

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): **June 12, 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 1.01. Entry into a Material Definitive Agreement.

On June 12, 2020, Xenetic Biosciences, Inc. (the “Company”) and PJSC Pharmsynthez (“Pharmsynthez”) entered into a Master Service Agreement (the “Agreement”) to advance the development of the Company’s XCART technology for B-cell malignancies. Under the Agreement, Pharmsynthez has agreed to provide services pursuant to work orders agreed upon by the parties from time to time, which services include, but are not limited to, acting as the Company’s primary contract research organization to assist in managing collaborations with multiple academic institutions in Russia and Belarus. The Company is required to pay reasonable fees, expenses and pass-through costs incurred by Pharmsynthez in providing the services in accordance with a budget and payment terms set forth in each work order. Additionally, in the event that a work order provides for milestone payments, the Company is required to make such payments to Pharmsynthez, or third party service providers designated by Pharmsynthez, in accordance with the terms set forth in the work order, which milestone payments may be made, at the sole discretion of the Company, in cash or shares of the Company’s common stock. The Agreement terminates and supersedes the Sponsored Research Agreement (the “SRA”), dated August 12, 2019, between the Company and Pharmsynthez.

Unless earlier terminated, the term of the Agreement continues from the date of the Agreement for five years or until the completion of services under all active work orders, if later. The Agreement or any work order may be terminated by the Company with 30 days advance written notice to Pharmsynthez. The Agreement or any work order may further be terminated by either party in the event of the other party’s uncured material breach under the Agreement or the bankruptcy of the other party.

The Company has exclusive rights to all data and information generated or derived by Pharmsynthez as a result of services performed under the Agreement, as well as any inventions that may evolve from such data and information, and Pharmsynthez has agreed to assign its rights in all such inventions and/or related patents to the Company. The Agreement also contains customary representations, warranties and covenants from the Company and Pharmsynthez, as well as customary provisions relating to confidentiality.

On June 12, 2020, the Company and Pharmsynthez executed a work order (the “Work Order”) under the Agreement pursuant to which Pharmsynthez has agreed to conduct a Stage 1 study of the Company’s XCART technology under the research program as set forth in the Work Order. The activities to be performed under the Work Order are currently expected to take approximately 20 months unless earlier terminated in accordance with the Agreement. Under the terms of the Work Order, the Company is required to pay Pharmsynthez \$51,000 as an initial payment for trial startup costs, which amount is credited against the amounts paid under the SRA. The Work Order provides for additional pass-through costs to be invoiced by Pharmsynthez upon execution of contracts with third party sites, which will be further credited against the SRA. The total cost under the Work Order is currently estimated to be approximately \$1.8 million. Additionally, the Work Order provides for milestone payments of up to an aggregate of \$1,050,000, or, in the Company’s sole discretion, up to an aggregate of 1,000,000 shares of the Company’s common stock, to be paid or issued, as applicable, by the Company upon achievement of milestones associated with completion of early stages of the research program as set forth in the Work Order.

The foregoing summaries of the Agreement and the Work Order are not complete and are qualified in their entirety by reference to the full text of the Agreement and the Work Order, which the Company intends to file with the Securities and Exchange Commission as exhibits to its next Quarterly Report on Form 10-Q.

Item 7.01 Regulation FD Disclosure.

On June 16, 2020, the Company issued a press release announcing that it has entered into the Agreement, a copy of which is attached hereto as Exhibit 99.1.

The press release attached to this report as Exhibit 99.1 is furnished pursuant to this Item 7.01 and shall not be deemed filed in this or any other filing of the Company under the Securities Exchange Act of 1934, as amended, unless expressly incorporated by specific reference in any 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, including but not limited to, statements regarding the Company’s expectations that activities under the Work Order will take approximately 20 months and the Company’s expectations that the total cost under the Work Order is currently estimated to be approximately \$1.8 million. 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. 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, as amended on April 29, 2020, and subsequent reports that the Company may file with the SEC. In addition, forward-looking statements may also be adversely affected by unexpected costs, charges or expenses resulting from the acquisition of XCART; uncertainty of the expected financial performance of the Company following completion of the acquisition of XCART; failure to realize the anticipated potential of the XCART technology; the ability of the Company to implement its business strategy; failure of Pharmsynthez to perform its obligations under the Agreement and the Work Order; failure of the Company and Pharmsynthez to reach agreements with third-party contract sites on terms favorable to the Company, or at all; failure to achieve milestones under the Work Order in accordance with the proposed timeline, or at all; 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; and 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 June 16, 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: June 16, 2020

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



Xenetic Biosciences, Inc. Announces Collaboration with Pharmsynthez and Multiple Academic Institutions in Russia and Belarus to Advance Development of XCART™ Platform

- *Goal of XCART collaboration to optimize XCART process, develop manufacturing processes and to ultimately dose non-Hodgkin lymphoma (NHL) patients*
- *Pharmsynthez to act as primary contract research organization coordinating activities throughout collaboration*
- *Academic Institutions include:*
 - o *Shemyakin and Ovchinnikov Institute of Bioorganic Chemistry of the Russian Academy of Sciences (IBCh RAS)*
 - o *Belarussian Research Center for Pediatric Oncology, Hematology and Immunology*
 - o *Institute of Bioorganic Chemistry of the National Academy of Sciences of Belarus*
 - o *Vitebsk Regional Clinical Oncological Center*

FRAMINGHAM, MA – (June 16, 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, announced today it has entered into a master services agreement (“MSA”) with PJSC Pharmsynthez to advance the development of the XCART technology for B-cell malignancies. Under the terms of the MSA, Pharmsynthez will act as the primary contract research organization (“CRO”) to assist in managing the collaboration with multiple academic institutions in Russia and Belarus.

