

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): **October 8, 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 7.01. Regulation FD Disclosure

On October 8, 2019, the Company issued a press release to provide an update on its business outlook. A copy of the press release is attached hereto and incorporated herein by reference in its entirety as Exhibit 99.1.

Item 9.01. Financial statements and Exhibits

(d) Exhibits

Exhibit Number	Description
99.1	Press release dated October 8, 2019

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: October 8, 2019

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



Xenetic Biosciences, Inc. Provides Business Outlook

- *Recent completion of acquisition of innovative CAR T technology platform (XCART) has the potential to drive significant value for shareholders –*
- *Management working with KOLs and subject matter experts to formalize XCART development plan –*
- *Completion of recent financing expected to fund operations through key development milestones –*
- *Proprietary technology, PolyXen™, expected to generate royalties as early as Q4 2019 –*

FRAMINGHAM, MA – (October 8, 2019) – Xenetic Biosciences, Inc. (NASDAQ: XBIO) (“Xenetic” or the “Company”), a biopharmaceutical company focused on advancing XCART, a personalized chimeric antigen receptor T cell (“CAR T”) platform technology engineered to target patient-specific tumor neoantigens, today provided a business outlook.

“2019 is proving to be a transformational year for Xenetic, marked by the shift in our corporate strategy with our entry into the CAR T arena through the acquisition of XCART. We believe the XCART platform has the potential to be a meaningful advancement in the treatment of cancer and address significant unmet medical needs. Since the closing of both our acquisition and recent financing, our team has been focused and dedicated to advancing our R&D efforts for our XCART platform to develop cell-based therapeutics for the treatment of multiple tumor types of B-cell Non-Hodgkin lymphomas, which has the potential to address an initial global market opportunity of over \$5 billion annually^[1],” commented Jeffrey Eisenberg, Chief Executive Officer of Xenetic. “By adding XCART to our existing proprietary drug development platform, PolyXen™, we have made great strides in building a solid foundation for the Company. Looking ahead, I believe we have multiple opportunities in the near- and long-term to build momentum and successfully achieve corporate, clinical and regulatory milestones to drive significant shareholder value.”

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.

^[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



Curtis Lockshin, Ph.D., Chief Scientific Officer of Xenetic, stated, “We have been working with leading advisors in the U.S. and Europe to clearly map out the best pathway forward for our XCART technology, including our aim to secure an academic collaboration with a leading institution to further advance our program toward the clinic. Importantly, we believe this platform technology has the potential to offer cancer patients substantial benefits over the existing standard of care and approved CAR T therapies. We look forward to unlocking the full potential of the XCART platform and its differentiated approach to cancer therapy, with the initial focus on 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 typically associated with CAR T lymphoma therapies, 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.^[1]

Dr. Guenther Koehne, Chief of Blood & Marrow Transplant and Hematologic Oncology at the Miami Cancer Institute, commented, “At this point, the power of CAR T therapy has been established, especially in the area of hematological malignancies. However, as the level of activity in the CAR T space suggests, there remains substantial unmet need in oncology treatments as existing therapies can be highly efficacious but not all patients respond, and they can often induce serious, even life-threatening side effects. A personalized treatment approach that only attacks cancerous cells through use of this novel XCART technology has the potential to address the critical unmet need that remains in a number of oncology indications.”

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



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.

Xenetic and its partners incorporate the Company's patented and proprietary PolyXen™ technology into drug candidates currently under development with biotechnology and pharmaceutical industry collaborators to create what the Xenetic believes will be the next-generation biologic drugs with improved pharmacological properties over existing therapeutics. Xenetic currently has an exclusive license agreement with Takeda Pharmaceuticals Co. Ltd. ("Takeda") in the field of coagulation disorders, under which 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 Company expects to receive royalties as a result of the sublicense agreement as early as the fourth quarter of this year.

About Xenetic Biosciences

Xenetic Biosciences, Inc. is a biopharmaceutical company focused on progressing XCART, a personalized CAR T platform technology engineered to target patient-specific tumor 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 expects to earn 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 capability of the XCART technology to drive significant value for shareholders; expectations that the completion of the Company's recent financing will fund operations through key development milestones; the Company's belief that the XCART technology has the potential to be a meaningful advancement in the treatment of cancer and address significant unmet medical needs; statements regarding the potential of the XCART technology to address an initial global market opportunity of over \$5 billion annually; the Company's anticipations that it will have multiple opportunities in the near- and long-term to build momentum and successfully achieve corporate, clinical and regulatory milestones to drive significant shareholder value; statements regarding the potential of the XCART technology to significantly enhance the safety and efficacy of cell therapy for B-cell lymphomas by generating patient- and tumor-specific CAR T cells and to offer cancer patients substantial benefits over the existing standard of care and approved CAR T therapies; the Company's expectations to unlock the full potential of the XCART platform and its differentiated approach to cancer therapy; the Company's plans to apply the XCART platform with the initial focus on Non-Hodgkin lymphomas; statements regarding the expected results for XCART to reduce off-tumor toxicities typically associated with CAR T lymphoma therapies, such as B-cell aplasia; the Company's anticipated plans to seek to confirm the early preclinical results for XCART, and to demonstrate 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 expectations regarding the XCART technology having the potential to address the critical unmet need that remains in a number of oncology indications; the Company's expectations regarding its stated goal of establishing an academic collaboration for XCART development; the Company's belief that XCART has the potential to fuel a robust pipeline of therapeutic assets targeting high-value oncology indications; the Company's belief that PolyXen has potential utility in other molecule classes such as small molecules; expectations that PolyXen's technology is being used in partnership 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; and the Company's expectations regarding potential royalties resulting from the sublicense with Takeda commencing as early as the fourth quarter of 2019. 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 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, 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.