**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
**Washington, DC 20549**

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.**
**For the fiscal year ended December 31, 2024**

☐ **TRANSITION REPORTS PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.**
**For the transition period from _____ to _____**

**Commission File Number: 001-37937**

# XENETIC BIOSCIENCES, INC.

**(Exact name of registrant as specified in its charter)**

| **Nevada** | **45-2952962** |
|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(IRS Employer Identification No.)** |

**945 Concord Street**
**Framingham, Massachusetts 01701**
**(Address of principal executive offices and zip code)**

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

**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 Capital Market |

**Securities registered pursuant to Section 12(g) of the Act:**
**None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act: Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act: Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files): Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer" "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

| | | | |
|---|---|---|---|
| Large accelerated filer | ☐ | Accelerated filer | ☐ |
| Non-accelerated filer | ☒ | Smaller reporting company | ☒ |
| | | 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. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive- based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Exchange Act Rule 12b-2): Yes ☐ No ☒

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant as of June 28, 2024, the last business day of the registrant's most recently completely second fiscal quarter, based upon the closing price of the registrant's common stock on the Nasdaq Capital Market on that date of $4.07, was approximately $5,301,818. For purposes of this computation, all officers, directors, and 10% beneficial owners of the registrant are deemed to be affiliates. Such determination should not be deemed to be an admission that such officers, directors or 10% beneficial owners are, in fact, affiliates of the registrant.

As of March 7, 2025, the number of outstanding shares of the registrant's common stock was 1,542,139.

## DOCUMENTS INCORPORATED BY REFERENCE

Information required in response to Part III of Form 10-K (Items 10, 11, 12, 13 and 14) is hereby incorporated by reference to portions of the registrant's definitive proxy statement for its 2025 Annual Meeting of Stockholders, information statement or an amendment to this Annual Report on Form 10-K. The registrant intends to file a definitive proxy statement, information statement or an amendment to this Annual Report on Form 10-K with the Securities and Exchange Commission no later than 120 days after the end of the registrant's fiscal year ended December 31, 2024.

**XENETIC BIOSCIENCES, INC.**
**2024 ANNUAL REPORT ON FORM 10-K**

**TABLE CONTENTS**


| | | |
|---|---|---|
| **PART I** | | 1 |
| Item 1 | Business | 1 |
| Item 1A | Risk Factors | 18 |
| Item 1B | Unresolved Staff Comments | 42 |
| Item 1C | Cybersecurity | 42 |
| Item 2 | Properties | 43 |
| Item 3 | Legal Proceedings | 43 |
| Item 4 | Mine Safety Disclosures | 43 |
| **PART II** | | 44 |
| Item 5 | Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities | 44 |
| Item 6 | [Reserved] | 44 |
| Item 7 | Management's Discussion and Analysis of Financial Condition and Results of Operations | 44 |
| Item 7A | Quantitative and Qualitative Disclosures About Market Risk | 48 |
| Item 8 | Financial Statements and Supplementary Data | 49 |
| Item 9 | Changes in and Disagreements with Accountants on Accounting and Financial Disclosure | 50 |
| Item 9A | Controls and Procedures | 57 |
| Item 9B | Other Information | 58 |
| Item 9C | Disclosure Regarding Foreign Jurisdictions that Prevent Inspections | 58 |
| **PART III** | | 59 |
| Item 10 | Directors, Executive Officers and Corporate Governance | 59 |
| Item 11 | Executive Compensation | 59 |
| Item 12 | Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters | 59 |
| Item 13 | Certain Relationships and Related Transactions, and Director Independence | 59 |
| Item 14 | Principal Accounting Fees and Services | 59 |
| **PART IV** | | 60 |
| Item 15 | Exhibits and Financial Statement Schedules | 60 |
| Item 16 | Form 10-K Summary | 60 |

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K ("Annual Report") contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 27A of the Securities Act of 1933, as amended. All statements contained in this Annual Report other than statements of historical fact, including statements regarding our future results of operations and financial position, our business strategy and plans, future revenues, projected costs, prospects and our objectives for future operations, are forward-looking statements. These forward-looking statements include, but are not limited to, statements concerning: anticipated effects of geopolitical events, including the conflicts in the Ukraine and the Middle East and associated sanctions imposed by the United States ("U.S.") and other countries in response; our plans to develop our proposed drug candidates; the uncertainty surrounding government actions, as well as any changes to existing or newly proposed legislation that may affect the healthcare regulatory space; our expectations regarding the nature, timing and extent of collaboration arrangements; the expected results pursuant to collaboration arrangements, including the receipts of royalty and other future payments that may arise pursuant to collaboration arrangements; the outcome of our plans to obtain regulatory approval of our drug candidates; the outcome of our plans for the commercialization of our drug candidates; our plans to advance innovative immune-oncology technologies addressing difficult to treat oncology indications; expectations regarding our Deoxyribonuclease ("DNase") technology, such as regarding the DNase technology being in development for the treatment of solid tumors and being aimed at improving outcomes of existing treatments, including immunotherapies, by targeting neutrophil extracellular traps ("NETs"); our expectations to focus our efforts and resources on advancing the DNase technology into the clinic as an adjunctive therapy for pancreatic carcinoma and locally advanced or metastatic solid tumors; our expectations regarding our PolyXen® platform and any partnerships with respect thereto; and all statements under the heading "Opportunity to Address Multiple Oncology Indications" in Item 1 of Part I to this Form 10-K.

In some cases, these statements may be identified by terminology such as "may," "will," "would," "could," "should," "expect," "plan," "anticipate," "believe," "estimate," "seek," "approximately," "intend," "predict," "potential," "projects," "upcoming", "opportunity", "target" or "continue," or the negative of such terms and other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained herein are reasonable, we cannot guarantee future results, the levels of activity, performance or achievements. These statements involve known and unknown risks and uncertainties that may cause our or our industry's results, levels of activity, performance or achievements to be materially different from those expressed or implied by forward-looking statements.

Some factors that could cause actual results to differ materially include without limitation:

- uncertainty of the expected financial performance of the Company;
- failure to realize the anticipated potential of the DNase technology;
- our ability to implement our business strategy;
- our failure to maintain compliance with the continued listing requirements of the Nasdaq Stock Market;
- our need to raise additional working capital in the future for the purpose of further developing our pipeline and to continue as a going concern;
- our ability to finance our business;
- our ability to successfully execute, manage and integrate key acquisitions and mergers;
- product development and commercialization risks, including our ability to successfully develop the DNase technology;
- the impact of adverse safety outcomes and clinical trial results for our therapies;
- our ability to secure and maintain a manufacturer for our technologies;
- the impact of new therapies and new uses of existing therapies on the competitive environment;
- our ability to successfully commercialize our current and future drug candidates;
- our ability to achieve milestone and other payments associated with our current and future co-development collaborations and strategic arrangements;
- our reliance on consultants, advisors, vendors and business partners to conduct work on our behalf;
- the impact of new technologies on our drug candidates and our competition;
- changes in laws or regulations of governmental agencies;
- interruptions or cancellation of existing contracts;
- impact of competitive products and pricing;
- product demand and market acceptance and risks;
- the presence of competitors with greater financial resources;
- continued availability of supplies or materials used in manufacturing at the current prices;
- the ability of management to execute plans and motivate personnel in the execution of those plans;
- our ability to attract and retain key personnel;
- costs, diversion and other adverse effects of the actions of activist shareholders;
- adverse publicity related to our products or the Company itself;
- adverse claims relating to our intellectual property;

- the adoption of new, or changes in, accounting principles;
- the costs inherent with complying with statutes and regulations applicable to public reporting companies, such as the Sarbanes-Oxley Act of 2002;
- other new lines of business that the Company may enter in the future;
- general economic and business conditions, as well as inflationary trends and financial market instability or disruptions to the banking system due to bank failures;
- the impact of natural disasters or public health emergencies, such as the COVID-19 global pandemic, and geopolitical events, such as the conflicts in the Ukraine and the Middle East, and related sanctions and other economic disruptions or concerns, on our financial condition and results of operations; and
- other factors set forth in the Risk Factors section of our Annual Report on Form 10-K and in subsequent filings with the Securities and Exchange Commission ("SEC").

These factors are not necessarily all of the important factors that could cause actual results to differ materially from those expressed in the forward-looking statements in this Annual Report. Other unknown or unpredictable factors also could have material adverse effects on our future results, including, but not limited to, those discussed in the section titled "Risk Factors." The forward-looking statements in this Annual Report are made only as of the date of this Annual Report, and we do not undertake any obligation to publicly update any forward-looking statements to reflect subsequent events or circumstances. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995.

As used in this Annual Report, unless otherwise indicated, all references herein to "Xenetic," the "Company," "we" or "us" refer to Xenetic Biosciences, Inc. and its wholly-owned subsidiaries.

Our brand and product names, including but not limited to, XDNASE™, XCART™, OncoHist™, PolyXen®, ErepoXen™ and ImuXen™ contained in this Annual Report are trademarks, registered trademarks or service marks of Xenetic Biosciences, Inc. and/or its subsidiaries in the United States of America ("USA" or "U.S.") and certain other countries. All other company and product names may be trademarks of the respective companies with which they are associated.

**Summary Risk Factors**

Our business is subject to numerous risks. In addition to the summary below, you should carefully review the "Risk Factors" section of this Annual Report on Form 10-K. We may be subject to additional risks and uncertainties not presently known to us or that we currently deem immaterial. These risks should be read in conjunction with the other information in this Annual Report on Form 10-K. Some of the principal risks relating to our business include:

- We have never been profitable and may never achieve or sustain profitability. If we are unable to generate sufficient revenue from our operations to pay expenses or we are unable to obtain additional financing on commercially reasonable terms, our business, financial condition and results of operations may be materially and adversely affected.

- We will require substantial additional funding to achieve our goals. Failure to obtain this necessary capital when needed on acceptable terms, or at all, may force us to delay, limit or terminate our product development efforts, other operations or commercialization efforts.

- Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or drug candidates.

- We may not continue to meet the continued listing requirements of the Nasdaq Stock Market ("Nasdaq"), which could result in a delisting of our common shares.

- Our business is substantially dependent on the success of the DNase technology.

- We operate in an extremely competitive environment and there can be no assurances that competing technologies would not harm our business development.

- We are an early-stage company in the business of developing pharmaceutical products including drug candidates and technologies. Given the uncertainty of such development, our business operations may never fully materialize and create value for investors.

- If conflicts arise between us and our collaborators or strategic partners, these parties may act in their self-interest, which may limit our ability to implement our strategies.

- We expect to rely on third parties to conduct, supervise and monitor our clinical studies, and if these third parties perform in an unsatisfactory manner, it may harm our business.

- Our collaborators or strategic partners may decide to adopt alternative technologies or may be unable to develop commercially viable products with our technology, which would negatively impact our revenues and our strategy to develop these products.

- We may seek to establish additional collaborations and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

- If we enter into one or more collaborations, we may be required to relinquish important rights to and control over the development of our drug candidates or otherwise be subject to unfavorable terms.

- We may find it difficult to enroll patients in our clinical studies, which could delay or prevent clinical studies of our pharmaceutical products.

- We may encounter substantial delays in commencement, enrollment or completion of our clinical trials, or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities, which could prevent us from commercializing our current and future drug candidates on a timely basis, if at all.

- If we complete the necessary preclinical and clinical studies, we cannot predict when or if we will obtain regulatory approval to commercialize a drug candidate, or the approval may be for a more narrow indication than we expect.

- If we obtain regulatory approval for a drug candidate, our drug candidate will remain subject to regulatory scrutiny.

- The commercial success of any current or future pharmaceutical products will depend upon the degree of market acceptance by physicians, patients, third-party payors and others in the medical community.

- The commercial potential of a pharmaceutical candidate in development is difficult to predict. If the market size for a new drug candidate or technology is significantly smaller than we anticipate, it could significantly and negatively impact our revenue, results of operations and financial condition.

- Failure to obtain or maintain adequate coverage and reimbursement for our drug candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

- We may use our financial and human resources to pursue a particular research program or drug candidate and fail to capitalize on programs or drug candidates that may be more profitable or for which there is a greater likelihood of success.

- We may not be successful in our efforts to identify or discover additional pharmaceutical products.

- The market opportunities for our drug candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small.

- We have no manufacturing, sales, marketing or distribution capabilities, and we may have to invest a significant amount of resources to develop these capabilities.

- Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

- If we fail to adequately protect or enforce our intellectual property rights, we may be unable to operate effectively.

- Issued patents covering our drug candidates could be found invalid or unenforceable if challenged in court.

- We may not be able to protect our intellectual property rights throughout the world.

- If we infringe on the intellectual property rights of others, our business and profitability may be adversely affected.

- If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third-parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

- We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

- We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

- Our inability to protect our confidential information and trade secrets would harm our business and competitive position.

- Our future success depends on our ability to retain principal members of our executive team, consultants and advisors and to attract, retain and motivate qualified personnel.

- We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

- We are a party to collaboration agreements and other significant agreements which contain complex commercial terms that could result in disputes, litigation or indemnification liability that could adversely affect our business, results of operations and financial condition.

- The market price of our securities may be highly volatile, and you may not be able to sell our securities.

- Actions of activist shareholders could cause us to incur substantial costs, divert management's attention and resources, and have an adverse effect on our business.

- Our preferred stockholders have rights, preferences and privileges that are not held by, and are preferential to, the rights of our common stockholders, which could result in the interests of our preferred stockholders differing from those of our common stockholders.

[This page intentionally left blank]

# PART I

## ITEM 1 – BUSINESS

### Overview

We are a biopharmaceutical company focused on advancing innovative immuno-oncology technologies addressing difficult to treat cancers. Our proprietary DNase technology is designed to improve outcomes of existing treatments, including immunotherapies, by targeting NETs, which are involved in cancer growth, metastasis and progression, and contribute to immunotherapy, chemotherapy and radiotherapy resistance.

The DNase technology 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, hypercoagulability and autoimmune pathologies, as well as creation of pro-tumorigenic niches in the case of cancer growth and metastasis.

We are focused on advancing the development of our DNase technology toward a first-in-human, multicenter, dose escalation and dose-expansion study of IV rhDNase I in subjects with locally advanced or metastatic solid tumors. Our systemic DNase program is initially targeting multi-billion-dollar indications including pancreatic ductal adenocarcinoma ("PDAC"), colorectal carcinoma ("CRC") and other gastrointestinal cancers. These are all cancer indications with significant unmet need, and with opportunities for substantial improvement of the currently available therapeutic options. PDAC has a low rate of early diagnosis, a high mortality rate and a poor five-year survival prognosis. Symptoms are usually non-specific and as a result, PDAC is often not diagnosed until it reaches an advanced stage. Once the disease has metastasized, or spread to other organs, it becomes especially difficult to treat. There were about approximately 511,000 new cases of pancreatic cancer globally in 2022 and according to the American Cancer Society, in 2025, an estimated 67,000 people in the U.S. will be diagnosed with pancreatic cancer, with approximately 52,000 deaths projected from the disease; this translates to a high mortality rate, as the five-year relative survival rate for pancreatic cancer remains around 13%, which constitutes the highest mortality rate among solid tumor malignancies; among those diagnosed with metastatic disease, the overall five-year survival rate is only 2%. Recent developments that have improved the survival in many cancer types have not been effective for pancreatic cancer patients, highlighting the urgent need for the development of newer, more effective therapeutic options. For those few patients that present with earlier stage PDAC, surgical resection followed by chemotherapy is possible, but for the majority of PDAC patients that present at diagnosis with advanced disease, chemotherapy is the only option, and has only very limited benefit. Second-line patients that were diagnosed already with metastatic disease have even fewer therapeutic options. The only approved regimen for second-line patients is Onivyde®, a liposomal irinotecan in combination with 5FU and LV. For these Stage IV at diagnosis patients reaching second-line therapy, median overall survival is only 4.7 months (Macarulla et al, Pancreas 2020 ).

CRC is the second most common cause of cancer death in the U.S. after lung cancer. CRC is the third most commonly diagnosed cancer in males and the second in females, globally, according to the World Health Organization GLOBOCAN database. In the U.S., CRC is the second most common cause of cancer death after lung cancer. According to the American Cancer Society, in 2025, an estimated 154,000 people in the US will be diagnosed with colorectal cancer, with approximately 52,900 deaths expected from the disease; this translates to around 107,000 new colon cancer cases and 47,000 new rectal cancer cases. CRC is in decline in older patients (>65 years) but that is offset by a steady increase in CRC diagnoses and deaths in individuals younger than 55 years of age. Despite continued overall declines, CRC is rapidly shifting to diagnosis at a younger age, at a more advanced stage, and in the left colon/rectum. If CRC is diagnosed at a localized stage, the 5-year survival rate is 91%. However, if the cancer has spread to surrounding tissues or organs and/or the regional lymph nodes, the 5-year relative survival rate is 72%. There are numerous treatment options for earlier stage CRC patients, but as they progress to advanced and metastatic disease ("mCRC"), those options become limited. Approximately 22% of CRC cases have metastasis at presentation, and 19% will develop metastasis after primary tumor removal. Unfortunately, if CRC has spread to distant parts of the body, the 5-year relative survival rate is 13%.

All major guidelines recommend patients with mCRC undergo testing of DNA for high DNA microsatellite instability (MSI-H), a mutation found in approximately 10% of all CRC, and up to 5% of mCRC. CRC patients that are MSI-H/MMRd (or "mismatch repair deficient") are candidates for immunotherapy using immune checkpoint inhibitors ("ICIs"); at present, there are three ICIs approved for MSI-H/MMRd CRC – Keytruda, Opdivo (anti-PD-1 antibodies) and Yervoy (anti-CTLA-4 antibody). While the ICI response rates in this small subset of CRC are encouraging at around 50%, a significant number of patients are resistant, or become refractory to ICI therapy. However, the vast majority of mCRC patients (>90%) are microsatellite stable ("MSS") and mismatch repair proficient ("MMRp"), where ICIs have not been shown to provide benefit. The lack of ICI response in this subset is due to poor immunogenicity and immunosuppression. Again, this highlights the urgent need for the development of newer, more effective therapeutic options.

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 and in particular, in gastrointestinal 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 preclinical 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 currently focused on advancing our systemic DNase program into the clinic as an adjunctive therapy for pancreatic carcinoma and locally advanced or metastatic solid tumors, including CRC.

Adoptive transfer of Chimeric Antigen Receptor ("CAR") T cells has emerged as one of the most promising advances in cancer immunotherapy. CAR T cell therapy, while highly effective against blood cancers, faces significant challenges when applied to solid tumors due to the complex tumor microenvironment which hinders CAR T cell infiltration, persistence, and efficacy, making it difficult for them to reach and attack cancer cells within the solid tumor mass; this includes barriers like dense connective tissue, abnormal blood vessels, and immunosuppressive cells that can exhaust the CAR T cells, limiting their anti-tumor activity. 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 immunosuppressive and conducive to tumor cell survival and metastasis. 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. 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. 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. The conduct of several CAR T in vivo models has been a primary focus of our Scripps collaboration.

Our collaboration with Belgian Volition SARL Limited ("Volition") is an early exploratory program to evaluate the potential combination of Volition's Nu.Q® technology and Xenetic's DNase-Armored CAR T platform to develop proprietary adoptive cell therapies potentially targeting multiple types of solid cancers for which current CAR T cell therapies have shown limited or no effect. Under the terms of the collaboration agreement, Volition will fund a research program and the two parties will share proceeds from commercialization or licensing of any products arising from the collaboration. Epigenetically modified nucleosomes are present on tumor cell surfaces and within the tumor microenvironment of multiple types of solid cancers, and thus these nucleosomes may represent generalizable tumor antigens that are not limited to a single cancer type. Volition's Nu.Q® technology can specifically recognize and target epigenetically modified nucleosomes, while our DNase-Armored CAR T platform is designed to enhance the function of CAR T cells within solid tumor microenvironments.

Additionally, we have partnered with biotechnology and pharmaceutical companies to develop our proprietary drug delivery platform, PolyXen, and receive royalty payments under an exclusive license arrangement in the field of blood coagulation disorders. PolyXen is an enabling platform technology for protein and peptide drug delivery. It uses the biological polymer polysialic acid ("PSA") to prolong the drug's half-life and potentially improve the stability of therapeutic peptides and proteins. Both the site of attachment and the length of the PSA chain can influence the properties of the therapeutic by changing the apparent hydrodynamic radius of the molecule, which in turn, can enhance a number of the biological characteristics of the therapeutic. It can also be used for small molecule drugs.

We incorporate our patented and proprietary technologies into drug candidates currently under development with biotechnology and pharmaceutical industry collaborators to create what we believe will be the next-generation biologic drugs with improved pharmacological properties over existing therapeutics. Our drug candidates have resulted from our research activities or that of our collaborators and are in the development stage. As a result, we continue to commit a significant amount of our resources to our research and development activities and anticipate continuing to do so for the near future. To date, none of our drug candidates have received regulatory marketing authorization or approval in the U.S. by the Food and Drug Administration ("FDA") nor in any other countries or territories by any applicable agencies. As noted above, we are receiving ongoing royalties pursuant to a license of our PolyXen technology to an industry partner. Although we hold a broad patent portfolio, the focus of our internal efforts in 2024 was on the licensing and advancement of our DNase technology.

