

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 15, 2019**

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 15, 2019, Xenetic Biosciences, Inc. (the "Company") issued a press release announcing results for the second quarter ended June 30, 2019.

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. These forward-looking statements include, but are not limited to, statements regarding the acquisition and development of the CAR T technology. 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, 2018 and filed with the Securities and Exchange Commission (the "SEC") on March 29, 2019, as amended on April 30, 2019, 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 August 15, 2019 pertaining to the financial results of the Company for the second quarter ended June 30, 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: August 15, 2019

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



Xenetic Biosciences, Inc. Reports Second Quarter 2019 Financial Results and Provides Corporate Update

– Building momentum with recent acquisition of innovative XCART platform technology and closing of \$15 million underwritten public offering

– Corporate strategy shift with entry into the CAR T space positions Company to drive significant value for shareholders

– Company executes on initial step in XCART development through recent signing of a research agreement enabling advancement towards its stated goal of establishing an academic collaboration for XCART development

FRAMINGHAM, MA – (August 15, 2019) – Xenetic Biosciences, Inc. (NASDAQ: XBIO) (“Xenetic” or the “Company”), a clinical-stage biopharmaceutical company focused on the discovery, research and development of next-generation biologic drugs and novel orphan oncology therapeutics, announced today its financial results for the quarter ended June 30, 2019 and provided a corporate update.

Recent Corporate Highlights

- Closed \$15.0 million underwritten public offering;
- Completed transformative acquisition of novel CAR T (“Chimeric Antigen Receptor T Cell”) platform technology, called “XCART,” a proximity-based screening platform capable of identifying CAR constructs that can target patient-specific tumor neoantigens, which has demonstrated proof-of-mechanism in B-cell Non-Hodgkin lymphomas;
- Commenced XCART development efforts to conduct initial tech transfer of XCART methods to a future academic collaborator; and
- Strengthened scientific advisory board with recent appointments and continued build out of expertise in hematologic cancers and cell therapy.

“Over the course of 2019 we have taken deliberate steps to transition Xenetic’s focus and opportunities with the acquisition of the XCART platform technology. We signed the acquisition agreement in the first quarter, then worked to not only fund the transaction but also to secure the capital required to advance this potentially game-changing technology through early development. Now that the financing and transaction closing are behind us, we believe we have opportunities to successfully achieve corporate, clinical and regulatory milestones and drive significant shareholder value,” commented Jeffrey Eisenberg, Chief Executive Officer of Xenetic.

“We acknowledge that this has been a challenging period for our stakeholders, and unfortunately, we believe our recent progress and momentum is not properly reflected in our current share price. However, I am pleased to say that today we are essentially a new company with a clear mission and vision, and we believe that our catalytic shift in strategy with this differentiated CAR T platform technology will prove to be transformational for Xenetic. Moving forward, our team is focused on leveraging our R&D efforts on the advancement of the XCART platform to develop cell-based therapeutics for the treatment of multiple tumor types of B-cell Non-Hodgkin lymphomas, with the potential to address an initial global market opportunity of over \$5 billion annually.^[1] I believe Xenetic has the potential to become a significant player in this dynamic CAR T oncology space,” added Mr. Eisenberg.

^[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



Platform Technologies Update

XCART Technology

On July 19, 2019, the Company completed its previously announced acquisition of a novel CAR T platform technology, called "XCART." XCART is a proximity-based screening platform capable of identifying CAR constructs that can target patient-specific tumor neoantigens, with a demonstrated proof of mechanism in B-cell Non-Hodgkin lymphomas. The XCART technology, developed by The Scripps Research Institute in collaboration with the Shemyakin-Ovchinnikov Institute of Bioorganic Chemistry, is believed to have the potential to significantly enhance the safety and efficacy of cell therapy for B-cell lymphomas by generating patient- and tumor-specific CAR T cells.

Curtis Lockshin, Ph.D., Chief Scientific Officer of Xenetic, stated, "Having completed the acquisition of our novel XCART technology platform, we are excited to embark on the development of a personalized CAR T therapy for B-cell lymphomas, with the potential to offer cancer patients substantial benefits over the existing standard of care and currently approved CAR T therapies. Our plan is to leverage this platform technology to innovate and develop new oncology therapeutics through regulatory approval and commercialization in areas of significant unmet medical need. Along the development path, we expect to identify multiple opportunities to collaborate with others in the CAR T field to maximize the potential and impact of XCART. We are intensely gratified to have this opportunity to improve human health, and by the enthusiasm of our growing team of scientific advisors in this novel and differentiated approach to Non-Hodgkin lymphomas."

The XCART technology platform was designed by its originators to utilize an established screening technique to identify peptide ligands that bind specifically to the unique B-cell receptor ("BCR") on the surface of an individual patient's malignant tumor cells. The peptide is then inserted into the antigen-binding domain of a CAR, and a subsequent transduction/transfection process is used to engineer the patient's T cells into a CAR T format which redirects the patient's T cells to attack the tumor. Essentially, the XCART screening platform is the inverse of a typical CAR T screening protocol wherein libraries of highly specific antibody domains are screened against a given target. In the case of XCART screening, the target is itself an antibody domain, and hence highly specific by its nature. The XCART technology creates the possibility of personalized treatment of lymphomas utilizing a CAR with an antigen-binding domain that should only recognize, and only be recognized by, the unique BCR of a particular patient's B-cell lymphoma.

