

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): **August 12, 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.)

**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)

**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 August 12, 2022, Xenetic Biosciences, Inc. (the "Company") issued a press release announcing results for the three months ended June 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) 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) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press Release dated August 12, 2022 pertaining to the financial results of the Company for the three months ended June 30, 2022.</a>
104	Cover Page Interactive Data File (embedded within the inline XBRL document)

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2

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**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: August 12, 2022

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

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3

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

- Second quarter marked by deal to in-license DNase-based oncology platform which expands pipeline with well-defined and accelerated path to clinic
- Advancing lead DNase program towards Phase 1 study for the treatment of pancreatic carcinoma and other locally advanced or metastatic solid tumors
- Ended the quarter with \$14.9 million of cash to fund operations and drive expanded pipeline development forward

**FRAMINGHAM, MA – (August 12, 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 second quarter of 2022 and provided a business update.

“The past quarter was marked by a shift in our focus and prioritization of our pipeline with the in-licensing of our DNase-based oncology platform. With this transaction, we now have a clear path toward a Phase 1 clinical study in pancreatic carcinoma and other advanced solid tumors, creating the potential for value driving regulatory and clinical milestones” commented Jeffrey Eisenberg, Chief Executive Officer of Xenetic. “As a demonstration of our commitment to advance this important program, we engaged Catalent, a preeminent contract development and manufacturing organization, to produce cGMP clinical supply for our planned Phase 1 study. We also entered into a research and development collaboration with Belgian Volition SARL, and we look forward to advancing this exploratory program to develop NETs-targeted adoptive cell therapies. We are focused on executing on our preclinical and clinical development plans and look forward to unlocking the full potential of this oncology platform.”

**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:**

- In April 2022, executed exclusive license and sublicense agreements with CLS Therapeutics to develop its interventional DNase-based oncology platform, which is designed to improve outcomes of existing treatments, including immunotherapies.
- Advancing toward planned first-in-human study to evaluate DNase combined with immune checkpoint inhibitors or chemotherapy.
- Systemic DNase program initially targeting multi-billion-dollar indications including pancreatic carcinoma.
- DNase armored CAR T program focused on demonstrating that armoring CAR T cells to secrete DNase can support depth and durability of response of CAR T therapy against solid tumor indications.
- In June 2022, entered into a manufacturing agreement with Catalent Pharma Solutions LLC, which will include cGMP manufacturing of Phase 1 clinical supply.
- Subsequent to quarter end, entered into a collaboration agreement with Belgian Volition SARL to develop NETs-targeted adoptive cell therapies for the treatment of cancer.



**XCART Platform Technology:** *Significantly differentiated, proprietary approach to personalized CAR T lymphoma therapy targeting tumor-specific neoantigens that target independently of CD19 or other surface antigens that are common to both normal and malignant B-cells.*

### **Program Highlights:**

- Bolstered intellectual property portfolio with issuance of a U.S. patent covering the co-administration of XCART-derived CAR T cells, together with a personalized vaccine designed to enhance the effectiveness of the CAR T therapy.

**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 June 30, 2022, representing an approximate 45% increase over the same period in 2021 as Takeda's sublicensee continued its worldwide launch of the product.

## Summary of Financial Results for Second Quarter 2022

Net loss for the quarter ended June 30, 2022 was approximately \$2.7 million. Research and development (“R&D”) expenses for the three months ended June 30, 2022 increased by approximately \$1.6 million, or 296.1%, to approximately \$2.1 million from approximately \$0.5 million in the comparable quarter in 2021 due to in-process research and development (“IPR&D”) expense of \$1.3 million. During the three months ended June 30, 2022, the Company expensed \$1.3 million of IPR&D associated with the Company's licensing of the DNase platform. There was no similar expense in 2021. Excluding the \$1.3 million of IPR&D expense from total R&D expense of \$2.1 million, R&D expense for the three months ended June 30, 2022 increased by \$0.3 million, or 47.3%, primarily due to increased spending related to our XCART™ platform technology program. General and administrative expenses for the three months ended June 30, 2022 increased by approximately \$0.1 million, or 15.2%, to approximately \$1.0 million from approximately \$0.9 million in the comparable quarter in 2021. The increase was primarily due to an increase in legal costs related to the licensing of the DNase platform during the three months ended June 30, 2022 compared to the same period in 2021.

The Company ended the quarter with approximately \$14.9 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](http://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 expansion of our pipeline development with accelerated path to clinic, advancing the DNase program towards a Phase 1 study for the treatment of pancreatic carcinoma and other advanced solid tumors, the potential for value driving clinical and regulatory milestones, unlocking the potential of this oncology platform, 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, that the DNase oncology platform is designed to improve outcomes of existing treatments, including immunotherapies, 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 with Belgian Volition SARL, including regarding advancing this exploratory program to develop NETs-targeted adoptive cell therapies; 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; 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, 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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