We were incorporated under the laws of the State of Nevada in August 2011. We, directly or indirectly, through our wholly-owned subsidiaries, Hesperix S.A. ("Hesperix") and Xenetic Biosciences (U.K.) Limited ("Xenetic U.K."), and the wholly-owned subsidiaries of Xenetic UK, Lipoxen Technologies Limited ("Lipoxen"), Xenetic Bioscience, Incorporated and SymbioTec, GmbH ("SymbioTec"), own various U.S. federal trademark registrations and applications, along with unregistered trademarks and service marks, including but not limited to XCART, OncoHist, PolyXen, ErepoXen and ImuXen.

**Our Strategy**

Our primary focus is aimed at advancing the systemic DNase program into the clinic as an adjunctive therapy for pancreatic cancer and other locally advanced or metastatic solid tumors, including CRC. Our goal is to provide solutions in the treatment of solid tumors by improving response and overcoming resistance to checkpoint inhibitors, chemotherapy, and other standard of care treatments. We also intend to pursue industry collaborations and potential licenses to develop DNase for other uses and indications.

We intend to pursue orphan drug designations and accelerated approval pathways for relevant oncology indications as appropriate in both the U.S. and Europe. If our orphan oncology drug candidates are granted orphan drug designation, then we may benefit from certain key advantages of orphan status including certain market exclusivities.

We intend to advance development of our DNase technology primarily through the use of contract manufacturing, contract research organizations ("CROs") and academic institutions in order to efficiently manage our resources. Continuous pipeline growth and advancement of out-licensed drug candidates is dependent, in part, on our ability to raise sufficient capital and to advance our existing co-development collaborations and strategic arrangements as well as enter into new such arrangements.

**Business Developments**

***University of Virginia ("UVA")***

On December 21, 2023, we entered into a Research Funding and Material Transfer Agreement with UVA (the "UVA Agreement") to advance the development of our systemic DNase program. Under the terms of the UVA Agreement, in addition to advancing our existing intellectual property, we have an option to acquire an exclusive license to any new intellectual property arising from the DNase research program. Allan Tsung, MD, a member of the Company's Scientific Advisory Board and Chair of the Department of Surgery at the UVA School of Medicine, oversees the research conducted under the UVA Agreement. In November 2024, we entered into an amendment to extend the term of the UVA Agreement through December 2025. UVA will build on the preclinical and translational data produced to date and continue to investigate combinations of DNase I with immunotherapies in models of primary and metastatic colorectal cancer.

***Scripps Research Institute ("Scripps Research")***

On March 17, 2023, we entered into a Research Funding and Option Agreement (the "Agreement") with Scripps Research, pursuant to which we agreed to provide Scripps Research an aggregate of up to $0.9 million to fund research relating to advancing the pre-clinical development of our DNase technology. Under the Agreement, we have the option to acquire a worldwide exclusive license to Scripps Research's rights in the Technology or Patent Rights (as defined in the Agreement), as well as a non-exclusive, royalty-free, non-transferrable license to make and use TSRI Technology (as defined in the Agreement) solely for our internal research purposes during the performance of the research program contemplated by the Agreement. During the second quarter of 2024, the Company amended the Agreement to extend the term to October 31, 2024 with no additional funding required.

On November 1, 2024, we entered into a Second Amendment to the Agreement with Scripps Research (the "Second Amendment") extending the term of the Agreement for an additional twelve (12) month period and to provide Scripps Research additional funding in an aggregate amount of up to approximately $400,000 to fund continuing research. The research funding is payable by us to Scripps Research on a monthly basis in accordance with a negotiated budget, which provides for an initial payment of approximately $65,000 on the date of the Amendment and subsequent monthly payments of approximately $65,000 over a 5-month period. All other terms of the Original Agreement remain unchanged.

**Our Technology and Drug Candidates**

*Potential Drug Candidates*

We incorporate our patented and proprietary technologies into a number of drug candidates which are currently under development internally or with our biotechnology and pharmaceutical collaborators, with the goal of creating what we believe will be the next generation of biologic drugs and therapeutics. While we primarily focus on researching and developing oncology drugs, we also have ownership and other economic interests in drugs being developed by our collaborators to treat other conditions.

*The Technologies*

During the year ended December 31, 2024, the focus of our internal development efforts was on the advancement of our DNase technology. We have not been actively pursuing development efforts for XCART or PolyXen or any of our other technologies.

DNase The DNase technology 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.

Program Highlights:

- Exclusive license and sublicense agreements with CLS Therapeutics Ltd. ("CLS") to develop its interventional DNase technology, which is aimed at improving outcomes of existing treatments, including immunotherapies;
- Value-driving milestones expected over the next 12 -24 months;
- Systemic DNase program initially targeting multi-billion-dollar indications including pancreatic carcinoma and other locally advanced or metastatic solid tumors including CRC;
- Ongoing collaboration with UVA to advance the development of our systemic DNase program;
- DNase-armored CAR T program in early pre-clinical development; and
- Ongoing collaboration with Scripps Research to conduct several CAR T in vivo models and enhance the function of CAR T cells within solid tumor microenvironments.

**Research, Outside Services and Collaborations**

Through partner efforts, we are developing our pipeline of next-generation bio-therapeutics and novel oncology drugs based on our DNase proprietary technology. In order to do this while efficiently managing our overhead, we rely on the services of contract manufacturers, CROs and our strategic collaborations. We currently do not have in-house research facilities to pursue these initiatives. Accordingly, continuous pipeline growth and advancement of our technologies and drug candidates is dependent on several important collaborations and strategic arrangements, including our arrangements with:

- Catalent Pharma Solutions LLC ("Catalent"), a global leader in enabling biopharma, cell, gene and consumer health partners to optimize development, launch, and supply of better patient treatments across multiple modalities;

- PJSC Pharmsynthez ("Pharmsynthez"), including its wholly-owned subsidiary SynBio LLC ("SynBio"), a beneficial owner of approximately 3.4% of our common stock;

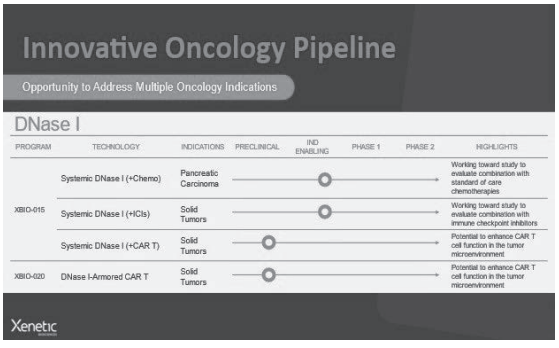
- Scripps Research, one of the world's largest, private non-profit research organizations; and

- The University of Virginia, a non-profit, educational, research and healthcare institution.

Accordingly, in addition to pursuing our development of the DNase technology, we also have significant interests in drug candidates being developed by our collaborators to treat other conditions. We may collect some combination of milestone payments and royalties pursuant to these collaborations to the extent that these drugs are successfully developed and marketed. However, other than royalty payments under a sublicense with Takeda Pharmaceutical Co. Ltd. (together with its wholly-owned subsidiaries, "Takeda") and potential royalty payments under our collaboration agreement with Pharmsynthez, we do not anticipate any milestone or royalty payments in the near term, if at all. For further detail, please read the section titled "Significant Collaborations and Strategic Arrangements" below.

**Our Drug Candidate Pipeline**

Our product pipeline contains drug candidates under development internally and with our biotechnology and pharmaceutical collaborators. The following table summarizes key information regarding our current drug candidates:



***ErepoXen***

ErepoXen, or polysialylated erythropoietin ("PSA-EPO"), uses our PolyXen platform technology for the treatment of anemia in chronic kidney disease ("CKD") patients. It is designed to reduce the dosing frequency by extending the circulating half-life of the therapeutic in the body. We are not pursuing clinical development of ErepoXen but continue to entertain out-license opportunities for the drug candidate in our licensed territories.

We have collaboration agreements with Pharmsynthez and Serum Institute to develop and launch ErepoXen in limited markets pursuant to which we will collect royalties if they are successful in these efforts.

Pharmsynthez received regulatory approval to commence a Phase II(b)/III human clinical trial of ErepoXen (also known as Epolong) in Russia with patient recruitment completed in 2020. In December 2020, Pharmsynthez reported positive data from this trial of Epolong, a treatment for anemia in patients with chronic kidney disease leveraging our PolyXen technology. Pharmsynthez filed a registration dossier to obtain approval in Russia and received a response letter indicating certain deficiencies in the dossier. Pharmsynthez developed a gap mitigation strategy and is currently determining next steps.

Serum Institute conducted Phase I and Phase II clinical trials of ErepoXen in ninety-five human subjects. These safety trials, which had no significant drug-related adverse events, provided us with the data to commence a Phase II, repeat dosing, International Conference on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use compliant clinical trial for ErepoXen in Australia, New Zealand and South Africa for CKD patients not on dialysis. We completed three cohorts of this study and then terminated the study.

In addition, Serum Institute finished Phase I/II clinical trials in India of ErepoXen for in-center-dialysis patients. Serum Institute is not actively pursuing this program but may seek to leverage Pharmsynthez' trial data and potential Russian marketing authorization to request a waiver for a Phase III clinical trial in India, subject to local regulatory authority approval.

**Pipeline Expansion Opportunities**

Operating under licenses from us within their home markets, our collaborators can potentially generate preclinical and clinical data related to our technologies across a wide spectrum of therapeutic areas. Under these agreements, we retain all rights for major markets and co-own the clinical data. We therefore have the opportunity to utilize the data in our decision-making process regarding development and commercialization in major markets.

**Significant Collaborations and Strategic Arrangements**

Significant collaborations with UVA and Scripps Research are described above under the "Business Developments" section of this Item 1 to Part I of the Form 10-K.

***Takeda***

In October 2017, the Company granted to Takeda the right to grant a non-exclusive sublicense to certain patents related to the Company's PolyXen technology that were previously exclusively licensed to Takeda in connection with products related to the treatment of blood and bleeding disorders. Royalty payments of approximately $2.5 million were recorded as revenue for each year by the Company during the years ended December 31, 2024 and 2023 and are based on single digit royalties on net sales of certain covered products.

***Belgian Volition SARL Limited ("Volition") Collaboration***

On August 2, 2022, we announced a research and development collaboration with Volition to develop NETs-targeted adoptive cell therapies for the treatment of cancer. The collaboration is an early exploratory program to evaluate the potential combination of Volition's Nu.Q® Technology Test and our DNase-Armored CAR T platform to develop proprietary adoptive cell therapies potentially targeting multiple types of solid cancers. Under the terms of the collaboration agreement, Volition will fund a research program and the two parties will share proceeds from commercialization or licensing of any products arising from the collaboration.

***Catalent Pharma Solutions LLC ("Catalent")***

On June 30, 2022, we entered into a Statement of Work (the "SOW") with Catalent to outline the general scope of work, timeline, and pricing pursuant to which Catalent will provide certain services to the Company to perform current Good Manufacturing Principles ("cGMP") manufacturing of the Company's recombinant protein, Human DNase I. The parties agreed to enter into a Master Services Agreement 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.

***Other Agreements***

We have also entered into various research, development, license and supply agreements with Serum Institute of India ("Serum Institute"), Pharmsynthez and SynBio, a wholly owned subsidiary of Pharmsynthez. Our collaborative partners continued to engage in research and development activities with no resultant commercial products through December 31, 2024. No amounts were recognized as revenue related to the Serum Institute, Pharmsynthez or SynBio agreements during each of the years ended December 31, 2024 and 2023.

**Our Intellectual Property**

We strive to protect and enhance the proprietary technology, inventions and improvements that are commercially important to our business, including seeking, maintaining and defending patent rights, whether developed internally or licensed from our collaborators or other third parties. Our policy is to seek to protect our proprietary position by, among other methods, filing patent applications in the U.S. and in jurisdictions outside of the U.S. covering our proprietary technology, inventions, improvements and product candidates that are important to the development and implementation of our business. We also rely on trade secrets and know-how relating to our proprietary technology and product candidates, continuing innovation and in-licensing opportunities to develop, strengthen and maintain our proprietary position in the field of oncology. We also plan to rely on data exclusivity, market exclusivity and patent term and supplemental patent certificate extensions when available. Our commercial success will depend in part on our ability to obtain and maintain patent and other proprietary protection for our technology, inventions and improvements; to preserve the confidentiality of our trade secrets; to obtain and maintain licenses to use intellectual property owned by third parties; to defend and enforce our proprietary rights, including any patents that we may own in the future; and to operate without infringing on the valid and enforceable patents and other proprietary rights of third parties.

Our drug candidates are in various stages of development, each protected by patent and pending patent applications in the U.S. with the U.S. Patent and Trademark Office ("USPTO") and in certain other developed countries. Our first issued patents began to expire in 2021 with the remaining PolyXen technology expiring in 2040. As these PolyXen related patents approach their expiration, we have not renewed these patents for the last years of their life. Our XCART and XDNASE patent families include patent applications that were recently filed, with those most recently filed having an expiration date of 2042.

Our patent strategy is to file patent applications on innovations and improvements in those jurisdictions that comprise the major pharmaceutical markets in the world or locations where a pharmaceutical may be manufactured. These jurisdictions generally include for our key patent portfolios, but are not limited to, the U.S., U.K., Australia, Japan, Canada, South Korea, China, India, Russia and certain other countries in the European Union ("E.U."), though we do not necessarily file a patent application in each of these jurisdictions for every patent family.

As of February 28, 2025, we directly or indirectly own (e.g., through a license with CLS), through our wholly-owned subsidiaries, Hesperix and Xenetic U.K., and Xenetic U.K.'s wholly-owned subsidiaries, Lipoxen, XTI and SymbioTec, 35 U.S. and international patents and pending patent applications that cover various aspects of our technologies. This number includes patents and patent applications that we have acquired or filed covering various aspects of our XDNASE and XCART platform technology, including all rights throughout the world in and to patents and patent applications related to "Articles And Methods Directed To Personalized Therapy Of Cancer," and our PolyXen platform technology covering polysialylation and advanced polymer conjugate technologies, respectively, as well as our other product candidates. More specifically, our patents and patent applications cover cancer treatments, method of use, drug conjugates, formulations, along with methods of administering polymer conjugates.

We have also received patent protection for our XDNASE technology, which covers the use of DNase for the treatment of cancer and amelioration of the side effects associated with a cancer treatment. The DNase can be administered alone or in combination with a cancer therapeutic. This portfolio and that of the XCART portfolio also provide coverage for the use of certain types of CAR-T cells, with or without the addition of a DNase to treat a cancer. The portfolio further covers the use of CAR-T cells with or without DNase that are administered with an immune checkpoint inhibitor or modulator to treat a cancer.

Issued patents can provide protection for varying periods of time, depending upon the date of filing of the patent application, the date of patent issuance and the legal term of patents in the countries in which they are obtained. In general, patents issued for applications filed in the U.S. can provide exclusionary rights for twenty years from the earliest effective filing date. In addition, in certain instances, the term of an issued U.S. patent that covers or claims an FDA approved product can be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period, which is called patent term extension in the United States and supplemental patent certificate in Europe and several other countries. The restoration period cannot be longer than five years, and the total patent term, including the restoration period, must not exceed fourteen years following FDA approval. The term of patents outside of the U.S. varies in accordance with the laws of the foreign jurisdiction but is typically also twenty years from the earliest effective filing date. However, the actual protection afforded by a patent varies on a product-by-product basis, from country-to-country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

In certain situations, where we work with drugs covered by one or more patents, our ability to develop and commercialize our technologies may be affected by limitations of our access to these proprietary drugs. Even if we believe we are free to work with a proprietary drug, we cannot guarantee that we will not be accused of, or be determined to be, infringing on a third party's rights and be prohibited from working with the drug or found liable for damages. Any such restriction on access or liability for damages would have a material adverse effect on our business, results of operations and financial condition.

The patent positions of pharmaceutical and biotechnology companies, such as ours, are uncertain and involve complex legal and factual issues. There can be no assurance that patents that have been issued will be held valid and enforceable in a court of law. Even for patents that are held valid and enforceable, the legal process associated with obtaining such a judgment is time consuming and costly. Additionally, issued patents can be subject to opposition or other proceedings that can result in the revocation of the patent or maintenance of the patent in amended form (and potentially in a form that renders the patent without commercially relevant and/or broad coverage). Further, our competitors may be able to circumvent and otherwise design around our patents. Even if a patent is issued and enforceable, because development and commercialization of pharmaceutical products can be subject to substantial delays, patents may expire early and provide only a short period of protection, if any, following the commercialization of products encompassed by our patent(s). We may have to participate in interference proceedings declared by the USPTO, which could result in a loss of the patent and/or substantial cost to us. Further, we understand that if any of our pending patent applications do not issue, or are deemed invalid following issuance, we may lose valuable IP protection.

U.S. and foreign patent rights and other proprietary rights exist that are owned by third parties and relate to pharmaceutical compositions and reagents, medical devices and equipment and methods for preparation, packaging and delivery of pharmaceutical compositions. We cannot predict with any certainty which, if any, of these rights will be considered relevant to our technology by authorities in the various jurisdictions where such rights exist, nor can we predict with certainty which, if any, of these rights will or may be asserted against us by third parties. We could incur substantial costs in defending ourselves and our partners against any such claims. Furthermore, parties making such claims may be able to obtain injunctive or other equitable relief, which could effectively block our ability to develop or commercialize some or all of our products in the U.S. and in other countries and could result in the award of substantial damages. In the event of a claim of infringement, we or our partners may be required to obtain one or more licenses from third parties. There can be no assurance that we can obtain a license to any technology that we determine we require on reasonable terms, if at all, or that we could develop or otherwise obtain alternative technology. The failure to obtain licenses, if required, may have a material adverse effect on our business, results of operations and financial condition. Further, we may not be able to obtain IP licenses related to the development of our drug candidates on a commercially reasonable basis, if at all.

It is our policy to require our employees and consultants, outside scientific collaborators, sponsored researchers and other advisors who receive confidential information from us to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. The agreements provide that all inventions conceived by an employee shall be our property. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for our trade secrets in the event of unauthorized use or disclosure of such information.

**Manufacturing and Supply**

We do not have the capability to manufacture our own materials necessary to support our drug candidate development programs nor do we intend to acquire such capability as part of our present business strategy. We currently have the SOW in place with Catalent to produce clinical materials for use in the development of drug candidates involving our DNase technology.

**Government Regulation**

***General***

Government authorities in the U.S. at the federal, state and local level, and other countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing and export and import of products such as those we are developing. Generally, a new drug must be approved by the FDA through the NDA process and a new biologic must be licensed by the FDA through the biologics license application ("BLA") process before it may be legally marketed in the U.S.

**U.S. Regulation**

***Drug Development Process***

In the U.S., the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act ("FDCA"), and in the case of biologics, also under the Public Health Service Act ("PHSA") and the FDCA, and their implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant to administrative actions or judicial sanctions. These actions or sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, required additional studies, license revocation, a clinical hold, warning letters or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Prior to marketing a drug or biologic in the U.S. the drug or biologic sponsor generally must complete the following steps:

- completion of preclinical laboratory tests, animal studies and formulation studies in accordance with Good Laboratory Practices ("GLP") regulations and other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials in accordance with Good Clinical Practice ("GCP") regulations to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of an NDA or BLA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with cGMPs requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and
- FDA review and approval of the NDA or BLA.

The drug or biologic manufacturer may also be subject to post-approval regulatory requirements. Once a pharmaceutical candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. The sponsor will also include a protocol detailing, among other things, the objectives of the first phase of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated, if the first phase lends itself to an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective thirty days after receipt by the FDA, unless the FDA, within the thirty-day time period, places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds may also be imposed by the FDA at any time before or during clinical trials due to safety concerns about ongoing or proposed clinical trials or noncompliance with specific FDA requirements, and the trials may not begin or continue until the FDA notifies the sponsor that the hold has been lifted.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCP regulations. They must be conducted under protocols detailing the objectives of the trial, dosing procedures, subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and timely safety reports must be submitted to the FDA if any serious and unexpected adverse events occur. An institutional review board ("IRB") at each institution participating in the clinical trial (or in some cases an independent IRB) must review and approve each protocol before a clinical trial commences at that institution. As part of its review, the IRB must also approve the information regarding the trial and the consent form that must be provided to each trial subject or his or her legal representative, monitor the study until completion and otherwise comply with IRB regulations.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- ***Phase I***: The drug candidate is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.

- ***Phase II***: This phase involves clinical trials in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and appropriate dosage.

- ***Phase III***: Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These clinical trials are intended to establish the overall risk-benefit ratio of the drug candidate and provide, if appropriate, an adequate basis for product labeling.

Post-approval trials, sometimes referred to as Phase IV studies, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase IV clinical trials as a condition of approval of an NDA or BLA.

The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. In addition, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial.

Concurrent with clinical trials, sponsors must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. In addition, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

While the IND is active and before approval, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report must be submitted at least annually to the FDA by the Sponsor, and written IND safety reports must be submitted to the FDA for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or in-vitro testing suggesting a significant risk to humans and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

There are also requirements governing the reporting of ongoing clinical trials and completed trial results to public registries. Sponsors of certain clinical trials of FDA-regulated products are required to register and disclose specified clinical trial information, which is publicly available at www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, trial sites and investigators and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved.

