

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): **November 10, 2022**

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.)

945 Concord Street
Framingham, Massachusetts
(Address of principal executive offices)

01701
(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
Purchase Warrants	XBIOW	The Nasdaq Stock Market

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 November 10, 2022, Xenetic Biosciences, Inc. (the "Company") issued a press release announcing results for the three months ended September 30, 2022 and providing a corporate update.

The full text of the press release 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 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) and geopolitical events, such as the Russian invasion of Ukraine, on economic activity, 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated November 10, 2022 pertaining to the financial results of the Company for the three months ended September 30, 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.

Date: November 10, 2022

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



Xenetic Biosciences, Inc. Reports Third Quarter 2022 Financial Results and Provides Business Update

- Continued advancement of lead technology, DNase-based oncology platform, in locally advanced or metastatic solid tumors towards Phase 1 clinical development

- Ended the quarter with \$13.8 million of cash expected to fund operations and drive expanded pipeline development forward

FRAMINGHAM, MA – (November 10, 2022) – Xenetic Biosciences, Inc. (NASDAQ: XBIO) (“Xenetic” or the “Company”), a biopharmaceutical company focused on advancing innovative immune-oncology technologies addressing hard to treat oncology indications, today reported its financial results for the third quarter of 2022 and provided a business update.

“We have continued to make encouraging progress with our recently in-licensed DNase-based oncology asset over the course of the past quarter and are excited about the potential of this platform technology,” commented Jeffrey Eisenberg, Chief Executive Officer of Xenetic. “Looking ahead, our top priority remains on the advancement of our DNase oncology platform and moving it closer towards the clinic.”

DNase Oncology Platform: Targeting Neutrophil Extracellular Traps (“NETs”) to improve cancer therapies with a focus on advancing systemic DNase program into the clinic as an adjunctive therapy for pancreatic carcinoma and other locally advanced or metastatic solid tumors.

Program Highlights:

- Systemic DNase program initially targeting multi-billion-dollar indications including pancreatic carcinoma.
- Advancing toward planned first-in-human study to evaluate DNase combined with immune checkpoint inhibitors or chemotherapy.
- In August 2022, entered into a research and development collaboration agreement with VolitionRX Limited to develop NETs targeted, adoptive cell therapies potentially targeting multiple types of solid cancers.
- In June 2022, entered into a manufacturing agreement with Catalent Pharma Solutions LLC, which will include cGMP manufacturing of Phase 1 clinical supply.

PolyXen Platform Technology: Patent-protected platform technology designed for protein or peptide therapeutics, enabling next-generation biological drugs by prolonging a drug's circulating half-life and potentially improving other pharmacological properties.

Program Highlight:

- Royalty payments of approximately \$0.4 million were received in the three months ended September 30, 2022, representing an approximate 18.6% increase over the same period in 2021 as Takeda’s sublicensee continued its worldwide launch of the product.



Summary of Financial Results for Third Quarter 2022

Net loss for the quarter ended September 30, 2022 was approximately \$0.8 million. Research and development expenses for the three months ended September 30, 2022 decreased by approximately \$0.4 million, or 48.9%, to approximately \$0.4 million from approximately \$0.8 million in the comparable quarter in 2021 due to decreased spending related to our XCART™ platform technology program partially offset by spending related to our DNase oncology platform. General and administrative expenses for the three months ended September 30, 2022 decreased by approximately \$82,000, or 8.7%, to approximately \$863,000 from approximately \$945,000 in the comparable quarter in 2021. The decrease was primarily due to a decrease in costs related to our intellectual property during the three months ended September 30, 2022, compared to the same period in 2021.

The Company ended the quarter with approximately \$13.8 million of cash.

About Xenetic Biosciences

Xenetic Biosciences, Inc. is a biopharmaceutical company focused on advancing innovative immune-oncology technologies addressing hard to treat cancers. The Company's DNase platform is designed to improve outcomes of existing treatments, including immunotherapies, by targeting neutrophil extracellular traps (NETs), which are involved in cancer progression. Xenetic is currently focused on advancing its systemic DNase program into the clinic as an adjunctive therapy for pancreatic carcinoma and locally advanced or metastatic solid tumors.

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.

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,” “look forward to,” “advancing,” “potential,” “targeting,” and other words of similar meaning, including, but not limited to, statements regarding: expectations regarding the DNase platform, including continuing to make encouraging progress with and excitement about the potential of this platform technology, expansion of our pipeline development, continued

advancement of lead technology, DNase-based oncology platform, in locally advanced or metastatic solid tumors towards Phase 1 clinical development, our plans to target NETs to improve cancer therapies with a focus on advancing systemic DNase program into the clinic as an adjunctive therapy for pancreatic carcinoma and other locally advanced or metastatic solid tumors, our expectations that the systemic DNase program is initially targeting multi-billion-dollar indications, including pancreatic carcinoma, and our expectations regarding advancing toward our first-in-human study to evaluate DNase combined with immune checkpoint inhibitors or chemotherapy; our expectations regarding our research and development collaboration agreement with Belgian Volition SARL, including regarding developing NETs-targeted adoptive cell therapies potentially targeting multiple types of solid cancers; 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 our manufacturing and collaboration agreements with Catalent and Volition; (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 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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