient biopsy study in Eastern Europe.
- Seeking U.S. FDA INTERACT meeting.
- Initiating process development for clinical CAR T manufacturing.

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

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.
 - o Takeda currently has one active development program underway.
 - o Royalty payments of approximately \$0.4 million received in 2020 as Takeda’s sublicensee has now launched the relevant product in multiple global markets.
- Company’s partner, PJSC 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 Fiscal Year 2020

Net loss for the year ended December 31, 2020 was approximately \$10.9 million. R&D expenses for the year ended December 31, 2020 were \$1.7 million compared to \$4.9 million for the year ended December 31, 2019. The decrease was primarily due to IPR&D expense of \$3.0 million incurred during the year ended December 31, 2019. General and administrative expenses decreased by approximately \$1.3 million, or 28.1% for the year ended December 31, 2020, to \$3.4 million from \$4.7 million in the comparable period in 2019, primarily due to approximately \$1.1 million of transaction costs associated with the XCART™ acquisition incurred during the year ended December 31, 2019. At December 31, 2020, the Company reported working capital was approximately \$11.4 million compared to \$9.7 million at December 31, 2019. During the year ended December 31, 2020, working capital increased by \$1.8 million due to the Company’s December 2020 registered direct common stock offering resulting in approximately \$5.4 million in net proceeds. This increase in working capital was substantially offset by the Company’s net loss for the year ended December 31, 2020. The Company ended the year with approximately \$11.5 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 progress, and expectations regarding timing of, advancing XCART™ through the preclinical development phase towards a Phase 1 study, including initiating an exploratory biopsy study in Eastern Europe; 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 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 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, 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.

Contact:

JTC Team, LLC
Jenene Thomas
(833) 475-8247
xbio@jtcir.com
Source: Xenetic Biosciences, Inc.