***U.S. Market Approval Process***

The results of product development, preclinical and other non-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information will be submitted to the FDA as part of an NDA or BLA requesting approval to market the product. The submission of an NDA or BLA is subject to the payment of user fees; a waiver of such fees may be obtained under certain limited circumstances. The FDA reviews all NDAs and BLAs submitted to ensure they are sufficiently complete for substantive review before it accepts them for filing. The FDA may request additional information rather than accept an NDA or BLA for filing. In this event, the NDA or BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing.

Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA may refer the NDA or BLA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. The approval process is lengthy and often difficult, and the FDA may refuse to approve an NDA or BLA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data and information. Even if such data and information are submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. The FDA reviews a BLA to determine, among other things whether the product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. Before approving an NDA or BLA, the FDA will inspect the facility or facilities where the product is manufactured.

After the FDA evaluates an NDA or BLA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes the specific deficiencies in the NDA or BLA identified by the FDA and may require additional clinical data, such as an additional pivotal Phase III trial or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a Complete Response Letter is issued, the sponsor must resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA or BLA does not satisfy the criteria for approval.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, the FDA may require a sponsor to conduct Phase IV testing, which involves clinical trials designed to further assess a drug's safety and effectiveness after NDA or BLA approval, and may require testing and surveillance programs to monitor the safety of approved products which have been commercialized. The FDA may also place other conditions on approval including the requirement for a risk evaluation and mitigation strategy ("REMS") to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS. The FDA will not approve the NDA or BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Marketing approval may be withdrawn for noncompliance with regulatory requirements or if problems occur following initial marketing.

***Orphan Drug Act***

The Orphan Drug Act provides incentives to manufacturers to develop and market drugs or biologics for rare diseases and conditions affecting fewer than 200,000 persons in the U.S. at the time of application for orphan drug designation or for a patient population greater than 200,000 in the U.S. where there is no reasonable expectation that the cost of developing the drug or biologic will be recovered from sales in the U.S. The first developer to receive FDA marketing approval for an orphan drug is entitled to a seven-year exclusive marketing period in the U.S. for that product. However, a drug that the FDA considers to be clinically superior to, or different from, another approved orphan drug, even though for the same indication, may also obtain approval in the U.S. during the seven-year exclusive marketing period. In addition, holders of exclusivity for orphan drugs are expected to assure the availability of sufficient quantities of their orphan drugs to meet the needs of patients. Failure to do so could result in the withdrawal of marketing exclusivity for the drug.

***Pediatric Information***

Under the Pediatric Research Equity Act of 2007 ("PREA"), NDAs or BLAs or supplements to NDAs or BLAs must contain data to assess the safety and effectiveness of the drug for the claimed indication(s) in all relevant pediatric sub-populations and to support dosing and administration for each pediatric sub-population for which the drug is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan drug designation has been granted. The Best Pharmaceuticals for Children Act ("BPCA") provides sponsors of NDAs with an additional six-month period of market exclusivity for all unexpired patent or non-patent exclusivity on all forms of the drug containing the active moiety if the sponsor submits results of pediatric studies specifically requested by the FDA under BPCA within required timeframes. The Biologics Price Competition and Innovation Act provides sponsors of BLAs an additional six-month extension for all unexpired non-patent market exclusivity on all forms of the biologic containing the active moiety pursuant to the BPCA if the conditions under the BPCA are met.

The Food and Drug Administration Safety and Innovation Act ("FDASIA"), which was signed into law on July 9, 2012, amended the FDCA. FDASIA requires that a sponsor who is planning to submit a marketing application for a drug or biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan ("PSP") within sixty days of an end-of-Phase II meeting or as may be agreed between the sponsor and FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from nonclinical studies, early phase clinical trials, and/or other clinical development programs.

***Expedited Development and Review Programs***

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug or biologic may request the FDA to designate the drug or biologic as a Fast Track product at any time during the clinical development of the product. For a Fast Track designated product, the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

Any product submitted to the FDA for marketing, including under a Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Fast Track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process. Any product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biological product designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. If the FDA concludes that a drug shown to be effective can be safely used only if distribution or use is restricted, it will require such post-marketing restrictions as it deems necessary to assure safe use of the drug, such as (i) distribution restricted to certain facilities or physicians with special training or experience or (ii) distribution conditioned on the performance of specified medical procedures.

FDASIA established a new category of drugs and biologics referred to as "breakthrough therapies" that may be eligible to receive Breakthrough Therapy Designation. A sponsor may seek FDA designation of a drug or biologic candidate as a "breakthrough therapy" if the product is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the Fast Track program features, as well as more intensive FDA interaction and guidance. The Breakthrough Therapy Designation is a distinct status from both accelerated approval and priority review, which can also be granted to the same drug if relevant criteria are met. If a product is designated as breakthrough therapy, the FDA will expedite the development and review of such drug. All requests for breakthrough therapy designation will be reviewed within 60 days of receipt, and the FDA will either grant or deny the request.

The 21st Century Cures Act, enacted in 2016, established a new expedited approval program for regenerative medicine products, including cell and gene therapies. The Regenerative Medicine Advanced Therapy ("RMAT") program established an expedited review program to facilitate development and review of regenerative medicine therapies intended to address an unmet medical need in patients with serious conditions. An investigational drug is eligible for RMAT designation if: (1) It meets the definition of regenerative medicine therapy (such as a cell therapy or gene therapy); (2) it is intended to treat, modify, reverse, or cure a serious condition; and (3) preliminary clinical evidence indicates that the regenerative medicine therapy has the potential to address unmet medical needs for such condition. Advantages of the RMAT designation include all the benefits of the fast track and breakthrough therapy designation programs, including early interactions with FDA.

***Post-Approval Requirements***

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements or standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. After approval, some types of changes to the approved product, such as adding new indications, certain manufacturing changes and additional labeling claims, are subject to further FDA review and approval. Drug and biologics manufacturers and other entities involved in the manufacture and distribution of approved drugs and biologics are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP regulations and other laws and regulations.

***U.S. Patent Term Restoration and Marketing Exclusivity***

The Biologics Price Competition and Innovation Act, or BPCIA, amended the Public Health Service Act to authorize the FDA to approve similar versions of innovative biologics, commonly known as biosimilars. A competitor seeking approval of a biosimilar must file an application to establish its molecule as highly similar to an approved innovator biologic, among other requirements. The BPCIA, however, bars the FDA from approving biosimilar applications based on the Company's data for twelve years after an innovator biological product receives initial marketing approval. This twelve-year period of data exclusivity may be extended by six months, for a total of twelve and a half years, if the FDA requests that the innovator company conduct pediatric clinical investigations of the product.

Depending upon the timing, duration and specifics of the FDA approval of our drug candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term extension cannot extend the remaining term of a patent beyond a total of fourteen years from the product's approval date. The patent term extension period is generally one-half the time between the effective date of an IND and the submission date of an NDA or BLA plus the time between the submission date of an NDA or BLA and the approval of that application up to a maximum of five years extension. Only one patent applicable to an approved drug is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for extension of the patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date where reasonably obtainable and depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA or BLA.

Marketing exclusivity provisions under the FDCA can also delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the U.S. to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application (ANDA), or a 505(b)(2) NDA submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovator drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder. The FDCA also provides three years of marketing exclusivity for an NDA or supplement to an existing NDA if new clinical investigations (other than bioavailability studies) that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application (e.g., new indications, dosages or strengths of an existing drug). This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of regulatory market exclusivity in the U.S. under the BPCA. Pediatric exclusivity provides for an additional six months of marketing exclusivity if a sponsor conducts clinical trials in children as addressed in the section named "Pediatric Information" above. In addition, orphan drug exclusivity, as described above, may offer a seven-year period of marketing exclusivity, except in certain circumstances.

***Foreign Regulation***

In addition to regulations in the U.S., we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our drug candidates.

Whether or not we obtain FDA approval for our drug candidates, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the drug candidates in those countries. Certain countries outside of the U.S. have a similar process that requires the submission of a clinical trial application ("CTA") much like the IND prior to the commencement of human clinical trials. In the European Union, for example, a CTA must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and the IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical study development may proceed.

The requirements and process governing the conduct of clinical trials, product approval and licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational drug or biological product under European Union regulatory systems, we must submit a marketing authorization application. The application used to file the NDA or BLA in the U.S. is similar to that required in the European Union, with the exception of, among other things, country-specific document requirements. The European Union also provides opportunities for market exclusivity. For example, in the European Union, upon receiving marketing authorization, new chemical entities generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic application. During the additional two-year period of market exclusivity, a generic marketing authorization can be submitted, and the innovator's data may be referenced, but no generic product can be marketed until the expiration of the market exclusivity. However, there is no guarantee that a product will be considered by the European Union's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity. Products receiving orphan designation in the European Union can receive ten years of market exclusivity, during which time no similar medicinal product for the same indication may be placed on the market. An orphan product can also obtain an additional two years of market exclusivity in the European Union for pediatric studies. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications.

The criteria for designating an "orphan medicinal product" in the European Union are similar in principle to those in the U.S. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the European Union when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the European Union to justify investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the European Union, or if such a method exists, the product will be of significant benefit to those affected by the condition, as defined in Regulation (EC) 847/2000. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity for the approved therapeutic indication. The application for orphan drug designation must be submitted before the application for marketing authorization. The applicant will receive a fee reduction for the marketing authorization application if the orphan drug designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The 10-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. In addition, marketing authorization may be granted to a similar product for the same indication at any time if:

- the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior;
- the applicant consents to a second orphan medicinal product application; or
- the applicant cannot supply enough orphan medicinal products.

For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical studies, product licensing or approval, pricing and reimbursement vary from country to country. In all cases, again, the clinical studies are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

***Other Regulatory Matters***

Manufacturing, sales, promotion and other activities following product approval are also potentially subject to regulation by numerous regulatory authorities in addition to the FDA, including, in the U.S., the Centers for Medicare & Medicaid Services, other divisions of the Department of Health and Human Services, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments. In the U.S., sales, marketing and scientific/educational programs must also comply with state and federal fraud and abuse laws, including state and federal anti-kickback, false claims, data privacy and security and physician payment transparency laws. Pricing and rebate programs must comply with the federal health care program (e.g., Medicaid) rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively the Affordable Care Act, as well as the Inflation Reduction Act of 2022. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. The handling of any controlled substances must comply with the U.S. Controlled Substances Act and Controlled Substances Import and Export Act. Products must meet applicable

child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities are also potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The failure to comply with regulatory requirements may subject us to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of product approvals or refusal to allow a firm to enter into supply contracts, including government contracts. In addition, even if a firm complies with FDA and other requirements, new information regarding the safety or efficacy of a product could lead the FDA to modify or withdraw product approval. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes or the interpretation of existing regulations, including those resulting from the new Trump Administration or the Executive Branch's actions, could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

**Reimbursement**

In both domestic and foreign markets, sales and reimbursement of any approved products will depend, in part, on the extent to which the costs of such products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly challenging the prices charged for medical products and services and imposing controls to manage costs. The containment of healthcare costs has become a priority of federal and state governments and the prices of drugs have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. For example, in the U.S. there have been several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare and reform government program reimbursement methodologies for drugs. Additionally, in May 2018, the Trump Administration laid out a "Blueprint" to lower drug prices and reduce out-of-pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out-of-pocket costs of drug products paid by consumers. In December of 2020, the Trump Administration issued interim final rules focused on attempting to lower drug prices, including permitting the importation of certain drugs from Canada, most-favored nation pricing for certain drug categories under Medicare Part B and modifications to the Medicare Part D drug rebate program by modifying the U.S. federal Anti-Kickback Statute. The Part B most-favored nation rule was blocked from taking effect on January 4, 2021, by a federal judge stating that the rule was rushed and the public was not provided time to give comment as required by the Administrative Procedures Act. Then, on December 29, 2021, CMS issued a final rule that formally rescinded the most-favored nation rule. There is also pending litigation to stay the changes to the Medicare Part D drug rebate program and the Anti-Kickback Statute. On January 30, 2021, the District Court for the District of Columbia granted the parties' stipulated request to delay the effective date of the Part D rebate rule to January 1, 2023. On August 7, 2022, Congress passed the Inflation Reduction Act of 2022 which delayed the implementation of the changes to the Medicare Part D drug rebate program and the U.S. Federal Anti-Kickback Statute until January 2032. As a result of the 2024 presidential election, it is unclear whether the new Trump Administration will renew, resume, or enact any similar efforts or proposals that may impact drug pricing and/or drug reimbursement in the U.S.

Additionally, the Inflation Reduction Act of 2022 may impact existing Medicare programs that cover prescription drugs. In addition to other relevant provisions, the Inflation Reduction Act of 2022 allow the Medicare program to directly negotiate the price of certain high-expenditure prescription drugs covered under Medicare Parts B and D, starting in the year 2028 and 2026, respectively, by setting certain "maximum fair prices." Moreover, the Inflation Reduction Act of 2022 requires manufacturers to pay rebates to the federal government if prices of certain drugs covered under the Medicare program rise faster than the rate of inflation.

More broadly, in 2024, the U.S. Supreme Court in *Loper Bright Enterprises v. Raimondo*, overturned the long-standing "Chevron" doctrine, which had accorded deference to an agency's interpretation of ambiguous laws since 1984. Following the *Loper* decision, the healthcare space may face increased judicial scrutiny of agency regulations, as courts are no longer required to defer to federal agencies' interpretations of ambiguous statutes. Although the full impact of this reversal remains to be seen, this change could lead to significant alterations in how healthcare laws and regulations are applied and enforced.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, to encourage importation from other countries and bulk purchasing.

Within the U.S., if we obtain appropriate approval in the future to market any of our product candidates, we may seek approval and coverage for those products under Medicaid, Medicare and the Public Health Service, or PHS, pharmaceutical pricing program and may also seek to sell the products to federal agencies. Medicaid is a joint federal and state program that is administered by the states for low-income and disabled beneficiaries. Under the Medicaid Drug Rebate Program, manufacturers are required to pay a rebate for each unit of product reimbursed by the state Medicaid programs. The amount of the rebate for each product is set by law and may be subject to an additional discount if certain pricing increases more than inflation. Medicare is a federal program administered by the federal government that covers individuals age 65 and over as well as those with certain disabilities. Medicare Part D provides coverage to enrolled Medicare patients for self-administered drugs (i.e., drugs that do not need to be administered by a physician). Medicare Part D is administered by private prescription drug plans approved by the U.S. government, and each drug plan and/or pharmacy benefit manager establishes its own Medicare Part D formulary for prescription drug coverage and pricing, which the drug plan and/or pharmacy benefit manager may modify from time-to-time. Medicare Part B covers most injectable drugs given in an in-patient setting and some drugs administered by a licensed medical provider in hospital outpatient departments and doctors' offices. Medicare Part B is administered by Medicare Administrative Contractors, which generally have the responsibility of making coverage decisions. Subject to certain payment adjustments and limits, Medicare generally pays for Part B covered drugs based on a percentage of manufacturer-reported average sales price. Drug products are subject to discounted pricing when purchased by federal agencies via the Federal Supply Schedule, or FSS. FSS participation is required for a drug product to be covered and paid for by certain federal agencies and for coverage under Medicaid, Medicare Part B and the PHS pharmaceutical pricing program. FSS pricing is negotiated periodically with the Department of Veterans Affairs. FSS pricing is intended to not exceed the price that a manufacturer charges its most-favored non-federal customer for its product. In addition, prices for drugs purchased by the Veterans Administration, Department of Defense (including drugs purchased by military personnel and dependents through the TRICARE retail pharmacy program), Coast Guard and PHS are subject to a cap on pricing (known as the "federal ceiling price") and may be subject to an additional discount if pricing increases more than inflation. To maintain coverage of drugs under the Medicaid Drug Rebate Program, manufacturers are required to extend discounts to certain purchasers under the PHS pharmaceutical pricing program. Purchasers eligible for discounts include hospitals that serve a disproportionate share of financially-needy patients, community health clinics and other entities that receive health services grants from the PHS.

In March 2010, the U.S. Congress enacted the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act, or the Affordable Care Act, which included changes to the coverage and payment for drug products under government health care programs. Since its enactment, there have been judicial and Congressional challenges to numerous elements of the Affordable Care Act, as well as efforts by both the executive and legislative branches of the federal government to repeal or replace certain aspects of the Affordable Care Act. For example, President Trump signed Executive Orders designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. In addition, the U.S. Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the Affordable Care Act, such as removing penalties, starting January 1, 2019, for not complying with the Affordable Care Act's individual mandate to carry health insurance, delaying the implementation of certain mandated fees and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. In December 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017, or the Tax Act. Although the Supreme Court ruled the plaintiffs did not have standing in June of 2021, any other executive, legislative or judicial action to "repeal and replace" all or part of the Affordable Care Act may have the effect of limiting the amounts that government agencies will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure, or may lead to significant deregulation, which could make the introduction of competing products and technologies much easier.

Regardless of the future of the Affordable Care Act provisions, the Congress will continue to debate a range of policies that could impact the prices pharmaceutical companies charge for products or how much they are reimbursed. Moreover, whether and to what extent the new Trump Administration will take actions, whether through new legislation, changes in regulations, or Executive Orders, that may impact pricing and/or reimbursement for pharmaceutical products remains to be seen.

**Environmental Regulation**

In addition to being subject to extensive regulation by the FDA, we must also comply with environmental regulation insofar as such regulation applies to us or our drug candidates. Our costs of compliance with environmental regulation as applied to similar pharmaceutical companies are minimal, since we do not currently, nor do we intend to, engage in the manufacturing of any of our drug candidates. We currently use unaffiliated manufacturers to produce all of our drug candidate material and receive final material from such manufacturer, without any involvement on our part in the manufacturing process at any stage of the process.

Although we believe that our safety procedures for using, handling, storing and disposing of our drug candidate materials comply with the environmental standards required by state and federal laws and regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. We do not carry a specific insurance policy to mitigate this risk to us or to the environment.

**Employees**

At December 31, 2024, we employed two full-time employees. We are not a party to any collective bargaining agreement with our employees, nor are any of our employees a member of any labor unions.

To complement our own professional staff, we utilize specialists in regulatory affairs, pharmacovigilance, process engineering, manufacturing, quality assurance, preclinical and clinical development, accounting and business development. These individuals include scientific advisors as well as independent consultants.

**Competition**

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition, and a strong emphasis on proprietary products. While we believe that our technology, development experience and scientific knowledge provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

Many of our competitors may have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology, and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

The key competitive factors affecting the success of all our product candidates, if approved, are likely to be their efficacy, safety, side effects, convenience, price, the level of generic competition, and the availability of reimbursement from government and other third-party payors.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products. There are many generic products currently on the market for the indications that we are pursuing, and additional products are expected to become available on a generic basis over the coming years. If our therapeutic product candidates are approved, we expect that they will be priced at a significant premium over competitive generic products.

The most common methods of treating patients with cancer are surgery, radiation and drug therapy, including chemotherapy, hormone therapy, immunotherapy, and targeted drug therapy. There are a variety of available drug therapies marketed for cancer. In many cases, these drugs are administered in combination to enhance efficacy. To the extent our product candidates are ultimately used in combination with or as an adjunct to existing drug or other therapies, our product candidates will not be competitive with them. Some of the currently approved drug therapies are branded and subject to patent protection, and others are available on a generic basis. Many of these approved drugs are well established therapies and are widely accepted by physicians, patients and third-party payors. In general, although there has been considerable progress over the past few decades in the treatment of cancer and the currently marketed therapies provide benefits to many patients, these therapies all are limited to some extent in their efficacy and frequency of adverse events, and none of them are successful in treating all patients. As a result, the level of morbidity and mortality from cancer remains high.

**DNase for pancreatic cancer and solid tumors**

In the field of pancreatic cancer, we will compete with the few, currently approved treatments for pancreatic carcinoma, including pancreatic ductal adenocarcinoma ("PDAC"). In the first line setting, Gemcitabine in combination with Abraxane® or FOLFIRINOX regimen are the current standard of care, although NALIRIFOX, which substitutes liposomal irinotecan (Onivyde) for irinotecan, recently received FDA approval for first-line treatment of metastatic pancreatic adenocarcinoma. Oncologists have limited options of existing therapies for second-line metastatic patients. The only FDA-approved second-line treatment is Onivyde® in combination with Fluorouracil (5FU) and leucovorin (LV) for gemcitabine-treated patients. In addition to chemotherapy, Merck's KEYTRUDA® was approved for MSI-H cancers (approximately 1% of all cases) and Lynparza® was approved for maintenance of BRCA (or "BReast CAncer gene") mutated pancreatic cancer (approximately 7% of all cases).

In the last years there have been a number of late-stage clinical failures of compounds for advanced PDAC. Most of these failed trials have been based on a single promising endpoint. There are very few compounds in advanced stages of development in PDAC.