An expected result for XCART is reduced off-tumor toxicities, such as B-cell aplasia. Xenetic's clinical development program will seek to confirm the early preclinical results, and to demonstrate a more attractive safety profile than existing therapies.

Xenetic recently entered into a research agreement to begin the process of technology transfer of the XCART technology and enable advancement towards Xenetic's stated goal of establishing an academic collaboration for XCART development. The Company's early activities will build off of the work of the XCART inventors which was previously described in a *Science Advances* article published in November 2018.^[2]

PolyXen™ Platform Technology

The Company's proprietary drug development platform, PolyXen, is a platform technology which can be applied to protein or peptide therapeutics, enabling next-generation biological drugs to prolong a drug's circulating half-life and potentially improve other pharmacological properties. PolyXen has been demonstrated in human clinical trials to confer prolonged half-life on biotherapeutics such as recombinant human erythropoietin and recombinant Factor VIII ("rFVIII"). Additionally, the Company believes that PolyXen has potential utility in other molecule classes such as small molecules.

[2] *Science Advances*, 14 Nov 2018: Vol. 4, no. 11, eaau4580 DOI: 10.1126/sciadv.aau4580



Xenetic incorporates its patented and proprietary technologies into a number of drug candidates currently under development with biotechnology and pharmaceutical industry collaborators to create what the Company believes will be the next-generation biologic drugs with improved pharmacological properties over existing therapeutics. The Company currently has an 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. In addition, in October 2017, Xenetic granted rights to Takeda to grant a nonexclusive sublicense to certain patents related to PolyXen to a third party. The potential royalty stream resulting from the sublicense could commence by the end of 2019.

Summary of Financial Results for Second Quarter 2019

Net loss for the six months ended June 30, 2019 decreased approximately 29% to approximately \$2.7 million compared to a net loss of approximately \$3.8 million for the same period in 2018. The Company has continued to reduce expenses, control non-essential spending and maximize its available resources to advance its research and development efforts. The Company ended the quarter with approximately \$1.0 million in cash. Subsequent to quarter end, the Company completed its \$15 million public offering resulting in approximately \$13.4 million of net proceeds to the Company.

“With the closing of our recent financing, the Company is now in a much stronger financial position to successfully execute on our strategic plan,” James Parslow, Chief Financial Officer of Xenetic concluded. “This is truly an exciting time for Xenetic and we look forward to continuing to leverage our innovative technologies, build shareholder value in both the near and long term, and ultimately provide important therapies by leveraging our XCART platform technology.”

About Xenetic Biosciences

Xenetic Biosciences, Inc. is a clinical-stage biopharmaceutical company focused on the discovery, research and development of next-generation biologic drugs and novel orphan oncology therapeutics. The Company recently announced its acquisition of the XCART platform, a novel CAR T technology engineered to target personalized, patient-specific tumor neoantigens. The Company plans to initially apply the XCART technology to develop cell-based therapeutics for the treatment of B-cell lymphomas.

Additionally, Xenetic's proprietary drug development platform, PolyXen™, enables next-generation biologic drugs by improving their half-life and other pharmacological properties. The Company has ongoing business development activities to explore partnerships utilizing its PolyXen delivery platform.

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 capability of the XCART technology to expand the potential of CAR T cell therapy; the benefits of the acquisition of the XCART technology; the Company's belief that our recent progress and momentum is not properly reflected in our current share price and that our catalytic shift in strategy with the differentiated CAR T platform technology will prove to be transformational for Xenetic; the expected results for XCART and the Company's anticipated goals for its clinical developmental program seeking to confirm the early preclinical results, and demonstrating a more attractive safety profile than existing therapies; the Company's plans to build off of the work of the XCART inventors; the Company's plans to initially apply the XCART technology to develop cell-based therapeutics for the treatment of B-cell lymphomas and to leverage R&D efforts on the advancement of the XCART platform; the Company's expectations regarding successfully achieving corporate, clinical and regulatory milestones and driving significant shareholder value both in near and long term; the Company's potential to address an initial global market opportunity of over \$5 billion annually; the Company's belief that it has the potential to become a significant player in the dynamic CAR T oncology space; anticipated plans to leverage the XCART platform technology to innovate, develop and provide important new oncology therapeutics through regulatory approval and commercialization in areas of significant unmet medical need; the Company's expectations regarding identifying multiple opportunities to collaborate with others in the CAR T field to maximize the potential and impact of XCART; the Company's business development activities to explore partnerships utilizing its PolyXen delivery platform; the Company's belief that PolyXen has potential utility in other molecule classes; the Company's expectations regarding potential royalties resulting from the sublicense with Takeda commencing by the end of 2019; and the Company's belief that it is currently in a much stronger financial position to execute on its strategic plan. 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. Important factors that could cause actual results to differ materially from such plans, estimates or expectations include, among others, (1) unexpected costs, charges or expenses resulting from the acquisition of the CAR T technology; (2) uncertainty of the expected financial performance of the Company following completion of the acquisition; (3) failure to realize the anticipated benefits of the acquisition; (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, 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:

Jenene Thomas Communications, LLC.
Jenene Thomas
(833) 475-8247
xbio@jtcir.com

Source: Xenetic Biosciences, Inc.