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 30, 2022**

Xenetic Biosciences, Inc.

(Exact name of registrant as specified in charter)

Nevada	**001-37937**	**45-2952962**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

40 Speen Street, Suite 102 **Framingham, Massachusetts**	**01701**
(Address of principal executive offices)	(Zip Code)

(781) 778-7720
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

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))

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

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 30, 2022, Xenetic Biosciences, Inc. (the "Company") entered into a Statement of Work (the "SOW") with Catalent Pharma Solutions, LLC ("Catalent") to outline the general scope of work, timeline, and pricing pursuant to which Catalent will provide certain services to the Company to perform cGMP manufacturing of the Company's recombinant protein, Human DNase I. The parties agreed to enter into a Master Services Agreement ("MSA") that will contain terms and conditions to govern the project contemplated by the SOW and that will supersede the addendum to the SOW containing Catalent's standard terms and conditions. In addition, in the event of any conflict between the project-specific terms and conditions set forth in the SOW and the MSA, the MSA terms and conditions shall govern. The estimated total cost of the project contemplated by the SOW is expected to be up to approximately $5 million (exclusive of certain fees and potential alternatives) for the manufacturing services over the course of the term of the project with each phase of the project invoiced separately in connection with the commencement of such phase. Unless earlier terminated, the manufacturing services contemplated by the SOW are currently expected to take approximately 17 months from the start date. The SOW is terminable by the Company at any time with 30 days' prior written notice to Catalent. The SOW also contains customary provisions related to, among other things, confidentiality, warranties, intellectual property and indemnification.

A copy of the SOW and, when executed, the MSA referenced above will be filed as exhibits in a subsequent periodic report to be filed under the Securities Exchange Act of 1934, as amended (the "Exchange Act").

Item 7.01. Regulation FD Disclosure.

On July 7, 2022, the Company issued a press release announcing the entry into the SOW. A copy of the press release is furnished as Exhibit 99.1 hereto and shall not be deemed "filed" for the purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

FORWARD-LOOKING STATEMENTS

This Form 8-K, including the press release, contains forward-looking statements that we intend to be subject to 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, 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 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, 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 outbreak (including any new variant strains of the underlying virus) 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)	Exhibit No.	Description
	99.1	Press Release issued by Xenetic Biosciences, Inc. dated July 7, 2022
	104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

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

Date: July 7, 2022

Xenetic Biosciences, Inc. Engages Catalent for Clinical Manufacturing to Advance DNase-Based Oncology Platform Towards Phase 1 Study

– DNase-based oncology platform has the potential to improve outcomes of existing therapeutic agents in multiple solid tumor indications

– Systemic DNase program initially targeting multi-billion-dollar indications including pancreatic carcinoma

FRAMINGHAM, MA – (July 7, 2022) – Xenetic Biosciences, Inc. (NASDAQ: XBIO) ("Xenetic" or the "Company"), a biopharmaceutical company focused on advancing innovative immune-oncology technologies addressing hard-to-treat cancers, today announced it has entered into a manufacturing agreement with Catalent Pharma Solutions LLC ("Catalent"), which will include cGMP manufacturing for the Company's recombinant protein, Human DNase I.

Catalent is the global leader in enabling biopharma, cell, gene, and consumer health partners to optimize development, launch, and supply of better patient treatments across multiple modalities.

"We are pleased to be working with a preeminent contract development and manufacturing organization such as Catalent, and to have the opportunity to leverage their broad expertise and successful track record with early-stage development through commercial manufacturing. We are excited to take this step forward on the path to the clinic and look forward to investigating systemic DNase as an adjunctive therapy for locally advanced or metastatic cancers," commented, Jeffrey Eisenberg, Chief Executive Officer of Xenetic.

"This agreement is an important step towards long-term collaboration between Catalent and Xenetic," added Vikalp Mohan, Global Vice President, Head of Drug Substance at Catalent Biologics. "We look forward to leveraging Catalent's proven biomanufacturing expertise at our site in Madison, Wisconsin to support the advancement of Xenetic's DNase clinical development program and accelerating their path to first-in-human studies."