With respect to other solid tumors, there are a large number of companies developing treatments intended to be used in combination with approved immunotherapies, including immune checkpoint inhibitors, to treat a variety of solid tumor indications. In the field of CRC, there are numerous approved treatments for CRC diagnosed at earlier stages. However, for mCRC, chemotherapy remains the mainstay of systemic treatment for MSS/MMRp mCRC, which at 95%, represent the majority of mCRC patients. Chemotherapy regimens will typically consist of a fluoropyrimidine (5-FU or capecitabine) paired in a two-drug regimen (doublet) with irinotecan or oxaliplatin. Treatment regimens can be 5-FU- or capecitabine-based and can be either oxaliplatin-based (FOLFOX or CAPEOX) or irinotecan- based (FOLFIRI or CAPIRI) with no difference in survival. Regimens with a three-drug (triplet) combination, FOLFIRINOX or FOLFOXIRI, are also available as first-line therapy and are commonly paired with the anti-VEGF antibody bevacizumab. Second-line therapy is tailored according to previous therapies. In general, patients who receive oxaliplatin-based chemotherapy upfront should be treated with irinotecan-based chemotherapy and vice versa [20–22]. Biologics such as aflibercept ramucirumab are added based on molecular profiling. After progression on second-line therapy, patients with RAS/BRAF wild-type disease receive an EGFR inhibitor combined with irinotecan. Alternatively, if they have HER2 mutation, trastuzumab is typically preferred. Patients with the $BRAF^{V600E}$ mutation typically receive an encorafenib-cetuximab regimen.

For those 5% of patients with MSI-H/dMMR mCRC, immune checkpoint inhibitors are now the preferred first line therapy. However, 50% of those will fail and the therapeutic options then become very limited. Immunotherapy is so far largely considered ineffective in MSS/MMRp mCRC. We will compete with novel combinations of ICIs with conventional cancer drugs or immunotherapeutics that have started to expose vulnerabilities in MSS/MMRp mCRC. These include dual immune checkpoint inhibition of both the PD-1/L1 axis and CTLA-4. Other combinations being explored include immunotherapies combined with anti-EGFR antibodies, small molecule VEGFR inhibitors, small molecule inhibitors against other targets (for example, KRAS), and novel ICIs targeting lymphocyte activation gene 3 (LAG3). These combination have shown modest benefit and with the exception of LAG3, do not directly address the main reasons for ICI failure, which are lower mutation and neoantigen loads in MSS/MMRp mCRC compared to MSI-H/MMRd mCRC, and immunosuppression.

**PSA for Drug Delivery**

Current competing platforms include PEGylation, Fc-fusion, albumin-fusion, HESylation, PASylation, and CTP-fusion, among others as well as those of academic institutions and other smaller pharmaceutical companies engaged in drug development. In addition to competing with universities and other research institutions in the development of drug products, therapies, technologies and processes, we may compete with other companies in acquiring rights to products or technologies from universities.

**Available Information**

Our website address is www.xeneticbio.com. The information on, or that can be accessed through, our website is not part of this Annual Report on Form 10-K. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K and amendments to those reports are available, free of charge, on or through our website as soon as practicable after we electronically file such forms, or furnish them to, the SEC. The SEC maintains an internet site that contains reports, proxy and information statements and other information regarding our filings at www.sec.gov.

In addition to disclosing current information pursuant to Section 13 or 15(d) of the Exchange Act and for reports of information required to be disclosed by Regulation FD through our SEC filings, we also intend to disclose such current information through our investor relations website, press releases, public conference calls and webcasts.

## ITEM 1A – RISK FACTORS

*Our business is subject to numerous risks. You should consider carefully the risks and uncertainties described below, in addition to other information contained in this Annual Report as well as our other public filings with the Securities and Exchange Commission. Any of the following risks could have a material adverse effect on our business, financial condition, results of operations and prospects and cause the trading price of our common stock to decline.*

### Risks Related to Our Financial Condition and Capital Requirements

***We have never been profitable and may never achieve or sustain profitability. If we are unable to generate sufficient revenue from our operations to pay expenses or we are unable to obtain additional financing on commercially reasonable terms, our business, financial condition and results of operations may be materially and adversely affected.***

We are a clinical-stage biopharmaceutical company with a limited operating history. Pharmaceutical product and technology development is a highly speculative undertaking and involves a substantial degree of risk. We have no products approved for commercial sale and have generated only limited revenue to date. Our primary focus is now on advancing our DNase technology via partnering opportunities or through regulatory approval and commercialization. We expect to continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we have never been profitable and we may not achieve profitability in the foreseeable future, if at all. Our ability to generate profits in the future will depend on a number of factors, including:

- Funding the costs relating to the research and development, regulatory approval, commercialization and sale and marketing of our drug candidates and technologies;
- Market acceptance of our drug candidates and technologies;
- Costs of acquiring and developing new drug candidates and technologies;
- Ability to bring our drug candidates to market;
- General and administrative costs relating to our operations;
- Increases in our research and development costs;
- Charges related to purchases of technology or other assets;
- Establishing, maintaining and protecting our intellectual property rights;
- Attracting, hiring and retaining qualified personnel; and
- Our ability to raise additional capital.

As of December 31, 2024, we had an accumulated deficit of approximately $197.2 million. We expect to incur additional significant operating losses as we expand our research and development activities and our commercialization, marketing and sales efforts. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. In addition, because of the numerous risks and uncertainties associated with pharmaceutical product development, including that our current drug candidates may not achieve the clinical endpoints of applicable trials, we are unable to predict the timing or amount of increased expenses and if or when we will achieve or maintain profitability. If we are unable to generate sufficient revenue from our operations to pay expenses or we are unable to obtain additional financing on commercially reasonable terms, our business, financial condition and results of operations may be materially and adversely affected.

***We will require substantial additional funding to achieve our goals. Failure to obtain this necessary capital when needed on acceptable terms, or at all, may force us to delay, limit or terminate our product development efforts, other operations or commercialization efforts.***

Developing drug candidates is an expensive, risky and lengthy process, and we expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, initiate clinical trials of, and seek marketing approval for, our drug candidates.

As of December 31, 2024, we had cash of approximately $6.2 million. We expect that we will require additional capital to commence and complete clinical trials, obtain regulatory approval for, and to commercialize, our drug candidates, including our other preclinical drug candidates and our future drug candidates. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned. Additional funding may come through public or private equity or debt financings, third-party funding, marketing and distribution arrangements or other collaborations, strategic alliances and licensing arrangements (or a combination of these approaches). In any event, we will require additional capital to pursue preclinical and clinical activities, pursue regulatory approval for, and to commercialize, our longer term pipeline drug candidates. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations.

Our ability to raise additional funds will depend on financial, economic, political, and market conditions and other factors over which we may have no or limited control. Market volatility resulting from economic, political or other factors, such as geopolitical tension, including the conflicts in the Ukraine and the Middle East, and any resulting sanctions, export controls or other restrictive actions, could also adversely impact our ability to access capital as and when needed. Additional funds may not be available when we need them, on terms and at a cost that are acceptable to us, or at all.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our drug candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may negatively impact the holdings or the rights of our stockholders, and the issuance of additional securities (whether equity or debt) by us, or the possibility of such issuance, may cause the market price of our shares to decline. The incurrence of indebtedness could result in increased fixed payment obligations, and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue our pre-clinical development program or the commercialization of any drug candidates. We may also be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could harm our business, financial condition and results of operations.

***Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or drug candidates.***

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity and debt financings, as well as selectively continuing to enter into collaborations, strategic alliances and licensing arrangements. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, equity interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Such debt financing may also be secured by all or a portion of our assets.

If we raise funds by selectively continuing to enter into collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish additional valuable rights to our technologies, future revenue streams, research programs or drug candidates, or we may have to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market drug candidates that we would otherwise prefer to develop and market ourselves. If we are unable to raise additional funds through collaborations, strategic alliances or licensing arrangements, we may be required to terminate product development or future commercialization efforts or to cease operations altogether.

**Risks Related to the Discovery and Development of our Pharmaceutical Products**

***Our business is substantially dependent on the success of the DNase technology.***

Our business will substantially depend on the successful clinical development, regulatory approval and commercialization of the DNase technology. It will require substantial clinical development and regulatory approval efforts before we are permitted to commence its commercialization, if ever. We have, and plan to continue to pursue our clinical development strategy through academic and strategic collaborations. If we have difficulty maintaining, obtaining, or are unable to obtain these collaborations and additional academic collaborations as planned, we may need to delay, limit or terminate any ongoing or planned clinical development, which would have an adverse effect on our business. The clinical trials and manufacturing and marketing of DNase and any other product candidates will be subject to extensive and rigorous review and regulation by numerous government authorities in the U.S., the European Union and other jurisdictions where we intend to test and, if approved, market our product candidates. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate through preclinical testing and clinical trials that the product candidate is safe and effective for use in each target indication and potentially in specific patient populations. This process can take many years and may include post-marketing studies and surveillance, which would require the expenditure of substantial resources beyond the proceeds we have currently raised. Of the large number of drugs in development for approval in the U.S. and the European Union, only a small percentage successfully complete the FDA or European Medicines Agency regulatory-approval processes, as applicable, and are commercialized. Accordingly, even if we are able to obtain the requisite financing or identify an academic or strategic collaboration partner to continue to fund our research, development and clinical programs, we cannot assure you that DNase or any of our other product candidates will be successfully developed or commercialized.

***We are an early stage company in the business of developing pharmaceutical products including drug candidates and technologies. Given the uncertainty of such development, our business operations may never fully materialize and create value for investors.***

We have invested substantially all of our efforts and financial resources in developing our products, and we currently do not have any products that have gained marketing approval. Our revenues currently consist primarily of royalty revenue from a single partner and not from product sales. Our ability to generate product revenues, which may not occur for several more years, if ever, will depend on the successful development and eventual commercialization of our drug candidates. We currently generate royalty revenue under a sub-license agreement but do not have revenue from sales of any drugs, and we may never be able to develop or commercialize a marketable drug. Each of our drug candidates will require development, management of development and manufacturing activities, marketing approval in multiple jurisdictions, obtaining manufacturing supply, building of a commercial organization, substantial investment and significant marketing efforts before we generate any revenues from drug sales. We have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly-evolving fields, particularly in the pharmaceutical area. For example, to execute our business plan we will need to successfully:

- Execute development activities for our drug candidates, including successful enrollment in and completion of clinical trials;
- Obtain required marketing approvals for the development and commercialization of our drug candidates;
- Obtain and maintain patent and trade secret protection or regulatory exclusivity for our drug candidates;
- Protect, leverage and expand our intellectual property portfolio;
- Establish and maintain clinical and commercial manufacturing capabilities or make arrangements with third-party manufacturers for clinical and commercial manufacturing;
- Build and maintain robust sales, distribution and marketing capabilities, either on our own or in collaboration with strategic partners, if our drug candidates are approved;
- Gain acceptance for our drug candidates, if approved, by patients, the medical community and third-party payors;
- Effectively compete with other therapies;
- Obtain and maintain healthcare coverages and adequate reimbursement;
- Maintain a continued acceptable safety profile for our drug candidates following approval;
- Develop and maintain any strategic relationships we elect to enter into, if any;
- Enforce and defend intellectual property rights and claims; and
- Manage our spending as costs and expenses increase due to preclinical development, clinical trials, marketing approvals and commercialization.

***We may find it difficult to enroll patients in our clinical studies, which could delay or prevent clinical studies of our pharmaceutical products.***

Identifying and qualifying patients to participate in clinical studies of our pharmaceutical products is critical to our success. The timing of our clinical studies depends on the speed at which we can recruit patients to participate in testing our pharmaceutical products. We may experience delays. If patients are unwilling to participate in our clinical studies because of negative publicity from adverse events in the biopharmaceutical industries or for other reasons, including competitive clinical studies for similar patient populations, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of potential products may be delayed. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology or termination of the clinical studies altogether.

We may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics to achieve diversity in a study, to complete our clinical studies in a timely manner. Patient enrollment is affected by many factors, including:

- Severity of the disease under investigation;
- Real or perceived availability of alternative treatments;
- Size and nature of the patient population;
- Eligibility criteria for and design of the trial in question;
- Perceived risks and benefits of the drug candidate under study;
- Proximity and availability of clinical sites for prospective patients;
- Ongoing clinical trials of potentially competitive agents;
- Physicians' and patients' perceptions as to the potential advantages of our drug candidates being studied in relation to available therapies or other products under development;
- Our CRO's and our trial sites' efforts to facilitate timely enrollment in clinical trials;
- Patient referral practices of physicians; and
- The need to monitor patients and collect patient data adequately during and after treatment.

We may not be able to initiate or continue clinical studies if we cannot enroll a sufficient number of eligible patients to participate in the clinical studies required by the FDA or other regulatory agencies. Our ability to successfully initiate, enroll and complete a clinical study in any foreign country is subject to numerous risks unique to conducting business in foreign countries, including:

- Difficulty in establishing or managing relationships with CROs and physicians;
- Different standards for the conduct of clinical studies;
- Our inability to locate qualified local consultants, physicians and partners; and
- The potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatment.

If we have difficulty enrolling a sufficient number of patients to conduct our clinical studies as planned, we may need to delay, limit or terminate ongoing or planned clinical studies, any of which would have an adverse effect on our business.

***We may encounter substantial delays in commencement, enrollment or completion of our clinical trials, or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities, which could prevent us from commercializing our current and future drug candidates on a timely basis, if at all.***

Before obtaining marketing approval from regulatory authorities for the sale of our current and future drug candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the drug candidates. We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical studies can occur at any stage of testing. Events that may prevent successful or timely completion of clinical development include:

- Delays in reaching a consensus with regulatory agencies on study design;
- Delays in reaching agreement on acceptable terms with prospective CROs and clinical study sites;
- Delays in obtaining required IRB, or Independent Ethics Committee approval at each clinical study site;
- Delays in recruiting suitable patients to participate in our clinical studies;
- Imposition of a clinical hold by regulatory agencies, including after an inspection of our clinical study operations or study sites;
- Failure by our CROs, other third parties or us to adhere to clinical study requirements;
- Failure to perform in accordance with the FDA's GCP or applicable regulatory requirements in other countries;
- Delays in the testing, validation, manufacturing and delivery of our drug candidates to the clinical sites;
- Delays in having patients complete participation in a study or return for post-treatment follow-up;
- Clinical study sites or patients dropping out of a study;
- Clinical trial results may fail to demonstrate the safety and/or efficacy of the drug candidate;
- Occurrence of serious adverse events associated with the drug candidate that are viewed to outweigh its potential benefits; or
- Changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

Any inability to successfully complete preclinical studies and clinical trials could result in additional costs to us or impair our ability to generate revenues from product sales, regulatory and commercialization milestones and royalties. In addition, if we make manufacturing or formulation changes to our drug candidates, we may need to conduct additional studies to bridge our modified drug candidates to earlier versions. Clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our drug candidates or allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our drug candidates and may harm our business, financial condition, results of operations and prospects.

If the results of our clinical studies are inconclusive or if there are safety concerns or adverse events associated with our pharmaceutical products, we may:

- Be delayed in obtaining marketing approval or licenses for our drug candidates, if we receive them at all;
- Obtain approval for indications or patient populations that are not as broad as intended or desired;
- Obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- Be subject to changes with the way the product is administered;
- Be required to perform additional clinical studies to support approval or be subject to additional post-marketing testing requirements;
- Have regulatory authorities withdraw their approval of the product or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy;
- Be subject to the addition of labeling statements, such as warnings or contraindications;
- Be sued; or
- Experience damage to our reputation.

As described above, any of these events could prevent us from achieving or maintaining market acceptance and approval of our pharmaceutical products and impair our ability to generate revenues.

***If we complete the necessary preclinical and clinical studies, we cannot predict when or if we will obtain regulatory approval to commercialize a drug candidate, or the approval may be for a more narrow indication than we expect.***

A drug candidate cannot be commercialized until the appropriate regulatory authorities have reviewed and approved the drug candidate. Even if our drug candidates demonstrate safety and efficacy in clinical studies, the regulatory agencies may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA Advisory Committee or other regulatory advisory group or authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action or changes in regulatory agency policy during the period of product development, clinical studies and the review process. Regulatory agencies also may approve a drug candidate for fewer or more limited indications than requested or may grant approval subject to the performance of post-marketing studies. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our drug candidates. Failure to obtain, or a delay in obtaining, regulatory approval to commercialize a drug candidate will impair our ability to generate revenues and harm our business prospects.

***If we obtain regulatory approval for a drug candidate, our drug candidate will remain subject to regulatory scrutiny.***

If our drug candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, reporting, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturing facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA, BLA or marketing authorization application ("MAA"). Accordingly, we and our collaborators and suppliers must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we or our collaboration partners receive for our drug candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval or may contain requirements for potentially costly additional clinical trials and surveillance to monitor the safety and efficacy of the drug candidate. We will be required to report certain adverse reactions, serious adverse events and production problems, if any, to the FDA and comparable foreign regulatory authorities. Any new legislation addressing drug safety or other issues related to regulatory review and approval could result in delays in product development or commercialization or increased costs to assure compliance. We will have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we are not allowed to promote our products for indications or uses for which they do not have approval. If our drug candidates are approved, we must submit new or supplemental applications and obtain approval for certain changes to the approved products, product labeling or manufacturing process. We could also be asked to conduct post-marketing clinical trials to verify the safety and efficacy of our products in general or in specific patient subsets. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with an approved product, such as adverse events of unanticipated severity or frequency or problems with our manufacturing facilities, or if a regulatory agency disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- Issue inspectional findings;
- Issue untitled and warning letters;
- Impose civil or criminal penalties;
- Suspend or withdraw regulatory approval or revoke a license;
- Suspend or hold any of our ongoing clinical trials;
- Require additional clinical trials;
- Refuse to approve pending applications or supplements to approved applications submitted by us;
- Impose restrictions on our operations, including closing our manufacturing facilities; or
- Seize or detain products or require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of the Company and our operating results will be negatively impacted.

***The commercial success of any current or future pharmaceutical products will depend upon the degree of market acceptance by physicians, patients, third-party payors and others in the medical community.***

Even with the requisite approvals, the commercial success of our pharmaceutical products will depend in part on the medical community, patients and third-party payors accepting our pharmaceutical products as medically useful, cost-effective and safe. Any pharmaceutical product that we, or our partners, bring to the market may not gain market acceptance by physicians, patients, third-party payors or others in the medical community. The degree of market acceptance of these pharmaceutical products, if approved for commercial sale, will depend on a number of factors, including:

- The effectiveness of our approved drug candidates as compared to currently available products;
- Patient willingness to adopt our approved drug candidates in place of current therapies;
- Our ability to provide acceptable evidence of safety and efficacy;
- Relative convenience and ease of administration;
- The prevalence and severity of any adverse side effects;
- Restrictions on use in combination with other products;
- Availability of alternative treatments;
- Pricing and cost-effectiveness assuming either competitive or potential premium pricing requirements, based on the profile of our drug candidates and target markets;
- Effectiveness of our or our partners' sales and marketing strategy;
- Our ability to obtain sufficient third-party coverage or reimbursement; and
- Potential product liability claims.

Even if a potential product displays a favorable efficacy and safety profile in preclinical and clinical studies, market acceptance of the product will not be known until after it is launched. Our efforts to educate the medical community and third-party payors on the benefits of the pharmaceutical products may require a significant amount of resources and may never be successful. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable.

***The commercial potential of a pharmaceutical candidate in development is difficult to predict. If the market size for a new drug candidate or technology is significantly smaller than we anticipate, it could significantly and negatively impact our revenue, results of operations and financial condition.***

It is very difficult to estimate the commercial potential of pharmaceutical products due to important factors, such as safety and efficacy compared to other available technologies or treatments, including changing standards of care, third-party payor reimbursement standards, patient and physician preferences, the availability of competitive alternatives that may emerge either during the long drug development process or after commercial introduction and the availability of generic versions of our successful drug candidates following approval by government health authorities, based on the expiration of regulatory exclusivity or our inability to prevent generic versions from coming to market by asserting our patents. If due to these factors, or others, the market potential for a pharmaceutical product is lower than we anticipated, it could significantly and negatively impact the commercial terms of any collaboration partnership potential for such pharmaceutical product or, if we have already entered into a collaboration for such pharmaceutical product, the revenue potential from royalty and milestone payments could be significantly diminished, which would negatively impact our business, financial condition and results of operations.

***Failure to obtain or maintain adequate coverage and reimbursement for our drug candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.***

The success of our drug candidates, if approved, depends on the availability of adequate coverage and reimbursement from third-party payors. In addition, because our drug candidates represent new approaches to the treatment of certain diseases, we cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our drug candidates or assure that coverage and reimbursement will be available for any product that we may develop.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from federal health care programs, such as Medicare and Medicaid, and commercial payors are critical to new product acceptance.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, as well as their pharmacy benefit managers decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- A covered benefit under its health plan;
- Safe, effective and medically necessary;
- Appropriate for the specific patient;
- Cost-effective; and
- Neither experimental nor investigational.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors and their contracted pharmacy benefit managers that manage prescription benefits for such payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors and their pharmacy benefit managers may not cover, or provide adequate reimbursement for, long-term follow-up evaluations that may be required for our products. Patients are unlikely to use our drug candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our drug candidates and/or if patient out-of-pocket costs (such as co-pays or co-insurance) are prohibitively high. There is significant uncertainty related to insurance coverage and reimbursement of newly-approved products. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our drug candidates.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly-approved products and, as a result, they may not cover or provide adequate payment for our drug candidates. We expect to experience pricing pressures in connection with the sale of any of our drug candidates due to the trend toward managed healthcare, value-based pricing, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes.