The initial stage of the collaboration will include an exploratory trial to evaluate and refine the XCART front-end process of target identification, screening and lead characterization, in a real-world clinical setting. This exploratory stage entails enrollment of NHL patients, obtaining tumor biopsies and then refining the XCART front-end methods. Subsequently the collaboration may be expanded to include development and qualification of manufacturing processes for producing autologous XCART T-cells. If successful, the Company has the potential to expand the clinical study component to dose a number of NHL patients in a Phase 1 dosing study.

“This agreement represents another significant milestone for the Company and provides access to a number of world-renowned academic institutions, researchers and clinical investigators in the area of oncology and hematology. Additionally, we are excited to again be working with the Shemyakin and Ovchinnikov Institute as they are intimately familiar with the XCART platform having been one of the primary inventors,” commented Jeffrey Eisenberg, Chief Executive Officer of Xenetic. “Coupled with our recently announced collaboration with Scripps Research, we believe we are well-positioned to execute on our strategic development plan as we work to advance this innovative technology, which we believe has the potential to address a significant unmet need in NHL.”

Alexander Gabibov, academic, Head of the Shemyakin and Ovchinnikov Institute of Bioorganic Chemistry RAS, commented, “The XCART platform was thoughtfully designed to target personalized, patient-specific tumor neoantigens and has demonstrated encouraging potential. Our team is uniquely positioned to carry out this important foundational work and, through this collaboration is able to leverage the additional expertise from the Belarus academic institutions. We are pleased to continue our collaboration with Xenetic through this agreement and look forward to helping to advance the XCART platform towards first-in-human dosing.”

The XCART technology platform was designed to utilize an established screening technique to identify polypeptide domains that selectively bind to the unique B-cell receptor (“BCR”) on the surface of an individual lymphoma patient’s malignant B-cell clones. This BCR-selective targeting domain is engineered into the antigen-binding domain of a chimeric antigen receptor (“CAR”), creating the possibility of a CAR T treatment that should only recognize a given patient’s malignant B-cell clones. An expected result for XCART is limited 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.

About Pharmsynthez

Pharmsynthez PJSC (MOEX: LIFE) is a Russian pharmaceutical company that develops new medicines, drug technologies for organ-specific delivery, and innovative methods of manufacturing pharmaceutical ingredients. The company is engaged in production and sale of both medicines for the treatment of respiratory diseases (original OM) and active pharmaceutical ingredients (API). The company has a research and production complex in Kapitolovo, commissioned in 2001. Pharmsynthez actively cooperates with North American, Canadian and European companies in the field of chemical compounds and API production.

About Shemyakin

Shemyakin and Ovchinnikov Institute of Bioorganic Chemistry RAS - the largest center of physical and chemical biology and biotechnology in Russia, employs more than 1000 employees in more than 40 laboratories. The Institute is part of the Department of Biological Sciences of the Russian Academy of Sciences and leads the work related to the chemical study of living matter. The Institute conducts research on the molecular mechanisms of various life processes, their practical use in the interests of medicine and agriculture, and also develops fundamental and applied aspects of biotechnology. The international advisory board of the IBCh RAS includes Nobel laureates Robert Huber, Aaron Chehanover, Kurt Wutrich, Sydney Altman, Richard Roberts, Roger Kornberg, as well as Professor of Scripps Institute Richard Lerner and head of the Department of Pharmacology at Yale University School of Medicine Joseph Schlessinger.

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 collaboration with Pharmsynthez, including, if successful, the potential to expand the collaboration to include development and qualification of manufacturing processes for producing autologous XCART CAR T cells, the Company's belief that we are well-positioned to execute on our strategic development plan as we work to advance our innovative technology, the Company's belief that XCART has the potential to address a significant unmet need in NHL, anticipations regarding advancing the XCART platform towards first-in-human dosing, expected results for XCART including limited off-tumor toxicities, such as B-cell aplasia, expectations that the Company's clinical development program will confirm the early preclinical results and demonstrate a more attractive safety profile than existing therapies, 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, the Company's plans to leverage PolyXen® by partnering with biotechnology and pharmaceutical companies, and the Company's 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 technology; (4) the ability of the Company to implement its business strategy; (5) failure of Pharmsynthez to perform its obligations under the MSA; (6) failure of the Company and Pharmsynthez to reach agreements with the contract sites on terms favorable to the Company, or at all, and (7) 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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