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

- *Company completed recent transaction to expand oncology pipeline with in-licensing of DNase based platform comprising multiple therapeutic modalities*
- *DNase based oncology platform has the potential to improve outcomes of existing therapeutic agents in multiple solid tumor indications*
- *Focusing resources on advancing DNase based oncology platform in locally advanced or metastatic solid tumors towards Phase 1 clinical development*
- *Ended the quarter with \$16.2 million of cash to fund operations and drive pipeline forward*

FRAMINGHAM, MA / ACCESSWIRE / May 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 first quarter of 2022 and provided a business update.

"Our strategic focus throughout the first quarter was working towards the completion of our exclusive license agreement with CLS Therapeutics ("CLS") to develop its interventional DNase based oncology platform. This platform was extremely attractive to us as we realized that adding the licensed programs could expand and enhance our oncology pipeline, provide an accelerated path to the clinic, create the potential for value-driving clinical and regulatory milestones, and position us as an emerging clinical-stage company," commented, [Jeffrey Eisenberg, Chief Executive Officer](#) of Xenetic. "Our team, along with advisors and preeminent key opinion leaders in this space, will make it a priority to advance the systemic DNase program into the clinic as an adjunctive therapy for locally advanced or metastatic cancers, as quickly and efficiently as possible."

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 locally advanced or metastatic cancers.*

The Company's interventional DNase based oncology platform is aimed at improving outcomes of existing treatments, including immunotherapies. The exclusive license to CLS' 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. 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.

The licensed DNase platform is designed to target 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.

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. 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. The Company plans to conduct pre-clinical research with the goal of demonstrating that arming CAR T cells to secrete DNase can support depth and durability of response against solid tumor indications.

Program Highlights:

- In April 2022, executed exclusive license and sublicense agreements with CLS Therapeutics to develop its interventional DNase based oncology platform, which is aimed at improving outcomes of existing treatments, including immunotherapies.
- Advancing toward first-in-human study with IND filing targeted for the end of 2023.
- Systemic DNase program initially targeting multi-billion-dollar indications including pancreatic carcinoma.
- DNase armored CAR T program focused on demonstrating that arming CAR T cells to secrete DNase can support depth and durability of response against solid tumor indications.

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:

- Advancing preclinical efforts through ongoing research and development [collaborations including with The Scripps Research](#) Institute and other institutions in the U.S. covering design and implementation of the pre-clinical development program, as well as activities supporting process development for clinical manufacturing.
- 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 March 31, 2022, representing an approximate 103.4% increase over the same period in 2021 as Takeda's sublicensee continued its worldwide launch of the product.

Summary of Financial Results for First Quarter 2022

Net loss for the quarter ended March 31, 2022 was approximately \$1.6 million. Research & development expenses for the three months ended March 31, 2022 increased by approximately \$0.5 million, or 74.9%, to approximately \$1.1 million from approximately \$0.6 million in the comparable quarter in 2021. The increase was primarily due to the Company's increase in spending related to XCART™ U.S. pre-clinical development efforts. General and administrative expenses for the three months ended March 31, 2022 decreased by approximately \$23,000, or 2.5%, to approximately \$0.9 million from approximately \$0.9 million in the comparable quarter in 2021. The decrease was primarily due to lower consulting costs offset by an increase in legal costs related to the CLS transaction during the three months ended March 31, 2022 compared to the same period in 2021.

The Company ended the quarter with approximately \$16.2 million of cash.

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: the transaction with CLS Therapeutics and the DNase platform, such as our belief that the DNase based oncology platform has the potential to improve outcomes of existing therapeutic agents in multiple solid tumor indications, our plans to focus resources on advancing the DNase platform in locally advanced or metastatic solid tumors towards Phase 1 clinical development, our plans to advance innovative immune-oncology technologies to address hard to treat oncology indications, our belief that adding the licensed programs will expand and enhance our oncology pipeline, provide an accelerated path to the clinic, create the potential for value-driving clinical and regulatory milestones, and position us as an emerging clinical-stage company, our plans to make it a priority to advance the systemic DNase program into the clinic as an adjunctive therapy for locally advanced or metastatic cancers as quickly and efficiently as possible, our plans 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, our expectations regarding advancing toward first-in-human study and timing of an IND filing targeted for the end of 2023; our anticipations that the systemic DNase program will initially target multi-billion-dollar indications including pancreatic carcinoma, and our plans regarding the DNase armored CAR T program's focus on demonstrating that armoring CAR T cells to secrete DNase can support depth and durability of response against solid tumor indications; our plans regarding the XCART platform technology, including expectations regarding advancing preclinical efforts through ongoing research and development collaborations covering design and implementation of the pre-clinical development program, as well as activities supporting process development for clinical manufacturing; and the matters set forth under the Program Highlights sections above. 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 licensing of the DNase platform; (2) uncertainty of the expected financial performance of the Company following completion of the transaction with CLS Therapeutics and the licensing of the

DNase platform; (3) failure to realize the anticipated potential of the DNase, 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, 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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