We intend to seek approval to market our drug candidates in both the United States and in select foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our drug candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, the pricing of pharmaceutical products is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our drug candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a drug candidate. In addition, market acceptance and sales of our drug candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our drug candidates and may be affected by existing and future health care reform measures. Failure to obtain or maintain adequate coverage and reimbursement for our drug candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

***We may use our financial and human resources to pursue a particular research program or drug candidate and fail to capitalize on programs or drug candidates that may be more profitable or for which there is a greater likelihood of success.***

Because we have limited resources, we may forego or delay pursuit of opportunities with certain programs, drug candidates or for indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for drug candidates may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through strategic collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate, or we may allocate internal resources to a drug candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement. Failure to pursue opportunities with greater commercial potential or relinquishing valuable rights to drug candidates may adversely impact our business, results of operations and prospects.

***We may not be successful in our efforts to identify or discover additional pharmaceutical products.***

The success of our business depends primarily upon our ability to identify and develop pharmaceutical products. Our research programs may fail to identify potential pharmaceutical products for clinical development for a number of reasons. Our research methodology may be unsuccessful in identifying potential pharmaceutical products, or our potential pharmaceutical products may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations. Research programs to identify new pharmaceutical products require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or pharmaceutical products that ultimately prove to be unsuccessful. If we are not successful in our efforts to identify or discover additional pharmaceutical products, it could adversely affect our business, results of operations and prospects.

***The market opportunities for our drug candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small.***

Cancer therapies are sometimes characterized as first line, second line or third line, and the FDA often approves new therapies initially only for third line use. When cancer is detected early enough, first line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first line therapy, which usually consists of chemotherapy, hormone therapy, surgery or a combination of these, proves unsuccessful, second line therapy may be administered. Second line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor targeted small molecules or a combination of these. Third line therapies can include bone marrow transplantation, antibody and small molecule targeted therapies, more invasive forms of surgery and new technologies. In markets with approved therapies, we expect to initially seek approval of our drug candidates as a later stage therapy for patients who have failed other approved treatments. Subsequently, for those drugs that prove to be sufficiently beneficial, if any, we would expect to seek approval as a second line therapy and potentially as a first line therapy, but there is no guarantee that our drug candidates, even if approved, would be approved for second line or first line therapy. In addition, we may have to conduct additional clinical trials prior to gaining approval for second line or first line therapy.

Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers in a position to receive later stage therapy and who have the potential to benefit from treatment with our drug candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers. The number of patients may turn out to be lower than expected. In addition, the potentially addressable patient population for our drug candidates may be limited or may not be amenable to treatment with our drug candidates. Even if we obtain significant market share for our drug candidates, we may never achieve profitability without obtaining regulatory approval for additional indications, including use as a first or second line therapy, which may adversely affect our business and results of operations.

***Clinical trials may fail to demonstrate the safety and efficacy of our pharmaceutical drug candidates and could prevent or significantly delay regulatory approval.***

Before receiving NDA or BLA approval to commercialize a drug candidate, we must demonstrate to the FDA, with substantial evidence from well-controlled clinical trials, that the drug candidate is both safe and effective or the biologic is safe, pure and potent. If these trials or future clinical trials are unsuccessful, our business and reputation could be harmed and our stock price could be adversely affected.

Clinical failure can occur at any stage of clinical development. Clinical trials may produce negative or inconclusive results, and we or any of our current and future collaborators may decide, or regulators may require us, to conduct additional clinical or preclinical testing. We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our drug candidates are as safe and effective for use in a specific patient population as the respective reference products before we can seek regulatory approvals for their commercial sale. Success in early clinical trials does not mean that future larger registration clinical trials will be successful because drug candidates in later-stage clinical trials may fail to demonstrate equivalent safety and efficacy to the satisfaction of the FDA and foreign regulatory agencies despite having progressed through initial clinical trials. Drug candidates that have shown promising results in early clinical trials may still fail in subsequent confirmatory clinical trials. Similarly, the outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials.

In addition, the design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We may be unable to design and execute a clinical trial to support regulatory approval. In some instances, there can be significant variability in safety or efficacy results between different trials of the same drug candidate due to numerous factors, including but not limited to, changes in trial protocols, differences in size and type of the patient populations, adherence to the dosing regimen and the rate of dropout among clinical trial participants.

Because of these risks, our research and development efforts, and those of our collaborative partners, may not result in any commercially viable products. If a significant portion of these development efforts is not successfully completed, or if required regulatory approvals are not obtained by us or our partners, or any approved products are not commercially successful, we may not generate significant revenues or become profitable.

***We may fail to obtain orphan drug designations from the FDA for our drug candidates, and even if we obtain such designations, we may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.***

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic intended to treat a rare disease or condition, which is defined as one occurring in a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug or biologic will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full NDA or BLA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity.

We may seek to obtain orphan drug designation for our active drug candidates for any qualifying indications they may be approved for in the future. Even if we obtain such designations, we may not be the first to obtain marketing approval of our drug candidate for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication, or may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan product is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug, nor gives the drug any advantage in the regulatory review or approval process. In addition, even if we seek orphan drug designation for our drug candidates, we may never receive such designations.

***Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.***

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory enactments in recent years that change the healthcare system in ways that could impact our future ability to sell our drug candidates profitably.

Furthermore, there have been and continue to be a number of initiatives at the federal and state level that seek to reduce healthcare costs. Most significantly, in March 2010, the Patient Protection and Affordable Health Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "ACA"), was signed into law, which includes measures that significantly change the way healthcare is financed by both governmental and private insurers. In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the ACA. In addition, on January 20, 2017, President Trump signed an executive order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Further, on October 12, 2017, President Trump issued another executive order requiring the Secretaries of HHA and the Departments of Labor and Treasury to consider proposing regulations or revising existing guidance to allow more employers to form association health plans that would be allowed to provide coverage across state lines, increase the availability of short-term, limited-duration health insurance plans, which are generally not subject to the requirements of the ACA, and increase the availability and permitted use of health reimbursement arrangements. On October 13, 2017, the Department of Justice announced that HHS was immediately stopping its cost sharing reduction payments to insurance companies based on the determination that those payments had not been appropriated by Congress. Furthermore, on December 22, 2017, President Trump signed the Tax Cuts and Jobs Act (the "TCJA") into law that, in addition to overhauling the federal tax system, also, effective as of January 1, 2019, repealed the penalties associated with the individual mandate. Congress or the President of the United States also could consider subsequent legislation or executive action to replace, eliminate or reaffirm elements of the ACA. We will continue to evaluate the effect that the ACA and any future measures to modify, repeal, replace or reaffirm the ACA have on our business.

Additionally, the Inflation Reduction Act of 2022 may impact existing Medicare programs that cover prescription drugs. In addition to other relevant provisions, the Inflation Reduction Act of 2022 allows the Medicare program to directly negotiate the price of certain high-expenditure prescription drugs covered under Medicare Parts B and D, starting in the year 2028 and 2026, respectively, by setting certain "maximum fair prices." Moreover, the Inflation Reduction Act of 2022 requires manufacturers to pay rebates to the federal government if prices of certain drugs covered under the Medicare program rise faster than the rate of inflation. We will continue to evaluate the effects that the Inflation Reduction Act of 2022 will have on our business.

In a 2024 U.S. Supreme Court ruling (*Loper Bright Enterprises v. Raimondo*) (the "*Loper* decision"), the Supreme Court overturned the long-standing Chevron doctrine, which had accorded deference to an agency's interpretation of ambiguous laws since 1984. Following the *Loper* decision, the healthcare space may face increased judicial scrutiny of agency regulations, as courts are no longer required to defer to federal agencies' interpretations of ambiguous statutes. This change could lead to significant alterations in how healthcare laws and regulations are applied and enforced. While the full impact of this reversal has yet to be examined, the *Loper* decision could lead to material changes to the healthcare system, particularly concerning the FDA, CMS, HHS, and other agencies. We will continue to evaluate the effects that the *Loper* decision will have on our business.

We are not able to provide any assurance that the continued healthcare reform debate will not result in legislation, regulation, litigation or executive action by the President of the United States that is adverse to our business. Moreover, we are not, at this time, able to evaluate any potential legislative, regulatory or Executive Order actions that the new presidential administration may take which could have a material impact on our business.

Laws and other reform and cost containment measures that may be proposed and adopted in the future remain uncertain but may contain provisions that restrict our ability to price our products and/or could result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our future customers and, accordingly, our ability to generate revenue, attain profitability or commercialize our products.

**Risks Related to Our Reliance on Third-Parties**

***If conflicts arise between us and our collaborators or strategic partners, these parties may act in their self-interest, which may limit our ability to implement our strategies.***

If conflicts arise between our corporate or academic collaborators or strategic partners and us, the other party may act in its self-interest, which may limit our ability to implement our strategies. Some of our academic collaborators and strategic partners are conducting multiple product development efforts within each area that is the subject of the collaboration with us. Our collaborators or strategic partners, however, may develop, either alone or with others, products in related fields that are competitive with the products or potential products that are the subject of these collaborations. Competing products, either developed by the collaborators or strategic partners or to which the collaborators or strategic partners have rights, may result in the withdrawal of partner support for our drug candidates.

Some of our collaborators or strategic partners could also become our competitors in the future. Our collaborators or strategic partners could develop competing products, preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely, or fail to devote sufficient resources to the development and commercialization of products. Any of these developments could harm our product development efforts, which may adversely affect our business, results of operations and prospects.

***We expect to rely on third parties to conduct, supervise and monitor our clinical studies, and if these third parties perform in an unsatisfactory manner, it may harm our business.***

We rely on CROs, clinical investigators and clinical study sites to ensure our clinical studies are conducted properly and on time. We will have limited influence over the performance by CROs, clinical investigators and clinical study sites, and we will control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our clinical studies is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. Furthermore, facilities used by these third party CROs, clinical investigators and clinical study sites may be negatively affected by catastrophic events, such as pandemics, terrorist attacks, wars or other armed conflicts, geopolitical tensions, such as the ongoing conflicts in the Ukraine and Middle East, and related sanctions and other economic disruptions or concerns, natural disasters, such as floods or fire, or such facilities could face manufacturing issues, such as contamination or regulatory concerns following a regulatory inspection of such facility. In such instances, we may need to locate an appropriate replacement third-party facility and establish a contractual relationship, which may not be readily available or on acceptable terms, which would cause additional delay and increased expense, including as a result of additional required FDA approvals, and may have a material adverse effect on our business.

We, our clinical investigators, and our CROs are required to comply with the FDA's GCPs for conducting, recording and reporting the results of clinical trials to assure that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. The FDA enforces these GCPs through periodic inspections of study sponsors, principal investigators and clinical trial sites. If we, our CROs or the clinical investigators fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA may require us to perform additional clinical trials before approving any marketing applications. Upon inspection, the FDA may determine that our clinical trials did not comply with GCPs. In addition, our future clinical trials will require a sufficient number of test subjects to evaluate the safety and efficacy of our drug candidates. Accordingly, if our CROs or clinical investigators fail to comply with these regulations or fail to recruit a sufficient number of patients, we may be required to repeat such clinical trials, which would delay the regulatory approval process.

Our CROs are not our employees, and we are therefore unable to directly monitor whether or not they devote sufficient time and resources to our clinical and nonclinical programs, which must be conducted in accordance with GCPs and GLPs, respectively. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies or other drug development activities that could harm our competitive position. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines or the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements (or for any other reasons), our clinical studies may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our pharmaceutical products. As a result, our financial results and the commercial prospects for our pharmaceutical products would be harmed, our costs could increase and our ability to generate revenues could be delayed.

We may also rely on other third parties to store and distribute our products for any clinical studies that we may conduct. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our pharmaceutical products or commercialization of our products, if approved, producing additional losses and depriving us of potential product revenue.

***Our collaborators or strategic partners may decide to adopt alternative technologies or may be unable to develop commercially viable products with our technology, which would negatively impact our revenues and our strategy to develop these products.***

Our collaborators or strategic partners may adopt alternative technologies, which could decrease the marketability of our products. Additionally, because our current or future collaborators or strategic partners are likely to be working on more than one development project, they could choose to shift their resources to projects other than those they are working on with us. If they do so, this would delay our ability to test our technology and would delay or terminate the development of potential products based on our platforms. Further, our collaborators and strategic partners may elect not to develop products arising out of our collaborative and strategic partnering arrangements or to devote sufficient resources to the development, manufacturing, marketing or sale of these products. The failure to develop and commercialize a drug candidate pursuant to our agreements with our current or future collaborator would prevent us from receiving future milestone and royalty payments, which would negatively impact our revenues.

***We may seek to establish additional collaborations and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.***

Our drug candidate development programs and the potential commercialization of our drug candidates will require substantial additional cash to fund expenses. For some of our drug candidates, we may decide to collaborate with additional pharmaceutical and biotechnology companies for the development and potential commercialization of those drug candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for any additional collaborations will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by FDA or similar regulatory authorities outside the U.S., the potential market for the subject drug candidate, the costs and complexities of manufacturing and delivering such drug candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of technology (which can exist if there is a challenge to such ownership without regard to the merits of the challenge) and industry and market conditions generally. The collaborator may also consider alternative drug candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our drug candidate. The terms of any additional collaborations or other arrangements that we may establish may not be favorable to us.

We may also be restricted under existing collaboration agreements from entering into future agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate additional collaborations on a timely basis on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the drug candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we may not be able to further develop our drug candidates or bring them to market and generate product revenue.

***We are a party to, and may enter into one or more collaborations in the future, pursuant to which we may be required to relinquish important rights to and control over the development of our drug candidates or otherwise be subject to unfavorable terms.***

Any current and future collaborations we enter into could subject us to a number of risks, including:

- We may not be able to control the amount and timing of resources that our collaborators devote to the development or commercialization of our drug candidates;
- Collaborators may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a drug candidate, repeat or conduct new clinical trials or require a new version of a drug candidate for clinical testing;
- Collaborators may not pursue further development and commercialization of products resulting from the strategic partnering arrangement or may elect to discontinue research and development programs;
- Collaborators may not commit adequate resources to the marketing and distribution of our drug candidates, limiting our potential revenues from these products;
- Disputes may arise between us and our collaborators that result in the delay or termination of the research, development or commercialization of our drug candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources;
- Collaborators may experience financial difficulties;
- Collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- Business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- Collaborators could decide to move forward with a competing drug candidate developed either independently or in collaboration with others, including our competitors; and
- Collaborators could terminate the arrangement or allow it to expire, which would delay the development and may increase the cost of developing our drug candidates.

***We have no manufacturing, sales, marketing or distribution capabilities, and we may have to invest a significant amount of resources to develop these capabilities.***

We have no internal manufacturing capabilities. As a result, for manufacturing we depend on third-party manufacturers. Our strategy is based on leveraging the ability of collaboration partners to develop and manufacture our products for commercialization in the pharmaceutical marketplace, and we will be dependent on collaborations with drug development and manufacturing capabilities. If we are not able to maintain existing collaborative arrangements or establish new arrangements on commercially acceptable terms, we would be required to undertake product manufacturing and development activities at our own expense. This would increase our capital requirements or require us to limit the scope of our development activities. Moreover, we have limited or no experience in conducting full-scale bioequivalence or other clinical studies, preparing and submitting regulatory applications and distributing and marketing pharmaceutical products. As such, we are reliant on contract parties for such efforts. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all.

If any of our developmental collaborators breach or terminate their agreements with us or otherwise fail to conduct their collaborative activities in a timely manner, the preclinical and/or clinical development and/or commercialization of our pharmaceutical products will be delayed and we would be required to devote additional resources to product development and commercialization or terminate certain development programs. Also, a license relationship may be terminated at the discretion of our collaborator, or at the end of contract terms, and in some cases with only limited notice to us. The termination of the collaborative arrangement could have a material adverse effect on our business, financial condition and results of operations. There also can be no assurance that disputes will not arise with respect to the ownership of rights to any technology developed with third parties. These and other possible disagreements with collaborators could lead to delays in the development or commercialization of our pharmaceutical products or could result in litigation or arbitration, which could be time-consuming and expensive and could have a material adverse effect on our business, financial condition and results of operations. Even if we decide to perform clinical trials, sales, marketing and distribution functions ourselves, we could face a number of additional related risks, including:

- We may not be able to attract clinical investigators and build effective clinical trials or a solid marketing department or sales force;
- The cost of establishing an internal clinical trials program, marketing department or sales force may exceed our available financial resources and the revenue generated by any of our current product candidates, if approved, or any other pharmaceutical products that we may develop, in-license or acquire; and
- Our direct sales and marketing efforts may not be successful.

Any failure to perform such activities could have a material adverse effect on our business, financial condition and results of our operations.

***Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.***

Because we rely on third parties to manufacture our pharmaceutical products, and because we collaborate with various organizations and academic institutions on the development of our pharmaceutical products, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. The need to share trade secrets and other confidential information when working with third parties increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

In addition, these agreements typically restrict the ability of our collaborators, advisors, employees and consultants to publish data potentially relating to our trade secrets. Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the collaboration. In other cases, publication rights are controlled exclusively by us, although in some cases we may share these rights with other parties. We may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. Our competitors may discover our trade secrets, either through breach of these agreements, independent development or publication of information including our trade secrets in cases where we do not have proprietary or otherwise protected rights at the time of publication. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

***Our contract manufacturers are subject to significant regulation with respect to manufacturing our products. The manufacturing facilities on which we rely may not continue to meet regulatory requirements and have limited capacity.***

We currently have relationships with a limited number of suppliers for the manufacturing of our pharmaceutical products. Each supplier may require licenses to manufacture components if such processes are not owned by the supplier or in the public domain, and we may be unable to transfer or sublicense the intellectual property rights we may have with respect to such activities.

All entities involved in the preparation of pharmaceutical products for clinical studies or commercial sale, including our existing contract manufacturers for our drug candidates, are subject to extensive regulation. Components of a finished pharmaceutical product approved for commercial sale or used in late-stage clinical studies must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants or to inadvertent changes in the properties or stability of our pharmaceutical products that may not be detectable in final product testing. Our contract manufacturers must supply all necessary documentation in support of an NDA or BLA on a timely basis and must adhere to the FDA's GLP and cGMP regulations enforced by the FDA through its facilities inspection program. The facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our pharmaceutical products or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our pharmaceutical products or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities do not pass a pre-approval plant inspection, FDA approval of the products will not be granted.

The regulatory authorities also may, at any time following approval of a product for sale, audit the manufacturing facilities of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we, or the relevant regulatory authority, may require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical study or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon third parties with whom we contract could materially harm our business.

If our third-party manufacturers fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a drug candidate or revocation of a pre-existing approval. As a result, our business, financial condition and results of operations may be materially harmed.

Additionally, if supply from one approved manufacturer is interrupted, there could be a significant disruption in commercial supply. The number of manufacturers with the necessary manufacturing capabilities is limited. In addition, an alternative manufacturer would need to be qualified through an NDA or BLA supplement which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines, which could materially harm our business and results of operations.

These factors could cause the delay of clinical studies, regulatory submissions, required approvals or commercialization of our pharmaceutical products and/or cause us to incur higher costs and prevent us from commercializing our products successfully. Furthermore, if our suppliers fail to meet contractual requirements, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical studies may be delayed or we could lose potential revenue, which could materially harm our business and results of operations.

**Risks Related to Our Intellectual Property**

***If we fail to adequately protect or enforce our intellectual property rights, we may be unable to operate effectively.***

Our success and ability to compete are substantially dependent on our patents, proprietary formulations and trademarks. There can be no assurance that our patents and associated trademarks and licenses will not be challenged and subsequently invalidated and/or canceled. The invalidation or cancellation of any one or all of the patents or trademarks would significantly damage our commercial prospects. Further, we may find it necessary to legally challenge parties infringing our patents or trademarks or licensed trademarks to enforce our rights thereto. There can be no assurance that any of the patents would ultimately be held valid or that efforts to defend any of the patents, trade secrets, know-how or other IP rights would be successful.

The patent positions of pharmaceutical and biotechnology companies, such as ours, are uncertain and involve complex legal and factual issues. We own numerous U.S. and foreign patents and a number of pending patent applications that cover various aspects of our drug candidates and technologies. There can be no assurance that patents that have been issued will be held valid and enforceable in a court of law. Even for patents that are held valid and enforceable, the legal process associated with obtaining such a judgment is time-consuming and costly. Additionally, issued patents can be subject to opposition or other proceedings that can result in the revocation of the patent or maintenance of the patent in amended form (and potentially in a form that renders the patent without commercially relevant and/or broad coverage). Further, our competitors may be able to circumvent and otherwise design around our patents. Even if a patent is issued and enforceable because development and commercialization of pharmaceutical products can be subject to substantial delays, patents may expire early and provide only a short period of protection, if any, following the commercialization of a product encompassed by our patents. We may have to participate in interference proceedings declared by the USPTO, which could result in a loss of the patent and/or substantial cost to us.

