

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 27, 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 March 27, 2020, Xenetic Biosciences, Inc. (the "Company") issued a press release announcing results for the year ended December 31, 2019 and provided a corporate update.

The full text of the press release issued in connection with the announcement 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, 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, 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 March 27, 2020 pertaining to the financial results of the Company for the year ended December 31, 2019.</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: March 27, 2020

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



Xenetic Biosciences, Inc. Reports 2019 Year End Results and Provides Corporate Update

– Company continues to advance preclinical development of its XCART™ CAR T therapy platform –

– Expands XCART resources by adding expertise in cell therapy translational science and CMC –

– Cash on hand expected to fund operations through mid-2021 –

FRAMINGHAM, MA – (March 27, 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 year ended December 31, 2019 and provided a corporate update.

Jeffrey Eisenberg, Chief Executive Officer of Xenetic, stated, “2019 proved to be a pivotal year for Xenetic with our completion of the acquisition of XCART, a differentiated CAR T platform technology that we believe has the potential to address a significant unmet need in B-cell non-Hodgkin lymphoma. Moving forward we believe 2020 will be an important year for the Company as we plan to continue driving the development of XCART. To that end, we have made encouraging progress with additions to our team and are advancing towards securing an academic collaboration. We believe this pathway will provide many advantages, including access to manufacturing suites, established CMC and regulatory infrastructure and cost and risk mitigation.”

“In the fourth quarter of last year, we received our first royalty payment under our agreement with Takeda involving our proprietary PolyXen® technology in the field of coagulation disorders. While the recognized payment was modest, it is what we expected given the early stages of this product launch. Importantly, the commencement of royalties reaffirms the value of our PolyXen intellectual property and the opportunity to leverage it to prolong a drug's circulating half-life and potentially improve other pharmacological properties. Further, in these unprecedented times, we are reviewing our portfolio of intellectual property assets to see if we can contribute in any way to the global effort to address the current health threat of COVID-19,” continued Mr. Eisenberg. “As we advance into the rest of 2020, despite the current climate of financial uncertainty, we are moving our operation and development efforts forward with a strong cash balance which we believe provides us with a cash runway through mid-2021.”

XCART Platform Technology Overview: Significantly differentiated, proprietary CAR T therapy designed to develop cell-based therapeutics 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 annually¹. Xenetic believes XCART has the potential to transform CAR T therapy.

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.

The Company has recently bolstered its cell therapy manufacturing and CMC expertise and capabilities with the appointments of Greg MacMichael, Ph.D. and Maksim Mamonkin, Ph.D., to its Scientific Advisory Board. Both Dr. MacMichael and Dr. Mamonkin are actively engaged with the Company to advance the development of the XCART technology platform.

Expected 2020 Milestones

- INTERACT meeting with the United States Food and Drug Administration (“FDA”)
- Enter into an academic site collaboration
- Advance IND-enabling studies
- Explore opportunities for Orphan Drug designation

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.
- The Company received \$17,000 in royalty revenue during the fourth quarter of 2019 representing its first payment under the Company’s license agreement with Takeda. This payment and expected future payments relate to a sublicense of Xenetic’s PolyXen intellectual property, entered into by Takeda with a third party in 2017. The Company expects this quarterly royalty payment to increase as the relevant product launch continues to be rolled out by the sublicensee.

Mr. Eisenberg concluded, “We are closely monitoring the evolving COVID-19 situation. While the situation is very fluid, to date we have not experienced any significant impact or delays on our projected timelines. The safety and wellness of our employees, partners and the community are of the utmost importance to us and we have implemented risk mitigation strategies to ensure the least amount of disruption to our operations as possible.”

Summary of Financial Results for Fiscal Year 2019

Net cash used in operating activities for the year was \$6.4 million. During 2019, our working capital increased by \$10.1 million primarily due to our March 2019 registered direct offering and our July 2019 public offering that resulted in \$16.1 million in combined net proceeds. This increase in working capital was partially offset by the Company’s reported net loss for the year ended December 31, 2019. The Company ended the year with approximately \$10.4 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 the Company's belief that 2020 will be an important year for the Company as it plans to continue driving the development of XCART, statements regarding advancing towards and the timing of securing an academic collaboration for the development of XCART, including the Company's belief that this pathway will provide many advantages, including access to manufacturing suites, established CMC and regulatory infrastructure and cost and risk mitigation, statements regarding the Company's belief that moving the Company's operation and development efforts forward with a strong cash balance will provide Xenetic with a cash runway through mid-2021, statements related to the Company's belief that XCART has the potential to transform CAR T therapy, all statements under the caption "Expected 2020 Milestones" including expected timing of completing INTERACT meetings with the FDA, entering into academic site collaborations, advancing IND-enabling studies and exploring opportunities for Orphan Drug designation, statements regarding the receipt of future quarterly royalty payments related to a sublicense of Xenetic's PolyXen intellectual property entered into by Takeda with a third party in 2017, including expectations that this quarterly royalty payment will increase as the relevant product launch continues to be rolled out by the sublicensee, the Company's 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, the Company's expectations that XCART has the potential to fuel a robust pipeline of therapeutic assets targeting high-value oncology indications, and the Company's expectations that XCART has the potential to address a significant unmet need in B-cell Hodgkin lymphoma. 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; and (5) 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.