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): **April 26, 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** (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)

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.

Exclusive Sublicense Agreement

On April 26, 2022, Xenetic Biosciences, Inc. (the "Company") entered into an Exclusive Sublicense Agreement (the "Sublicense Agreement") with CLS Therapeutics LTD, a company organized under the laws of Guernsey ("CLS"), pursuant to which the Company received an exclusive license, under certain patent rights and know-how owned or controlled by CLS, to develop and commercialize pharmaceutical products and methods incorporating Deoxyribonuclease ("DNase") enzyme for use in treatment of cancer (the "Sublicensed Products"). Under the terms of the Sublicense Agreement, the Company will have sole responsibility for, and shall use commercially reasonable efforts to, among other things, research, develop and obtain marketing approval for the Sublicensed Products in the United States and certain European markets, and to commercialize such Sublicensed Products in the relevant market once marketing approval is obtained.

In consideration for the license and other rights granted to the Company under the Sublicense Agreement, the Company issued to CLS 375,000 shares of the Company's common stock (the "Sublicense Agreement Shares"), of which 250,000 Sublicense Agreement Shares were issued directly to OPKO Health, Inc. ("OPKO") in lieu of transfer indirectly from CLS to EirGen Pharma Ltd. ("EirGen"), a wholly owned subsidiary of OPKO, in satisfaction of certain third-party contractual obligations between CLS and EirGen. Additionally, the Company is obligated to pay to CLS up to $13,000,000 in cash in potential milestone payments for the achievement of certain clinical and regulatory milestones, as well as issue an additional 950,000 shares of the Company's common stock to CLS based on the achievement of certain regulatory milestones (the "Additional Shares"). In addition, the Company is obligated to pay tiered royalties ranging from the mid-single to low-double digits on net sales of licensed products falling within the scope of the license during the Royalty Term (as defined in the Sublicense Agreement), as well as pay a percentage share in the low-to-mid teens of certain consideration received by the Company from any sublicensees.

The Sublicense Agreement will remain in effect on a country-by-country and licensed product-by-licensed product basis until terminated. The Sublicense Agreement may be terminated by (i) either party for the other party's failure to cure a default within 60 days after receipt of written notice, (ii) CLS, (a) in the event the Company ceases all development activities for a period of 12 consecutive months, and does not cure such cessation within 60 days after receipt of written notice from CLS or (b) immediately upon written notice by CLS in the event of the Company's bankruptcy or insolvency, and (iii) the Company, at any time, for any reason with three months' prior written notice to CLS. In addition, CLS has the right to terminate the Sublicense Agreement upon written notice to the Company in the event that the Company directly or indirectly challenges in a legal or administrative proceeding the patentability, enforceability or validity of any licensed patent or the scope or construction of any valid claim. The Sublicense

Agreement also contains customary representations, warranties and covenants, as well as customary provisions relating to indemnification, confidentiality and other matters.

Pursuant to the Sublicense Agreement, on April 26, 2022, the Company entered into subscription agreements with CLS and OPKO pursuant to which the Company agreed to issue to CLS and OPKO, and CLS and OPKO agreed to subscribe for, 125,000 and 250,000 of the Sublicense Agreement Shares, respectively. The subscription agreements also contain customary representations, warranties and covenants. One of the Company's directors, Adam Logal, is the Chief Financial Officer of OPKO.

Exclusive License Agreement

On April 26, 2022, the Company entered into an Exclusive License Agreement (the "License Agreement") with CLS, pursuant to which the Company received an exclusive license under certain patent rights and know-how owned or controlled by CLS to develop and commercialize pharmaceutical products and methods incorporating DNase in conjunction with CAR T therapies (the "Licensed Products"). Under the terms of the License Agreement, the Company will have sole responsibility for, and shall use commercially reasonable efforts to, among other things, research, develop and obtain marketing approval for the Licensed Products in the United States and certain European markets, and to commercialize such Licensed Products in the relevant market once marketing approval is obtained.

In consideration for the license and other rights granted to the Company under the License Agreement, the Company paid CLS a one-time fee of $500,000 in cash, issued to CLS 500,000 shares of the Company's common stock (the "License Agreement Shares" and together with the Sublicense Agreement Shares, the "Shares"), and is obligated to pay up to $13,000,000 in cash in potential milestone payments for the achievement of certain clinical and regulatory milestones for each Licensed Product. In addition, the Company is obligated to pay tiered royalties ranging from the mid-single to low-double digits on net sales of licensed products falling within the scope of the license during the Royalty Term (as defined in the License Agreement), as well as pay a percentage share in the mid-teens to low double digits of certain consideration received by the Company from any sublicensees.