We have filed patent applications and plan to file additional patent applications covering various aspects of our drug candidates and technologies. There can be no assurance that the patent applications for which we apply would actually be issued as patents, or do so with commercially relevant and/or broad coverage. The coverage claimed in a patent application can be significantly reduced before the patent is issued. The scope of our claim coverage can be critical to our ability to enter into licensing transactions with third parties and our right to receive royalties from our collaboration partnerships. Since publication of discoveries in scientific or patent literature often lags behind the date of such discoveries, we cannot be certain that we were the first inventor of inventions covered by our patents or patent applications. In addition, there is no guarantee that we will be the first to file a patent application directed to an invention.

An adverse outcome in any judicial proceeding involving IP, including patents, could subject us to significant liabilities to third parties, require disputed rights to be licensed from or to third parties or require us to cease using the technology in dispute. In those instances where we seek an IP license from another, we may not be able to obtain the license on a commercially reasonable basis, if at all, thereby raising concerns on our ability to freely commercialize our technologies and/or products. It is also possible that we or our licensors or licensees will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications (or to maintain the patents) covering technology that we license from or license to third parties. We are reliant on our licensors or licensees. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If our current or future licensors or licensees fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our licensors or licensees are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised.

Failure to adequately protect or enforce our intellectual property rights could have a material adverse impact on our business, results of operations and prospects.

***Issued patents covering our drug candidates could be found invalid or unenforceable if challenged in court.***

If we or one of our licensing partners initiated legal proceedings against a third-party to enforce a patent covering one of our drug candidates, the defendant could counterclaim that the patent covering our drug candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our drug candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our drug candidates. Such a loss of patent protection would have a material adverse impact on our business.

***We may not be able to protect our intellectual property rights throughout the world.***

Filing, prosecuting and defending patents on drug candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our inventions in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Failure to adequately protect our intellectual property rights throughout the world could have a material adverse impact on our business, results of operations and prospects.

***If we infringe on the intellectual property rights of others, our business and profitability may be adversely affected.***

Our commercial success will also depend, in part, on us and our collaborative partners not infringing on the patents or proprietary rights of others. There can be no assurance that the technologies and products used or developed by our collaborative partners and marketed and sold by us will not infringe such rights. If such infringement occurs and neither we nor our collaborative partner is able to obtain a license from the relevant third party, we will not be able to continue the development, manufacture, use or sale of any such infringing technology or product. There can be no assurance that necessary licenses to third-party technology will be available at all, or on commercially reasonable terms. In some cases, litigation or other proceedings may be necessary to defend against or assert claims of infringement or to determine the scope and validity of the proprietary rights of third parties. Any potential litigation could result in substantial costs to, and diversion of, our resources and could have a material and adverse impact on us. An adverse outcome in any such litigation or proceeding could subject us to significant liabilities, require us to cease using the subject technology or require us to license the subject technology from the third party, all of which could have a material adverse effect on our business.

***If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.***

We are a party to a number of intellectual property license agreements that are important to our business, and we expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license.

We may need to obtain licenses from third parties to advance our research, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop the affected drug candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current drug candidates or future products, resulting in either an injunction prohibiting the sales, or, with respect to the sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

In many cases, patent prosecution of our licensed technology is controlled solely by the licensor. If our licensors fail to obtain and maintain patent or other protection for the proprietary intellectual property we license from them, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using the intellectual property. In certain cases, we control the prosecution of patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- The scope of rights granted under the license agreement and other interpretation-related issues;
- The extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- The sublicensing of patent and other rights under our collaborative development relationships;
- Our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- The ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- The priority of invention of patented technology.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected drug candidates, which could have a material adverse effect on our business.

***We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.***

We employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employee's former employers or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

***We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.***

We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may have in the future ownership disputes arising, for example, from conflicting obligations of consultants or others who are involved in developing our drug candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

***Our inability to protect our confidential information and trade secrets would harm our business and competitive position.***

In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing or unwilling to protect trade secrets. If a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position and our business.

***We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.***

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid, is unenforceable and/or is not infringed, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

***Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.***

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity and is, therefore, costly, time-consuming and inherently uncertain. In addition, the United States has enacted and is expected to continue to implement wide-ranging patent reform legislation. Further, certain U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and/or weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our and our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents. Provisions of the Leahy-Smith America Invents Act (the "Leahy-Smith Act"), adopted in September 2011, made a number of significant changes to U.S. patent law, the effects of which are still unfolding. The Leahy-Smith Act and its implementation, in addition to any new regulation, could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

***Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the U. S. in several stages over the lifetime of the patents and/or applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. Non-compliance may result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market, and this circumstance would have a material adverse effect on our business.

**Risks Related to Our Business Operations**

***We operate in an extremely competitive environment and there can be no assurances that competing technologies would not harm our business development.***

We are engaged in a rapidly-evolving field. Competition from numerous pharmaceutical companies is intense and expected to increase. The large and rapidly-growing market for oncology treatments is likely to attract new entrants. Numerous biotechnology and pharmaceutical companies are focused on developing cancer treatments and immuno-oncology technologies. Many, if not all, of these companies have greater financial and other resources and development capabilities than we do. Many of our competitors also have greater collective experience in undertaking preclinical and clinical testing of products, obtaining regulatory approvals and manufacturing and marketing prescription pharmaceutical products. There can be no assurance that our under-development drug candidates will be more effective or achieve greater market acceptance than competitive products or that our competitors will not succeed in developing products and technologies that are more effective than those being developed by us or that would render our products and technologies less competitive or obsolete. Additionally, there can be no assurance that the development by others of new or improved drugs will not make our pharmaceutical products superfluous or obsolete.

***Our future success depends on our ability to retain principal members of our executive team, consultants and advisors and to attract, retain and motivate qualified personnel.***

We are highly dependent on principal members of our executive team, the loss of whose services may adversely impact the achievement of our objectives. Recruiting and retaining other qualified employees, consultants and advisors for our business, including scientific and technical personnel, will also be critical to our success. Competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for individuals with similar skill sets. In addition, failure to succeed in preclinical or clinical studies may make it more challenging to recruit and retain qualified personnel. The inability to recruit or loss of the services of any executive, consultant or advisor may impede the progress of our research and development objectives.

***We will need to expand our organization and we may experience difficulties in managing this growth, which could disrupt our operations.***

As of December 31, 2024, we had two full-time employees. As we mature, we may need to expand our full-time employee base and to hire more consultants and contractors. Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees, all of which may have a material adverse effect on our business, results of operations and prospects. Any future growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional drug candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize drug candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

***We are a party to collaboration agreements and other significant agreements which contain complex commercial terms that could result in disputes, litigation or indemnification liability that could adversely affect our business, results of operations and financial condition.***

We currently derive, and expect to derive in the foreseeable future, all or much of our revenue from collaboration agreements with biotechnology and pharmaceutical companies. These collaboration agreements contain complex commercial terms, including:

- Clinical development and commercialization obligations that are based on certain commercial reasonableness performance standards that can often be difficult to enforce if disputes arise as to adequacy of our partner's performance;
- Research and development performance and reimbursement obligations for our personnel and other resources allocated to partnered drug candidate development programs;
- Clinical and commercial manufacturing agreements, some of which are priced on an actual cost basis for products supplied by us to our partners with complicated cost allocation formulas and methodologies;
- Intellectual property ownership allocation between us and our partners for improvements and new inventions developed during the course of the collaboration;
- Royalties on drug sales based on a number of complex variables, including net sales calculations, geography, scope of patent claim coverage, patent life, generic competitors, bundled pricing and other factors; and
- Indemnity obligations for intellectual property infringement, product liability and certain other claims.

From time to time, we may have informal dispute resolution discussions with third parties regarding the appropriate interpretation of the complex commercial terms contained in our agreements. One or more disputes may arise or escalate in the future regarding our collaboration agreements, transaction documents or third-party license agreements that may ultimately result in costly litigation and unfavorable interpretation of contract terms, which would have a material adverse effect on our business, financial condition and results of operations.

***Market conditions and changing circumstances, some of which may be beyond our control, could impair our ability to access our existing cash, cash equivalents and investments and to timely pay collaborators and others.***

Market conditions and changing circumstances, some of which may be beyond our control, could impair our ability to access our existing cash, cash equivalents and investments and to timely pay key vendors and others. If banks and financial institutions with whom we have banking relationships enter receivership or become insolvent in the future, we may be unable to access, and we may lose, some or all of our existing cash, cash equivalents and investments to the extent those funds are not insured or otherwise protected by the FDIC. In addition, in such circumstances we might not be able to make timely payments to our collaborators or others. The Company maintains its primary banking relationship with one large financial institution and all cash on deposit is federally insured. The Company has not experienced any losses on its accounts, and does not believe it is exposed to any unusual credit risk beyond the normal credit risk currently associated with commercial banking relationships. However, any delay in our ability to access our cash, cash equivalents and investments or to timely pay our collaborators and others could have a material adverse effect on our operations and cause us to need to seek additional capital sooner than planned.

***Potential new accounting standards or legislative actions may adversely impact our future financial position or results of operations.***

Future changes in financial accounting standards may cause adverse, unexpected fluctuations in the timing of the recognition of revenues or expenses, and may affect our financial position or results of operations. New standards may occur in the future and may cause us to be required to make changes in our accounting policies. Compliance with changing regulation of corporate governance and public disclosure may result in additional expenses. Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002 (or the Sarbanes-Oxley Act), new SEC regulations, Public Company Accounting Oversight Board (or PCAOB) standards and Nasdaq rules, are creating uncertainty for companies such as ours. Insurance, accounting and auditing costs are high as a result of this uncertainty and other factors.

We have limited capital resources and currently have only one full-time employee in our finance department. We rely on outside consultants to supplement our internal expertise and are committed to maintaining high standards of corporate governance and public disclosure. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.

**Risks Related to Our Common Stock**

***We may not continue to meet the continued listing requirements of Nasdaq, which could result in a delisting of our common shares.***

Our common shares are listed on the Nasdaq. While we are currently in compliance, we have in the past been, and may in the future be, unable to comply with certain listing standards that we are required to meet to maintain the listing of our common shares on the Nasdaq. For instance, on June 3, 2022, we received written notification from the Listing Qualifications Department of Nasdaq notifying us that the closing bid price for our common stock had been below $1.00 for 30 consecutive business days and that we, therefore, were not in compliance with the Nasdaq minimum bid price requirement. After approval from the Company's Board of Directors, on May 15, 2023, we effected a reduction, on a 1-for-10 basis, in our authorized common stock, par value $0.001, along with a corresponding and proportional decrease in the number of shares issued and outstanding(the "Reverse Stock Split"). On May 30, 2023, we received a letter from Nasdaq notifying us that we had regained compliance with the minimum bid price requirement as a result of the closing bid price of our common stock being at $1.00 per share or greater for the 10 consecutive business days from May 15, 2023 through May 26, 2023 and that this matter was closed.

***The market price of our securities may be highly volatile, and you may not be able to sell our securities.***

Companies trading in the stock market in general have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our securities, regardless of our actual operating performance.

The market price of our securities may be volatile. Our securities could be subject to wide fluctuations in price in response to a variety of factors, including the following:

- Failure to realize the anticipated potential of the DNase technologies;
- Adverse results, delays, or holds in pre-clinical or clinical studies;
- Inability to obtain additional funding;
- Any delay in filing an IND or BLA for any of our drug candidates and any adverse development or perceived adverse development with respect to the FDA's review of that IND or BLA;
- Failure to develop successfully our drug candidates;
- Failure to maintain our existing strategic collaborations or enter into new collaborations;
- Failure by us or our licensors and strategic collaboration partners to prosecute, maintain or enforce our intellectual property rights;
- Changes in laws or regulations applicable to future products;
- Inability to obtain adequate product supply for our drug candidates or the inability to do so at acceptable prices;
- Adverse regulatory decisions;
- Introduction of new products, services or technologies by our competitors;
- Failure to meet or exceed financial projections we may provide to the public;
- Failure to meet or exceed the financial projections of the investment community;
- The perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- Announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us, our strategic collaboration partner or our competitors;
- Disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- Additions or departures of key scientific or management personnel;
- Significant lawsuits, including patent or stockholder litigation;
- Changes in the market valuations of similar companies;
- Sales of our securities by us or our stockholders in the future;
- Adverse economic conditions, including potential adverse effects of public health issues, such as the coronavirus outbreak, and geopolitical events, such as the Russian invasion of Ukraine, and related sanctions and other economic disruptions or concerns, on economic activity generally; and
- Trading volume of our securities.

***Actions of activist shareholders could cause us to incur substantial costs, divert management's attention and resources, and have an adverse effect on our business.***

We actively engage in discussions with our shareholders regarding further strengthening our Company and creating long-term shareholder value. Some shareholder activism, including potential proxy contests, could result in substantial costs, such as legal fees and expenses, disrupt our operations, and divert management's and our Board of Directors' attention and resources from our business and strategic plans. Public shareholder activism can create perceived uncertainties as to our future direction, strategy, or leadership and may result in the loss of potential business opportunities, harm our ability to attract new employees, investors, collaborators and other partners, and cause our stock price to experience volatility. These risks could adversely affect our financial performance.

***Our preferred stockholders have rights, preferences and privileges that are not held by, and are preferential to, the rights of our common stockholders, which could result in the interests of our preferred stockholders differing from those of our common stockholders.***

The holders of our preferred stock have the right to receive a liquidation preference entitling them to be paid out of our assets available for distribution to stockholders before any payment may be made to holders of any common stock or any series of preferred stock ranked junior to such class of preferred stock. The existence of a liquidation preference may reduce the value of our common stock, make it harder for us to sell shares of common stock in offerings in the future or prevent or delay a change of control. Additionally, each share of Series B Preferred Stock are convertible into shares of our common stock, subject to an issuable maximum and subject to certain adjustments, which may cause significant dilution to our common stockholders. The preferential rights could result in divergent interests between the holders of shares of preferred stock and holders of our common stock.

***The issuance of future shares of common stock may result in dilution to our stockholders.***

As of March 7, 2025, we had approximately 1.5 million shares of common stock outstanding, excluding approximately 0.3 million of potentially dilutive common stock related to outstanding preferred stock, warrants and options.

The issuance of these shares of common stock and the sale of these shares of common stock, or even the potential of such issuance and sale, may have a depressive effect on the market price of our common stock, and the issuance of such common stock will cause dilution to our stockholders.

***We could be subject to securities class action litigation.***

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because we have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

***An active, liquid and orderly market for our common stock may not develop.***

Our common stock trades on the Nasdaq Capital Market. An active, liquid trading market for our common stock may never develop or be sustained. If an active, liquid market for our common stock does not continue to develop or is not sustained, it may be difficult for investors to sell shares or purchase warrants without depressing the market price, and investors may not be able to sell the shares at all. An inactive or illiquid market may also impair our ability to raise capital by selling common stock and may impair our ability to acquire other businesses, applications or technologies using our common stock or purchase warrants as consideration, which, in turn, could materially adversely affect our business.

***We have entered into agreements with our stockholders.***

We have in the past, and may continue to enter into from time to time, agreements with our stockholders, which may result in conflicts of interest. In addition, these arrangements may not have been negotiated at arm's length and may contain terms and conditions that are not in our best interest.

***We do not intend to pay dividends on our common stock or preferred stock so any returns will be limited to the value of our stock.***

We have never declared or paid any cash dividends on our common stock or preferred stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to common or preferred stockholders will therefore be limited to the appreciation of their stock.

***Certain provisions of our Articles of Incorporation, Bylaws, and the Nevada Revised States may be deemed to have an anti-takeover effect, which could cause the market price of our common stock to decline.***

Certain provisions of our Articles of Incorporation, Bylaws, and the Nevada Revised States may be deemed to have an anti-takeover effect. Such provisions may delay, deter or prevent a tender offer or takeover attempt that a stockholder might consider to be in that stockholder's best interests, including attempts that might result in a premium over the market price for the shares held by stockholders, which could cause the market price of our common stock to decline.

**General Risk Factors**

***We face potential product liability claims, and, if successful claims are brought against us, we may incur substantial liability and costs. If the use of our drug candidates harms patients, or is perceived to harm patients even when such harm is unrelated to our drug candidates, our regulatory approvals could be revoked or otherwise negatively impacted, and we could be subject to costly and damaging product liability claims.***

The use of our drug candidates in clinical studies and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. There is a risk that our drug candidates may induce adverse events. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in, among other negative effects:

- Impairment of our business reputation;
- Withdrawal of clinical study participants;
- Costs due to related litigation;
- Distraction of management's attention from our primary business;
- Substantial monetary awards to patients or other claimants;
- The inability to commercialize our drug candidates; and
- Decreased demand for our drug candidates, if approved for commercial sale,

all of which may have a material adverse effect on our business, results of operations and prospects.

***Our financial condition, results of operations, business and cash flow may be negatively affected by unfavorable U.S. or global economic conditions.***

Our financial condition, results of operations, business and cash flow may be negatively affected by general conditions in the global economy and in the global financial markets and uncertainty about economic stability. The global economy has experienced extreme volatility and disruptions, including as a result of public health epidemics and pandemics, or other outbreaks of communicable diseases, such as the COVID-19 pandemic, as well as from international conflicts, terrorism or other geopolitical events, such as the conflicts in the Ukraine and the Middle East, and related sanctions and other economic disruptions or concerns.

Additionally, the global economy and financial markets may also be adversely affected by the current or anticipated impact of military conflict, terrorism or other geopolitical events, such as the conflicts in Ukraine and the Middle East. Sanctions imposed by the United States and other countries in response to such conflicts, may also adversely impact the financial markets and the global economy, and the economic countermeasures by the affected countries or others could exacerbate market and economic instability. For example, in response to the Russian invasion of Ukraine, the United States and certain other countries imposed significant sanctions and trade actions against Russia and could impose further sanctions, trade restrictions, and other retaliatory actions as the conflict continues or if it worsens. It is not possible to predict the broader consequences of such conflict or any others, such as the war in the Middle East, including related geo-political tensions, and the measures and retaliatory actions that will be taken by the United States and other countries in respect thereof, as well as any countermeasures or retaliatory actions Russia or any other country may take in response, are likely to cause regional instability and geo-political shifts and could materially adversely affect global trade, currency exchange rates, regional economies, and the global economy. While it is difficult to anticipate the impact of any of the foregoing on our Company in particular, the conflict and actions taken in response to the conflict could increase our costs, disrupt our supply chain, impair our ability to raise or access additional capital when needed on acceptable terms, if at all, or otherwise adversely affect our business, financial condition, and results of operations.

There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for any product candidates we may develop and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could impair our ability to achieve our growth strategy, could harm our financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that our current or future service providers, manufacturers or other collaborators may not survive such difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget. We cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

***Our ability to use potential future operating losses and our federal and state NOL carryforwards to offset taxable income from revenue generated from operations or corporate collaborations could be limited.***

The use of our NOL carryforwards may have limitations resulting from certain future ownership changes or other factors under the Code and other taxing authorities, including foreign tax regimes. The TCJA changed both the federal deferred tax value of the NOL carryforwards and the rules of utilization of federal NOL carryforwards.

If our NOL carryforwards are limited, and we have taxable income which exceeds the available NOL carryforwards for that period, we would incur an income tax liability even though NOL carryforwards may be available in future years prior to their expiration. Any such income tax liability may adversely affect our future cash flow, financial position and financial results.

***Tax reform may significantly affect the Company and our stockholders.***

Due to the potential for changes to tax laws and regulations or changes to the interpretation thereof, the ambiguity of tax laws and regulations, the subjectivity of factual interpretations and other factors, our estimates of effective tax rate and income tax assets and liabilities may be incorrect and our financial statements could be adversely affected. The impact of these factors referenced in the first sentence of this paragraph may be substantially different from period-to-period.

In addition, the amount of income taxes we pay is subject to ongoing audits by U.S. federal, state and local tax authorities and by non-U.S. tax authorities. If audits result in payments or assessments different from our reserves, our future results may include unfavorable adjustments to our tax liabilities and our financial statements could be adversely affected. Any further significant changes to the tax system in the United States or in other jurisdictions (including changes in the taxation of international income as further described below) could adversely affect our financial statements.

***Governments may impose price controls, which may adversely affect our future profitability.***

We intend to seek approval to market our drug candidates in both the United States and in foreign jurisdictions. In some foreign countries and jurisdictions, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug candidate. To obtain reimbursement or pricing approval in some countries, we may be required to conduct clinical trials to compare the cost effectiveness of our drug candidates to other available therapies, which is time-consuming and costly. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

***Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.***

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA and non-U.S. regulators, provide accurate information to the FDA and non-U.S. regulators, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and cause serious harm to our reputation or could cause regulatory agencies not to approve our drug candidates. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

***Use of our drug candidates could be associated with adverse side effects.***

As with most biopharmaceutical products, use of our drug candidates could be associated with side effects or adverse events which can vary in severity and frequency. Side effects or adverse events associated with the use of our drug candidates may be observed at any time, including in clinical trials or once a product is commercialized, and any such side effects or adverse events may negatively affect our ability to obtain regulatory approval or market our drug candidates. Side effects such as toxicity or other safety issues associated with the use of our drug candidates could require us to perform additional studies or halt development or sale of these drug candidates or expose us to product liability lawsuits which will harm our business.