Xenetic's interventional DNase based oncology platform is aimed at improving outcomes of existing treatments, including immunotherapies. The Company exclusively licensed intellectual property for uses of DNases in cancer include systemic co-administration of DNases along with standard therapies, including chemotherapy, radiation and checkpoint inhibitors, or along with conventional chimeric antigen receptor (CAR) T therapies.

The DNase platform is designed to target neutrophil extracellular traps ("NETs"), which are weblike structures composed of extracellular chromatin coated with histones and other proteins. NETs are expelled by activated neutrophils, in response to microbial or pro-inflammatory challenges. However, excessive production or reduced clearance of NETs can lead to aggravated inflammatory and autoimmune pathologies, as well as creation of pro-tumorigenic niches in the case of cancer growth and metastasis.

The Company is working toward its planned first-in-human study to evaluate DNase combined with immune checkpoint inhibitors or chemotherapy.

About Catalent

Catalent is the global leader in enabling pharma, biotech, and consumer health partners to optimize product development, launch, and full life-cycle supply for patients around the world. With broad and deep scale and expertise in development sciences, delivery technologies, and multi-modality manufacturing, Catalent is the industry's preferred partner for personalized medicines, consumer health brand extensions, and blockbuster drugs. Catalent helps accelerate over 1,000 partner programs and launch over 150 new products every year. Its flexible manufacturing platforms at over 50 global sites supply over 70 billion doses of nearly 7,000 products to over 1,000 customers annually. Catalent's expert workforce exceeds 19,000, including more than 2,500 scientists and technicians. Headquartered in Somerset, New Jersey, the company generated $4 billion in revenue in its 2021 fiscal year. For more information, visit www.catalent.com.

About Xenetic Biosciences

Xenetic Biosciences, Inc. is a biopharmaceutical company focused on advancing innovative immune-oncology technologies addressing hard to treat oncology indications. The Company's DNase oncology platform, in development for the treatment of solid tumors, is aimed at improving outcomes of existing treatments, including immunotherapies, by targeting neutrophil extracellular traps (NETs). The Company is also developing its personalized CAR T platform technology, XCART™, to develop 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.

Additionally, Xenetic is leveraging PolyXen®, its proprietary drug delivery platform, to partner 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 receives royalty payments under an exclusive license arrangement in the field of blood coagulation disorders.

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 that we intend to be subject to 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: expectations regarding the manufacturing agreement with Catalent and the DNase platform, including our plans to use Catalent for clinical manufacturing to advance the DNase platform towards a Phase 1 study, our belief that the DNase based oncology platform has the potential to improve outcomes of existing therapeutic agents in multiple solid tumor indications, our expectations that the systemic DNase program is initially targeting multi-billion-dollar indications, including pancreatic Carcinoma, our plans to investigate systemic DNase as an adjunctive therapy for locally advanced or metastatic cancers, that the DNase oncology platform is aimed at improving outcomes of existing treatments, including immunotherapies, by targeting NETs, our plans to advance innovative immune-oncology technologies to address hard to treat oncology indications, and our expectations regarding working toward our first-in-human study to evaluate DNase combined with immune checkpoint inhibitors or chemotherapy; plans regarding our personalized CAR T platform technology, XCART™, being used to develop 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; our plans to leverage PolyXen®, our proprietary drug delivery platform, to partner with biotechnology and pharmaceutical companies; and our expectations regarding the receipt of royalty payments under an exclusive license agreement in the field of blood coagulation disorders. 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 manufacturing agreement with Catalent; (2) unexpected costs, charges or expenses resulting from the licensing of the DNase platform; (3) uncertainty of the expected financial performance of the Company following the licensing of the DNase platform; (4) failure to realize the anticipated potential of the DNase, XCART or PolyXen technologies; (5) the ability of the Company to implement its business strategy; and (6) 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, 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, and geopolitical events, such as the Russian invasion of Ukraine, 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.