Pursuant to the License Agreement, CLS granted the Company a right of first refusal in the event CLS or any of its affiliates desires to, or enters into any arrangement with respect to, sell, license, research or develop any product incorporating the delivery of DNase for treatment of cancer through gene therapy such that the Company shall have the right of first refusal to enter into an agreement with CLS or its affiliate on terms no less favorable than those on which CLS or its affiliate proposed to enter into with the applicable third party.

The term of the License Agreement is substantially the same as the term of the Sublicense Agreement described above. The License Agreement also contains customary representations, warranties and covenants, as well as customary provisions relating to indemnification, confidentiality and other matters.

Pursuant to the License Agreement, the Company and CLS entered into a subscription agreement on April 26, 2022, pursuant to which the Company agreed to issue, and CLS agreed to subscribe for, the License Agreement Shares. The subscription agreement also contains customary representations, warranties and covenants.

One of the Company's directors, Roger Kornberg, is a member of the scientific advisory board of CLS, however, Mr. Kornberg does not own any equity of CLS and is not receiving any economic benefit as a result of the transactions contemplated by the License Agreement and Sublicense Agreement.

A copy of each of the License Agreement, the Sublicense Agreement and the form of subscription agreement referenced above will be filed as an exhibit in a subsequent periodic report to be filed under the Securities Exchange Act of 1934, as amended (the "Exchange Act").

Item 2.01. Completion of Acquisition or Disposition of Assets

The information set forth above in Item 1.01 of this Current Report on Form 8-K is incorporated into this Item 2.01 by reference.

Item 3.02. Unregistered Sales of Equity Securities

The information set forth above in Item 1.01 of this Current Report on Form 8-K is incorporated into this Item 3.02 by reference.

The Shares were sold on April 26, 2022. The Shares were offered and sold, and any Additional Shares will be offered and sold, in transactions exempt from registration under the Securities Act of 1933, as amended (the "Securities Act"), in reliance on Section 4(a)(2) thereof and the provisions of Regulation D thereunder. Each of CLS and OPKO represented that it was an "accredited investor," as defined in Regulation D, and was acquiring the Shares, and will acquire any Additional Shares, for investment only and not with a view towards, or for resale in connection with, the public sale or distribution thereof. Accordingly, none of the Shares or Additional Shares have been registered under the Securities Act and none of the Shares or Additional Shares may be offered or sold in the United States absent registration or an exemption from registration under the Securities Act and any applicable state securities laws.

Neither this Current Report on Form 8-K nor the exhibits attached hereto is an offer to sell or the solicitation of an offer to buy shares of the Company's common stock or any other securities of the Company.

Item 7.01. Regulation FD Disclosure.

On April 27, 2022, the Company issued a press release announcing the entry into the License Agreement and the Sublicense Agreement, as well as providing a business update. 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 April 27, 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.

Dated: April 27, 2022

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

Exhibit 99.1

Xenetic Biosciences, Inc. Expands Oncology Pipeline with In-Licensing of DNase Based Oncology Platform Comprising Multiple Therapeutic Modalities

Transaction with CLS Therapeutics for DNase platform includes two pre-clinical development programs and creates near-term clinical development opportunity

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

Xenetic plans to conduct a Phase 1 clinical study of lead asset in locally advanced or metastatic solid tumors

Company to host update conference call and webcast today, April 27th at 8:30 AM ET

FRAMINGHAM, MA – (April 27, 2022) – Xenetic Biosciences, Inc. (NASDAQ: XBIO) ("Xenetic" or the "Company"), a biopharmaceutical company focused on advancing innovative immune-oncology technologies for the treatment of hard to treat cancers, today announced that it has entered into exclusive license and sublicense agreements with CLS Therapeutics ("CLS") to develop its interventional DNase based oncology platform, which is aimed at improving outcomes of existing treatments, including immunotherapies. Xenetic will host a conference call and webcast, today, April 27, 2022, at 8:30 a.m. ET (details below).

Under the terms of the agreements, Xenetic has an exclusive license to CLS' intellectual property, for uses of DNases in cancer, including 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. In addition, the licenses cover "DNase-armored" CAR T therapies in which novel CAR T products are engineered to secrete DNases into the tumor microenvironment to potentially improve T-cell infiltration, activity and persistence. As part of the agreements, Xenetic will make an upfront payment of $500,000 in cash and issue 875,000 shares of common stock, and will make future payments based on the achievement of certain clinical and regulatory milestones of up to $13 million per program, as well as issue up to an additional 950,000 shares of common stock based on the achievement of certain milestones. Additionally, Xenetic will pay tiered royalty payments ranging from mid-single to low-double digits on any potential future sales, as well as a percentage share of certain consideration received by Xenetic from sublicensees.

The licensed 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.

A substantial amount of scientific literature has implicated NETs in the context of cancer pathogenesis and resistance to cancer therapies (including chemo, radio, and immunotherapies such as checkpoint inhibitors and cell therapies). In published reports, elevated levels of NETs have been a biomarker associated with poor prognosis in patients with a variety of cancers.

In addition, resistance to existing therapeutic agents can involve the release of immunosuppressive signaling factors from NETs, or physical barriers created by NETs which can impede the infiltration, activity, and survival of cytotoxic T cells in the tumor microenvironment.

Published pre-clinical models have demonstrated the effectiveness of systemically administered DNase, alone or in combination with other agents, for the elimination of NETs and prevention of tumor growth and metastasis.

"We are excited to in-license this oncology platform. Based on the compelling pre-clinical efficacy data seen to date, we believe the DNase-based oncology platform has the potential to improve the outcomes of chemotherapy and immunotherapy treatments in multiple solid tumor indications," commented Jeffrey Eisenberg, Chief Executive Officer of Xenetic. "This transaction provides Xenetic with near term opportunities for value-driving milestones, and an anticipated timeline to clinic that now positions us as an emerging clinical-stage company. This gives us the confidence to focus our capital and human resources on advancing the DNase pipeline. Our primary efforts are now aimed at advancing the systemic DNase program into the clinic as an adjunctive therapy for locally advanced or metastatic cancers. Our goal is to provide solutions in the treatment of solid tumors by improving response and overcoming resistance to checkpoint inhibitors or chemotherapy. Ultimately, we expect these programs to drive value for shareholders in the near and long term."

Adoptive transfer of CAR T cells has emerged as one of the most promising advances in cancer immunotherapy. Engineered CAR T cells, designed to recognize cancer-associated antigens, are capable of sustained and selective killing of tumor cells, with substantial reduction of tumor burden. CAR T therapies have exhibited remarkable clinical success against hematological malignancies but thus far have failed to demonstrate success in the context of solid tumors. Published evidence suggests that in addition to immunosuppressive factors, mechanical barriers formed by NETs can impede T-cell penetration and occlude T-cell contact with tumor cells.

"To successfully treat solid tumors, CAR T cells must be able to infiltrate, persist, and maintain anti-tumor function in a hostile tumor microenvironment that is itself adept at immunosuppression and conducive to tumor cell survival. Recent approaches to CAR T design include "armored" CAR-T cells, so named because they can express additional factors to resist immunosuppression or degrade physical components of the tumor's extracellular matrix, including NETs. We intend to conduct pre-clinical research with the goal of demonstrating that armoring CAR T cells to secrete DNase can support depth and durability of response against solid tumor indications," said Curtis Lockshin, Chief Scientific Officer of Xenetic.

Conference Call and Webcast

Xenetic management will host a conference call and webcast presentation for investors, analysts, and other interested parties to discuss the in-licensing today, April 27, 2022, at 8:30 AM ET.

Interested participants and investors may access the conference call by dialing (877) 407-9708 (domestic) or (201) 689-8259 (international). The live webcast will be accessible on the Events page of the Investors section of the Xenetic website, xeneticbio.com, and will be archived for 90 days.

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 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 transaction with CLS Therapeutics, including all statements regarding the DNase platform, such as our expectations regarding the DNAse platform creating near-term clinical development opportunity and our belief that the DNase based oncology platform has the potential to improve outcomes of existing therapeutic agents in multiple solid tumor indications, expectations regarding future cash and equity payments under the licenses based on the achievement of certain clinical and regulatory milestones, expectations regarding payment of royalties or sublicensee income, our plans to conduct a Phase 1 clinical study of lead asset in locally advanced or metastatic solid tumors, our belief that the CLS transaction provides us with near term opportunities for value-driving milestones and an anticipated timeline to clinic that now positions us as an emerging clinical-stage company, our plans to focus our capital and human resources on advancing the DNase pipeline, expectations that our primary efforts are now aimed at advancing the systemic DNase program into the clinic as an adjunctive therapy for locally advanced or metastatic cancers, our expected goal to provide solutions in the treatment of solid tumors by improving response and overcoming resistance to checkpoint inhibitors or chemotherapy, our expectations that these programs will drive value for shareholders in the near and long term, and our intentions to conduct pre-clinical research with the goal of demonstrating that armoring CAR T cells to secrete DNase can support depth and durability of response against solid tumor indications; expectations regarding our focus on advancing innovative immune-oncology technologies addressing hard to treat oncology indications; our plans to develop our 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; and our plans to leverage PolyXen® by partnering with biotechnology and pharmaceutical companies. 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 transaction with CLS Therapeutics and the acquisition of the DNase platform; (2) uncertainty of the expected financial performance of the Company following completion of the transaction with CLS Therapeutics and the acquisition of the DNase platform; (3) failure to realize the anticipated potential of the DNase platform or XCART or PolyXen technologies; (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.