The emergence of unforeseen safety issues or adverse events may lead to regulatory agencies requiring us to conduct additional preclinical or clinical trials regarding the safety and efficacy of our drug candidates, which we have not planned or anticipated. We cannot assure you that we will resolve any issues related to any product-related adverse events to the satisfaction of the FDA or any regulatory agency in a timely manner or ever, which could harm our business, prospects and financial condition. We may also inadvertently fail to report adverse events we become aware of within the prescribed timeframe. We may also fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we fail to comply with our reporting obligations, the FDA or other foreign regulatory agencies could take action including criminal prosecution, the imposition of civil monetary penalties, seizure of our products, or delay in approval or clearance of future products.

***If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.***

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

The workers' compensation insurance we maintain to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries may not provide adequate coverage against potential liabilities. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions, which may have a material adverse effect on our business and results of operations.

***Non-cash charges such as share-based payments may adversely impact our results of operations.***

We record non-cash charges related to share-based expense, which could fluctuate materially as the Company expects to continue to issue share-based payments awards and may adversely impact our results of operations.

***Varying interpretations of existing accounting standards and rules have occurred with frequency and may cause us to have to restate previously reported result of operations.***

Varying interpretations of existing standards of accounting policies or accounting treatments of existing transactions may cause us to have to restate previously reported result of operations.

***Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.***

We are subject to the periodic reporting requirements of the Exchange Act. Any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected, which may have a material adverse effect on our business and results of operations.

***Failure in our information technology systems or those of our third-party service providers, including by cybersecurity attacks or other data security incidents, could significantly disrupt our operations.***

Our operations depend, in part, on the continued performance of our information technology systems, which are cloud-based and maintained by third-party service providers. Our information technology systems are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptions. Failure of our information technology systems could adversely affect our business, profitability and financial condition.

A successful cybersecurity attack or other data security incident could result in the misappropriation and/or loss of confidential or personal information, create system interruptions or deploy malicious software that attacks our systems. It is possible that a cybersecurity attack might not be noticed for some period of time. The occurrence of a cybersecurity attack or incident could result in business interruptions from the disruption of our information technology systems, or negative publicity resulting in reputational damage with our clinical trial participants, customers, stockholders and other stakeholders and/or increased costs to prevent, respond to or mitigate cybersecurity events. In addition, the unauthorized dissemination of sensitive personal information or proprietary or confidential information could expose us or other third parties to regulatory fines or penalties, litigation and potential liability, or otherwise harm our business.

***We are a smaller reporting company, and the reduced reporting requirements applicable to smaller reporting companies may make our common stock less attractive to investors.***

We are a smaller reporting company ("SRC"), which allows us to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not SRCs, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, reduced disclosure obligations regarding executive compensation in our Annual Report and our periodic reports and proxy statements and providing only two years of audited financial statements in our Annual Report and our periodic reports. We will remain an SRC until (a) the aggregate market value of our outstanding common stock held by non-affiliates as of the last business day our most recently completed second fiscal quarter exceeds $250 million or (b) (1) we have over $100 million in annual revenues and (2) the aggregate market value of our outstanding common stock held by non-affiliates as of the last business day our most recently completed second fiscal quarter exceeds $700 million. We cannot predict whether investors will find our common stock less attractive if we rely on certain or all of these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile and may decline.

## ITEM 1B – UNRESOLVED STAFF COMMENTS

Not applicable.

## ITEM 1C – CYBERSECURITY

### Risk management and strategy

We, through our third-party provider that manages our information technology systems and networks, maintain policies and processes for assessing, identifying, and managing material risk from cybersecurity threats, and have integrated these processes into our overall risk management systems and processes. Primary responsibility for assessing, monitoring and managing our cybersecurity risks rests with the Chief Financial Officer, who manages the Company's overall risk assessment and mitigation process.

In addition to monitoring cybersecurity threats to the Company's information systems, the Company's risk management practices are intended to help monitor, mitigate and prevent cybersecurity risks from external sources. We operate as a virtual company and maintain vital information, including financial and payroll information, on servers owned and maintained by our vendors. As such, we rely on the internal controls of our third party vendors to protect our vital information. We obtain and review reports on the internal controls of our vendors on an annual basis to ensure that we believe their cybersecurity procedures are adequate and to confirm that there have been no data breaches affecting our information.

We engage third party services in connection with our cybersecurity risk assessment processes. These service providers assist us to design and implement our cybersecurity policies and procedures, as well as to monitor and test our safeguards. Our managed information technology service provider monitors and alerts us of cybersecurity threats and potential breaches. Our managed information technology service provider has the ability to implement and maintain appropriate security measures, consistent with all applicable laws, to implement and maintain reasonable security measures in connection with their work with us, and to promptly report any suspected breach of its security measures that may affect our company. Employee training and phishing campaigns are conducted every year. The Company's employees are expected to help safeguard the Company's information systems and to assist in the discovery and reporting of cybersecurity incidents.

Although we may face a number of cybersecurity risks in connection with our business, we have not experienced any cybersecurity threats, incidents, or challenges that have materially affected, or are reasonably likely to materially affect, our business strategy, results of operations, or financial condition. For additional information regarding risks from cybersecurity threats, please refer to Item 1A, "Risk Factors," in this annual report on Form 10-K.

**Governance**

One of the key functions of our board of directors is informed oversight of our risk management process, including risks from cybersecurity threats. Our board of directors is responsible for monitoring and assessing strategic risk exposure, and our executive officers, with assistance from third-party consultants or advisors as appropriate, are responsible for the day-to-day management of the material risks we face. Our Chief Financial Officer oversees our cybersecurity risk assessment and mitigation process, and is responsible for the timely reporting of any material cybersecurity incident or threat, as well as any other cybersecurity related risks, to our board of directors.

## ITEM 2 – PROPERTIES

We rent office space at an office share location at 945 Concord Street in Framingham, Massachusetts. The lease agreement is for 6-months through March 31, 2025. We believe that this space is adequate for our current needs and that if additional space is required, it can be obtained at commercially reasonable terms nearby.

In addition, we leased 360 sq. ft. of office space in Miami, Florida. The lease provided for an initial term of 12 months, which commenced on December 1, 2016, and had been extended on a year-by-year basis through November 30, 2024. This lease was not renewed in December 2024.

## ITEM 3 – LEGAL PROCEEDINGS

From time to time, we may be a party to litigation and subject to claims incident to the ordinary course of business. Although the results of litigation and claims cannot be predicted with certainty, we currently believe that the final outcome of these ordinary course matters will not have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

There are no matters, as of December 31, 2024, that, in the opinion of management, might have a material adverse effect on our financial position, results of operations or cash flows.

## ITEM 4 – MINE SAFETY DISCLOSURES

Not applicable.

## PART II

### ITEM 5 – MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock is listed on the Nasdaq Capital Market under the symbol "XBIO".

**Holders of Record**

As of March 7, 2025, there were 425 holders of record of our common stock.

**Dividends**

We have never previously declared or paid any cash dividends on our common stock. We currently intend to retain earnings and profits, if any, to support our business strategy and do not intend to pay any cash dividends within the foreseeable future. Any future determination to pay cash dividends will be at the sole discretion of our Board of Directors and will depend upon the financial condition of the Company, our operating results, capital requirements, general business conditions and any other factors that the Board of Directors deems relevant.

**Equity Compensation Plan Information**

The information required by Item 5 with respect to securities authorized for issuance under equity compensation plans is incorporated herein by reference to Part III, Item 12 of this Form 10-K.

**Recent Sales of Unregistered Securities**

None.

**Repurchases of Equity Securities of the Issuer**

During the quarter ended December 31, 2024, we did not repurchase any of our outstanding shares of common stock.

### ITEM 6 – [RESERVED]

Reserved.

### ITEM 7 – MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

### BUSINESS OVERVIEW

We are a biopharmaceutical company focused on advancing innovative immune-oncology technologies addressing difficult to treat cancers. Our Deoxyribonuclease ("DNase") technology is designed to improve outcomes of existing treatments, including immunotherapies, by targeting neutrophil extracellular traps ("NETs"), which are involved in cancer progression. We are currently focused on advancing our systemic DNase program into the clinic as an adjunctive therapy for pancreatic carcinoma and locally advanced or metastatic solid tumors.

We incorporate our patented and proprietary technologies into drug candidates currently under development with biotechnology and pharmaceutical industry collaborators to create what we believe will be the next-generation biologic drugs with improved pharmacological properties over existing therapeutics. Our drug candidates have resulted from our research activities or that of our collaborators and are in the development stage. As a result, we continue to commit a significant amount of our resources to our research and development activities and anticipate continuing to do so for the near future. To date, none of our drug candidates have received regulatory marketing authorization or approval in the United States ("U.S.") by the Food and Drug Administration ("FDA") nor in any other countries or territories by any applicable agencies. We are receiving ongoing royalties pursuant to a license of our legacy PolyXen technology to an industry partner. Although we hold a broad patent portfolio, the focus of our internal efforts during the year ended December 31, 2024, was on the advancement of our DNase technology.

**Critical Accounting Estimates**

The preparation of our financial statements in conformity with U.S. generally accepted accounting principles ("U.S. GAAP") requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenue, costs and expenses during the reporting period. On an ongoing basis, we evaluate our estimates that are based on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. The result of these evaluations forms the basis for making judgments about the carrying values of assets and liabilities and the reported amount of expenses that are not readily apparent from other sources. Because future events and their effects cannot be determined with certainty, actual results and outcomes may differ materially from our estimates, judgments and assumptions.

Management believes that the following accounting estimates are the most critical to aid in fully understanding and evaluating our reported financial results, and they require management's most difficult subjective or complex judgments, resulting from the need to make estimates about the effect of matters that are inherently uncertain. The following narrative describes these critical accounting estimates, judgments and assumptions and the effect if actual results differ from these assumptions.

***Research and Development Expenses***

Research and development expenses consist of expenses incurred in performing research and development activities, including compensation and benefits, facilities expenses, overhead expenses, pre-clinical development, clinical trial and related clinical manufacturing expenses, fees paid to contract research organizations ("CROs") and contract manufacturing organizations ("CMOs") and other outside expenses. We expense research and development costs as incurred. We expense upfront, non-refundable payments made for research and development services as obligations are incurred, except when deposits are made for specifically identified services. The value ascribed to intangible assets acquired but which have not met capitalization criteria is expensed as research and development at the time of acquisition. Upfront payments under license agreements are expensed upon receipt of the license. Milestone payments under license agreements are accrued, with a corresponding expense being recognized, in the period in which the milestone is determined to be probable of achievement and the related amount is reasonably estimable.

We are required to estimate accrued research and development expenses at each reporting period. This process involves reviewing open contracts and purchase orders, communicating with our personnel and consultants to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met. However, some require advanced payments. We make estimates of accrued expenses as of each balance sheet date in the financial statements based on facts and circumstances known at that time. We periodically confirm the accuracy of the estimates with the service providers and make adjustments, if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- Collaborative partners performing research and development and pre-clinical activities;
- Program managers in connection with overall program management of clinical trials;
- CMOs in connection with cGMP manufacturing;
- CROs in connection with clinical trials; and
- Investigative sites in connection with clinical trials.

We base our expenses related to research and development, pre-clinical activities, manufacturing and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple research institutions, CMOs and CROs that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or prepaid accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

***Warrants***

In connection with certain financing, consulting and collaboration arrangements, we issued warrants to purchase shares of our common stock. The outstanding warrants are standalone instruments that are not puttable or mandatorily redeemable by the holder and are classified as equity awards. We measure the fair value of the awards using the Black-Scholes option pricing model as of the measurement date. Warrants issued to collaboration partners in conjunction with the issuance of common stock are initially recorded at fair value as a reduction in additional paid-in capital of the common stock issued.

All other warrants are recorded at fair value as expense on a straight-line basis over the requisite service period or at the date of issuance if there is not a service period or if service has already been rendered. For warrants that contain vesting triggers based on the achievement of certain objectives, we apply judgment to estimate the probability and timing of the achievement of those objectives. These estimates involve inherent uncertainties, and as a result, if the probability or timing of the achievement of those objectives change, expense related warrants could be materially different in the future. For warrants issued in connection with financing arrangements we allocate the proceeds based on the relative fair value of the award and other instrument(s).

**Impact of Global Conflicts on Operations**

The short and long-term implications of Russia's invasion of Ukraine and conflict in the Middle East are difficult to predict at this time. The imposition of current and future sanctions and counter sanctions may have an adverse effect on the economic markets generally and could impact our business, financial condition, and results of operations.

**Results of Operations**

The table below sets forth the comparison of our historical results of operations for the year ended December 31, 2024 to the year ended December 31, 2023.

| Description | 2024 | 2023 | Increase (Decrease) | Percentage Change |
|---|---|---|---|---|
| Revenue: | | | | |
| Royalty revenue | $ 2,500,284 | $ 2,539,986 | $ (39,702) | (1.6)% |
| Operating costs and expenses: | | | | |
| Research and development | (3,288,332) | (3,494,765) | (206,433) | (5.9)% |
| General and administrative | (3,416,380) | (3,560,936) | (144,556) | (4.1)% |
| Total operating costs and expenses | (6,704,712) | (7,055,701) | (350,989) | (5.0)% |
| Loss from operations | (4,204,428) | (4,515,715) | (311,287) | (6.9)% |
| Other income (expense): | | | | |
| Other (expense) income | (5,708) | 25,380 | (31,088) | (122.5)% |
| Interest income, net | 249,861 | 355,757 | (105,896) | (29.8)% |
| Net loss | $ (3,960,275) | $ (4,134,578) | $ (174,303) | (4.2)% |

*Revenue*

Revenue for the year ended December 31, 2024 was relatively flat with that of the year ended December 31, 2023.

*Research and Development Expense*

Overall, R&D expenses for the year ended December 31, 2024 decreased by approximately $0.2 million, or 5.9%, to $3.3 million from $3.5 million in the comparable period in 2023 primarily due to decreased spending in connection with our DNase process development efforts. During the year ended December 31, 2024, the Company expensed approximately $0.7 million related to the impairment of long-lived assets associated with our legacy PSA technology. There was no similar expense in 2023. Excluding the $0.7 million impairment charge from total R&D expense of $3.3 million for the year ended December 31, 2024, adjusted R&D expenses for the year ended December 31, 2024 decreased approximately $0.9 million, or 26.1%, to $2.6 million, from $3.5 million for the year ended December 31, 2023. The table below sets forth the R&D costs incurred by us, by category of expense, for the years ended December 31, 2024 and 2023:

| Category of Expense | Year ended December 31, 2024 | 2023 |
|---|---|---|
| Impairment of long-lived assets | $ 704,431 | $ – |
| Outside services and contract research organizations | 1,898,121 | 2,886,985 |
| Salaries and wages | 562,571 | 417,952 |
| Share-based expense | 11,434 | 56,112 |
| Other | 111,775 | 133,716 |
| Total research and development expense | $ 3,288,332 | $ 3,494,765 |

The decrease in outside services and contract research organizations expense was primarily due to the aforementioned decreased spending in connection with our process development efforts, partially offset by increased third-party pre-clinical development efforts related to our DNase technology. The increase in personnel costs is due to certain severance and benefits expensed in connection with a separation agreement entered into during the second quarter of 2024 with our former Chief Scientific Officer.

*General and Administrative Expense*

General and administrative expenses for the year ended December 31, 2024 was $3.4 million, decreasing by approximately $0.1 million, or 4.1%, compared to the same period in the prior year. The decrease was primarily due to a reduction in legal and accounting costs during the year ended December 31, 2024 compared to the prior year. These decreases were substantially offset by certain severance and benefits expensed in connection with a separation agreement entered into during the second quarter of 2024 with our former Chief Executive Officer.

*Other (Expense) Income*

Other expense was approximately $6,000 for the year ended December 31, 2024 compared to other income of approximately $25,400 for the same period in 2023. This decrease in other income was primarily related to fees associated with the Pharmsynthez Loan recognized during the year ended December 31, 2023 for which there were no similar fees received in the same period in 2024.

*Interest Income, net*

Interest income, net decreased to approximately $250,000 during the year ended December 31, 2024 as compared to approximately $356,000 in the prior year. This decrease is primarily due to lower average invested funds during the year ended December 31, 2024 compared to the prior year, as well as a decrease in interest income received on the Pharmsynthez Loan.

**Non-GAAP Measures**

In our narrative discussion of operations above, we exclude the impact of certain non-cash expenses from R&D expenses, which narrative discussion includes reconciliation of such adjusted financial measures to the directly comparable GAAP financial measure. We believe these adjusted operating measures may provide investors with useful information regarding our underlying performance from period to period and allow investors to better understand our results of operations. Management uses these adjusted measures when assessing the performance of the business.

**Liquidity and Capital Resources**

We incurred a net loss of approximately $4.0 million for the year ended December 31, 2024. We had an accumulated deficit of approximately $197.2 million at December 31, 2024, as compared to an accumulated deficit of approximately $193.2 million at December 31, 2023. Working capital was approximately $5.7 million at December 31, 2024, and approximately $8.8 million at December 31, 2023, respectively. During the year ended December 31, 2024, our working capital decreased by approximately $3.1 million primarily due to our net loss for the year ended December 31, 2024.

Our principal source of liquidity consists of cash. At December 31, 2024, we had approximately $6.2 million in cash and approximately $0.9 million in current liabilities. At December 31, 2023, we had approximately $9.0 million in cash and approximately $0.8 million in current liabilities. We have historically relied upon sales of our equity securities to fund our operations.

We evaluate whether there are conditions or events, considered in the aggregate that raise substantial doubt about our ability to continue as a going concern within one year after the date that the financial statements are issued. We have incurred substantial losses since our inception, and we expect to continue to incur operating losses in the near-term. We believe that our existing resources will be adequate to fund our operations for a period of at least twelve months from the date of the issuance of these financial statements. However, we anticipate we will need additional capital in the long-term to pursue our business initiatives. While we believe that we have access to capital resources through possible public or private equity offerings, debt financings, corporate collaborations, related party funding, or other means to continue as a going concern, the terms, timing and extent of any future financing will depend upon several factors, including the achievement of progress in our clinical development programs, our ability to identify and enter into licensing or other strategic arrangements, our continued listing on the Nasdaq Stock Market (“Nasdaq”), and factors related to financial, economic, geo-political, industry and market conditions, many of which are beyond our control. The capital markets for the biotech industry can be highly volatile, which make the terms, timing and extent of any future financing uncertain.

**Cash Flows from Operating Activities**

Cash flows used in operating activities for the year ended December 31, 2024 totaled approximately $2.8 million, which was primarily due to our net loss for the period, partially offset by non-cash charges associated with share-based expense. In addition, prepaid expenses and other decreased approximately $0.2 million, other assets decreased by approximately $0.7 million due to the impairment of long-lived assets and accounts payable, accrued expenses and other current liabilities increased approximately $0.1 million during the year ended December 31, 2024 compared to the prior year. Cash flows used in operating activities for the year ended December 31, 2023 totaled approximately $4.1 million, which was primarily due to our net loss for the period, partially offset by non-cash charges associated with share-based expense and, to a lesser extent, a decrease in accounts payable, accrued expenses and other current liabilities.

**Cash Flows from Investing Activities**

There were no cash flows from investing activities for each of the years ended December 31, 2024 and 2023.

**Cash Flows from Financing Activities**

There were no cash flows from financing activities for each of the years ended December 31, 2024 and 2023.

**Contractual Obligations**

Contractual obligations represent future cash commitments and liabilities under agreements with third-parties and exclude contingent liabilities for which we cannot reasonably predict future payment. Our contractual obligations result from a property lease for office space. Although we do have obligations for CMO and CRO services, the table below excludes potential payments we may be required to make under our agreements with CMOs and CROs because timing of payments and actual amounts paid under those agreements may be different depending on the timing of receipt of goods or services or changes to agreed-upon terms or amounts for some obligations, and those agreements are cancelable upon written notice by the Company and therefore, not long-term liabilities. The contracts may also contain variable costs that are hard to predict as they are based on such things as patients enrolled and clinical trial sites, which can vary and, therefore, are also not included in the table below. Additionally, the expected timing of payment of the obligations presented below is estimated based on current information.

The following tables represent our contractual obligations as of December 31, 2024, aggregated by type:

| | Payments Due by Period As of December 31, 2024 | | | | |
|---|---|---|---|---|---|
| | Total | Less than 1 year | 1-3 years | 3-5 years | More than 5 years |
| Lease obligations | $ 3,036 | $ 3,036 | $ – | $ – | $ – |
| Total | $ 3,036 | $ 3,036 | $ – | $ – | $ – |

**Recent Accounting Standards**

Refer to Note 3, *Summary of Significant Accounting Policies*, of the accompanying financial statements set forth in Item 8.

**ITEM 7A – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We are not required to provide the information required by this Item because we are a “smaller reporting company” (as defined in Rule 12b-2 of the Exchange Act).

**ITEM 8 – FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**


Report of Independent Registered Public Accounting Firm (PCAOB ID 688) ..... F-1

Consolidated Balance Sheets as of December 31, 2024 and 2023 ..... F-2

Consolidated Statements of Operations for the years ended December 31, 2024 and 2023 ..... F-3

Consolidated Statements of Stockholders' Equity for the years ended December 31, 2024 and 2023..... F-4

Consolidated Statements of Cash Flows for the years ended December 31, 2024 and 2023 ..... F-5

Notes to Consolidated Financial Statements..... F-6

[This page intentionally left blank]

## Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors of
Xenetic Biosciences, Inc.

**Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Xenetic Biosciences, Inc. (the "Company") as of December 31, 2024 and 2023, the related consolidated statements of operations, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2024, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

**Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

**Critical Audit Matters**

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Marcum LLP

We have served as the Company's auditor since 2015.

Hartford, CT
March 18, 2025

**XENETIC BIOSCIENCES, INC.**
**CONSOLIDATED BALANCE SHEETS**

| | December 31, 2024 | December 31, 2023 |
|---|---|---|
| ASSETS | | |
| Current assets: | | |
| Cash | $ 6,165,568 | $ 8,983,046 |
| Prepaid expenses and other | 421,954 | 603,828 |
| Total current assets | 6,587,522 | 9,586,874 |
| Other assets | 313,921 | 1,018,352 |
| Total assets | $ 6,901,443 | $ 10,605,226 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | $ 283,615 | $ 240,832 |
| Accrued expenses and other current liabilities | 610,648 | 568,753 |
| Total current liabilities | 894,263 | 809,585 |
| Total liabilities | 894,263 | 809,585 |
| Commitments and contingencies (Note 12) | | |
| Stockholders' equity: | | |
| Preferred stock, 10,000,000 shares authorized | | |
| Series B, $0.001 par value: 1,804,394 shares issued and outstanding as of December 31, 2024 and December 31, 2023 | 1,804 | 1,804 |
| Common stock, $0.001 par value; 10,000,000 shares authorized as of December 31, 2024 and December 31, 2023; 1,544,840 and 1,543,385 shares issued as of December 31, 2024 and December 31, 2023, respectively; 1,542,139 and 1,540,684 shares outstanding as of December 31, 2024 and December 31, 2023, respectively | 1,545 | 1,544 |
| Additional paid in capital | 208,225,748 | 208,053,935 |
| Accumulated deficit | (197,194,471) | (193,234,196) |
| Accumulated other comprehensive income | 253,734 | 253,734 |
| Treasury stock | (5,281,180) | (5,281,180) |
| Total stockholders' equity | 6,007,180 | 9,795,641 |
| Total liabilities and stockholders' equity | $ 6,901,443 | $ 10,605,226 |

The accompanying notes are an integral part of these consolidated financial statements.

**XENETIC BIOSCIENCES, INC.**
**CONSOLIDATED STATEMENTS OF OPERATIONS**

| | FOR THE YEARS ENDED DECEMBER 31, | |
|---|---|---|
| | **2024** | **2023** |
| Revenue | | |
| Royalty revenue | $ 2,500,284 | $ 2,539,986 |
| Total revenue | 2,500,284 | 2,539,986 |
| Operating costs and expenses: | | |
| Research and development | (3,288,332) | (3,494,765) |
| General and administrative | (3,416,380) | (3,560,936) |
| Total operating costs and expenses | (6,704,712) | (7,055,701) |
| Loss from operations | (4,204,428) | (4,515,715) |
| Other income (expense): | | |
| Other (expense) income | (5,708) | 25,380 |
| Interest income, net | 249,861 | 355,757 |
| Total other income, net | 244,153 | 381,137 |
| Net loss | $ (3,960,275) | $ (4,134,578) |
| Basic and diluted net loss per share | $ (2.57) | $ (2.71) |
| Weighted-average shares of common stock outstanding, basic and diluted | 1,541,339 | 1,528,210 |

The accompanying notes are an integral part of these consolidated financial statements.

**XENETIC BIOSCIENCES, INC.**
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**

| | Preferred Stock | | Common Stock | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Number of Shares | Par Value ($0.001) | Number of Shares | Par Value ($0.001) | Additional Paid in Capital | Accumulated Deficit | Accumulated Other Comprehensive Income | Treasury Stock | Total Stockholders' Equity |
| **Balance as of January 1, 2023** | 2,774,394 | $ 2,774 | 1,519,360 | $ 1,520 | $207,769,904 | $(189,099,618) | $ 253,734 | $(5,281,180) | $ 13,647,134 |
| Issuance of common stock to adjust for reverse split rounding | – | – | 15,941 | 16 | (16) | – | – | – | – |
| Conversion of Series A preferred stock to shares of common stock | (970,000) | (970) | 8,084 | 8 | 962 | – | – | – | – |
| Share-based expense | – | – | – | – | 283,085 | – | – | – | 283,085 |
| Net loss | – | – | – | – | – | (4,134,578) | – | – | (4,134,578) |
| **Balance as of December 31, 2023** | 1,804,394 | $ 1,804 | 1,543,385 | $ 1,544 | $208,053,935 | $(193,234,196) | $ 253,734 | $(5,281,180) | $ 9,795,641 |
| Issuance of common stock in connection with restricted stock units | – | – | 417 | – | – | – | – | – | – |
| Exercise of purchase warrants | – | – | 1,038 | 1 | (1) | – | – | – | – |
| Share-based expense | – | – | – | – | 171,814 | – | – | – | 171,814 |
| Net loss | – | – | – | – | – | (3,960,275) | – | – | (3,960,275) |
| **Balance as of December 31, 2024** | 1,804,394 | $ 1,804 | 1,544,840 | $ 1,545 | $208,225,748 | $(197,194,471) | $ 253,734 | $(5,281,180) | $ 6,007,180 |

The accompanying notes are an integral part of these consolidated financial statements.

**XENETIC BIOSCIENCES, INC.**
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

| | FOR THE YEARS ENDED DECEMBER 31, | |
|---|---|---|
| | **2024** | **2023** |
| **CASH FLOWS FROM OPERATING ACTIVITIES:** | | |
| Net loss | $ (3,960,275) | $ (4,134,578) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Share-based expense | 171,814 | 283,085 |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other | 181,874 | (47,734) |
| Other long-term assets | 704,431 | 48,579 |
| Accounts payable, accrued expenses and other liabilities | 84,678 | (263,571) |
| Net cash used in operating activities | (2,817,478) | (4,114,219) |
| Net change in cash | (2,817,478) | (4,114,219) |
| Cash at beginning of period | 8,983,046 | 13,097,265 |
| Cash at end of period | $ 6,165,568 | $ 8,983,046 |
| **SUPPLEMENTAL CASH FLOW INFORMATION:** | | |
| Cash paid for interest | $ – | $ – |
| **SUPPLEMENTAL SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:** | | |
| Issuance of common stock from cashless exercise of purchase warrants | $ 1 | $ – |
| Issuance of common stock to adjust for Reverse Stock Split | $ – | $ 16 |
| Conversion of Series A preferred stock to common stock | $ – | $ 970 |

The accompanying notes are an integral part of these consolidated financial statements.

## 1. The Company

### *Background*

Xenetic Biosciences, Inc. ("Xenetic" or the "Company"), incorporated in the state of Nevada and based in Framingham, Massachusetts, is a biopharmaceutical company focused on advancing innovative immune-oncology technologies addressing difficult to treat cancers. The Company's proprietary Deoxyribonuclease ("DNase") technology 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, directly or indirectly, through its wholly-owned subsidiaries, Hesperix S.A. ("Hesperix") and Xenetic Biosciences (U.K.) Limited ("Xenetic UK"), and the wholly-owned subsidiaries of Xenetic UK, Lipoxen Technologies Limited ("Lipoxen"), Xenetic Bioscience, Incorporated and SymbioTec, GmbH ("SymbioTec"), own various United States ("U.S.") federal trademark registrations and applications along with unregistered trademarks and service marks, including but not limited to XCART, OncoHist™, PolyXen®, ErepoXen™, and ImuXen™, which are used throughout this Annual Report. All other company and product names may be trademarks of the respective companies with which they are associated.

### *Going Concern and Management's Plan*

Management evaluates whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. The Company has incurred substantial losses since its inception and expects to continue to incur operating losses in the near-term. The Company believes that its existing resources will be adequate to fund the Company's operations for a period of at least twelve months from the date of the issuance of these financial statements. However, the Company anticipates it will need additional capital in the long-term to pursue its business initiatives. While the Company believes that it has access to capital resources through possible public or private equity offerings, debt financings, corporate collaborations, related party funding, or other means to continue as a going concern, the terms, timing and extent of any future financing will depend upon several factors, including the achievement of progress in its product development programs, its ability to identify and enter into licensing or other strategic arrangements, its continued listing on the Nasdaq Stock Market ("Nasdaq"), and factors related to financial, economic, geo-political, industry and market conditions, many of which are beyond its control. The capital markets for the biotech industry can be highly volatile, which make the terms, timing and extent of any future financing uncertain.

## 2. Risks and Uncertainties

### *Impact of Global Conflicts on Operations*

The short and long-term implications of the conflicts in the Ukraine and Middle East are difficult to predict at this time. The imposition of current and future sanctions and counter sanctions may have an adverse effect on the economic markets generally and could impact our business, financial condition, and results of operations.

## 3. Summary of Significant Accounting Policies

### *Preparation of Financial Statements*

On May 15, 2023, the Company effected a reduction, on a 1-for-10 basis, in its authorized common stock, par value $0.001, along with a corresponding and proportional decrease in the number of shares issued and outstanding (the "Reverse Stock Split"). On the effective date of the Reverse Stock Split, (i) every 10 shares of common stock were reduced to one share of common stock, with any fractional amounts rounded up to one share; (ii) the number of shares of common stock into which each outstanding warrant, restricted stock unit ("RSU"), or option to purchase common stock was convertible into was proportionately reduced on the same basis as the common stock; (iii) the exercise price of each outstanding warrant or option to purchase common stock was proportionately increased on a 1-to-10 basis; and (iv) the number of shares of common stock into which each share of preferred stock was convertible into was proportionately reduced on the same basis as the common stock. Unless otherwise indicated, all of the share numbers, share prices, and exercise prices have been adjusted in this Annual Report, on a retroactive basis, to reflect this 1-for-10 Reverse Stock Split.

***Principles of Consolidation***

The consolidated financial statements of the Company include the accounts of Hesperix, Xenetic UK and Xenetic UK's wholly-owned subsidiaries: Lipoxen, Xenetic Bioscience, Incorporated, and SymbioTec. Certain of the Company's subsidiaries require guarantees of support from Xenetic. While all intercompany balances and transactions have been eliminated in consolidation, the Company has $0.2 million of cash collateralizing these guarantees.

***Use of Estimates***

The consolidated financial statements and accompanying notes are prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"). The preparation of the financial statements in accordance with U.S. GAAP requires management to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, the reported amounts of revenue, costs and expenses in the financial statements and disclosures in the accompanying notes. Actual results and outcomes may differ materially from management's estimates, judgments and assumptions.

***Functional Currency Change***

The functional currency for the Company's foreign subsidiaries is the U.S. dollar. The functional currency of the Company's UK-based subsidiaries changed from the British Pound Sterling to the U.S. dollar when the Company relocated to the U.S. in 2014. The change in functional currency was applied on a prospective basis. Therefore, any gains and losses that were previously recorded in accumulated other comprehensive income remain unchanged.

***Foreign Currency Transactions***

Realized and unrealized gains and losses resulting from foreign currency transactions arising from exchange rate fluctuations on balances denominated in currencies other than the functional currencies are recognized in "Other (expense) income" in the consolidated statements of operations. Monetary assets and liabilities that are denominated in a currency other than the functional currency are re-measured to the functional currency using the exchange rate at the balance sheet date and gains or losses are recorded in the consolidated statements of operations.

***Fair Value of Financial Instruments***

Accounting Standards Codification ("ASC") Topic 820, *Fair Value Measurement,* defines fair value as the price that would be received to sell an asset or be paid to transfer a liability in an orderly transaction between market participants at the measurement date. The Company applies the following fair value hierarchy, which prioritizes the inputs used to measure fair value into three levels and bases the categorization within the hierarchy upon the lowest level of input that is available and significant to the fair value measurement. Level 1 inputs are quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date. Level 2 utilizes quoted market prices in markets that are not active, broker or dealer quotations or alternative pricing sources with reasonable levels of price transparency. Level 3 inputs are unobservable inputs for the asset or liability in which there is little, if any, market activity for the asset or liability at the measurement date. As of December 31, 2024 and 2023, the carrying amount of certain of the Company's financial instruments approximates fair value due to their short maturities. See Note 7, *Fair Value Measurements*, for discussion of the Company's fair value measurements.

***Cash and Concentrations of Credit Risk***

The Company considers all highly liquid investments with an original maturity of 90 days or less from the date of purchase to be cash equivalents. Investments with original maturities of greater than 90 days from the date of purchase but less than one year from the balance sheet date are classified as short-term investments, while investments with maturities of one year or beyond from the balance sheet date are classified as long-term investments. Management determines the appropriate classification of its cash equivalents and investment securities at the time of purchase and re-evaluates such determination as of each balance sheet date. The carrying amount of cash equivalents approximate their fair value due to the short-term nature of these instruments.

Financial instruments that potentially subject the Company to credit risk consist primarily of cash on deposit with financial institutions, the balances of which may exceed federally insured limits. The Company has not experienced any losses on such accounts, and does not believe it is exposed to any unusual credit risk beyond the normal credit risk currently associated with commercial banking relationships. The Company maintains its primary banking relationship with one large financial institution and all cash on deposit is covered under federally insured limits.

***Indefinite-Lived Intangible Assets***

Assets acquired and liabilities assumed in business combinations, licensing and other transactions are generally recognized at the date of acquisition at their respective fair values. At acquisition, the Company generally determines the fair value of intangible assets, including in-process research and development ("IPR&D"), using the "income method." Acquired IPR&D intangible assets are considered indefinite-lived intangible assets and are not amortized until completion or abandonment of the associated research and development efforts. Substantial additional research and development may be required before the Company's IPR&D reaches technological feasibility. Upon completion of the IPR&D project, the IPR&D assets will be amortized over their estimated useful lives.

Indefinite-lived intangible assets are not amortized but are reviewed for impairment at least annually or when events or changes in the business environment indicate that it is more likely than not that the carrying value may be impaired. The Company also has the option to first assess qualitative factors to determine whether the existence of events or circumstances leads the Company to determine that it is more likely than not (that is, a likelihood of more than 50%) that the acquired indefinite-lived intangible assets are impaired. If the Company chooses to first assess the qualitative factors and it is determined that it is not more likely than not acquired indefinite-lived intangible assets are impaired, the Company is not required to take further action to test for impairment. The Company also has the option to bypass the qualitative assessment and perform only the quantitative impairment test, which the Company may choose to perform in some periods but not in others. The impairment loss, if any, is measured as the excess of the carrying value of the intangible asset over its fair value.

Intangible assets are highly vulnerable to impairment charges, particularly newly acquired assets for IPR&D. Considering the high risk nature of research and development and the industry's success rate of bringing developmental compounds to market, indefinite-lived intangible asset impairment charges are likely to occur in future periods. Estimating the fair value of indefinite-lived intangible assets for potential impairment is highly sensitive to changes in projections and assumptions and changes to assumptions could potentially lead to impairment. The Company believes its estimates and assumptions are reasonable and otherwise consistent with assumptions market participants would use in their estimates of fair value. However, if future results are not consistent with the Company's estimates and assumptions, then the Company may be exposed to an impairment charge, which could be material. Use of different estimates and judgments could yield materially different results in the Company's analysis and could result in materially different asset values or expense.

***Revenue Recognition***

The Company enters into supply, license and collaboration arrangements with pharmaceutical and biotechnology partners, some of which include royalty agreements based on potential net sales of approved commercial pharmaceutical products.

The Company recognizes revenue in accordance with ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue at a point in time, or over time, as it satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that it will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract, determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

As part of the accounting for these arrangements, the Company must use judgment to determine: a) the number of performance obligations based on the determination under step (ii) above; b) the transaction price under step (iii) above; and c) the stand-alone selling price for each performance obligation identified in the contract for the allocation of transaction price in step (iv) above. The Company uses judgment to determine whether milestones or other variable consideration should be included in the transaction price as described further below. The transaction price is allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. In developing the stand-alone price for a performance obligation, the Company considers applicable market conditions and relevant entity-specific factors, including factors that were contemplated in negotiating the agreement with the customer and estimated costs. The Company validates the stand-alone selling price for performance obligations by evaluating whether changes in the key assumptions used to determine the stand-alone selling prices will have a significant effect on the allocation of transaction price between multiple performance obligations. The Company recognizes a contract asset or liability for the difference between the

Company's performance (i.e., the goods or services transferred to the customer) and the customer's performance (i.e., the consideration paid by, and unconditionally due from, the customer).

The terms of the Company's license agreements may include delivery of an intellectual property license to a collaboration partner. The Company may be compensated under license arrangements through a combination of non-refundable upfront receipts, development and regulatory objective receipts and royalty receipts on future product sales by partners. The Company anticipates recognizing non-refundable upfront license payments and development and regulatory milestone payments received by the Company in license and collaboration arrangements that include future obligations, such as supply obligations, ratably over the Company's expected performance period under each respective arrangement. The Company makes its best estimate of the period over which the Company expects to fulfill the Company's performance obligations, which may include technology transfer assistance, research activities, clinical development activities, and manufacturing activities from development through the commercialization of the product. Given the uncertainties of these collaboration arrangements, significant judgment is required to determine the duration of the performance period.

When the Company enters into an arrangement to sublicense some of its patents, it will consider the performance obligations to determine if there is a single element or multiple elements to the arrangement as it determines the proper method and timing of revenue recognition. The Company considers the terms of the license or sublicense for such elements as price adjustments or refund clauses in addition to any performance obligations for it to provide such as services, patent defense costs, technology support, marketing or sales assistance or any other elements to the arrangement that could constitute an additional deliverable to it that could change the timing of the revenue recognition. Non-refundable upfront license and sublicense fees received, whereby continued performance or future obligations are considered inconsequential or perfunctory to the relevant licensed technology, are recognized as revenue upon delivery of the technology.

The Company expects to recognize royalty revenue in the period of sale, based on the underlying contract terms, provided that the reported sales are reliably measurable, the Company has no remaining performance obligations, and all other revenue recognition criteria are met. The Company anticipates reimbursements for research and development services completed by the Company related to the collaboration agreements to be recognized in operations as revenue on a gross basis. The Company's license and collaboration agreements with certain collaboration partners could also provide for future milestone receipts to the Company based solely upon the performance of the respective collaboration partner in consideration of deadline extensions or upon the achievement of specified sales volumes of approved drugs. For such receipts, the Company expects to recognize the receipts as revenue when earned under the applicable contract terms on a performance basis or ratably over the term of the agreement. These receipts may also be recognized as revenue when continued performance or future obligations by the Company are considered inconsequential or perfunctory.

See also Note 4, *Significant Strategic Collaborations*.

***Research and Development Expenses***

Research and development expenses consist of expenses incurred in performing research and development activities, including compensation and benefits, facilities expenses, overhead expenses, pre-clinical development, clinical trial and related clinical manufacturing expenses, fees paid to contract research organizations ("CROs") and contract manufacturing organizations ("CMOs") and other outside expenses. The Company expenses research and development costs as incurred. The Company expenses upfront, non-refundable payments made for research and development services as obligations are incurred, except when deposits are made for specifically identified future services. The value ascribed to intangible assets acquired but which have not met capitalization criteria is expensed as research and development at the time of acquisition. Upfront payments under license agreements are expensed upon receipt of the license. Milestone payments under license agreements are accrued, with a corresponding expense being recognized, in the period in which the milestone is determined to be probable of achievement and the related amount is reasonably estimable.

The Company is required to estimate accrued research and development expenses at each reporting period. This process involves reviewing open contracts and purchase orders, communicating with Company personnel and consultants to identify services that have been performed on its behalf and estimating the level of service performed and the associated cost incurred for the service when the Company has not yet been invoiced or otherwise notified of actual costs. The majority of the Company's service providers invoice in arrears for services performed, on a pre-determined schedule or when contractual milestones are met. However, some require advanced payments. The Company makes estimates of accrued expenses as of each balance sheet date in the financial statements based on facts and circumstances known at that time. The Company periodically confirms the accuracy of the estimates with the service providers and makes adjustments, if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- Collaborative partners performing research and development and pre-clinical activities;
- Program managers in connection with overall program management of clinical trials;
- CMOs in connection with cGMP manufacturing;
- CROs in connection with clinical trials; and
- Investigative sites in connection with clinical trials.

The Company bases its expenses related to research and development, pre-clinical activities, manufacturing and clinical trials on its estimates of the services received and efforts expended pursuant to quotes and contracts with multiple research institutions, CMOs and CROs that conduct and manage clinical trials on the Company's behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company adjusts the accrual or prepaid accordingly. Although it does not expect its estimates to be materially different from amounts actually incurred, the Company's understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to the Company's prior estimates of accrued research and development expenses. The Company has recorded approximately $0.3 million and $0.5 million of prepayments as a component of prepaid expenses and other current assets as of December 31, 2024 and 2023, respectively. In addition, the Company had recorded accrued program expense of approximately $0.2 million and $0.1 million as a component of accrued expenses as of each of December 31, 2024 and 2023, respectively.

***Share-based Expense***

The Company grants share-based payments in the form of options and RSUs to employees and non-employees to purchase shares of the Company's common stock. In addition, prior to the Company relocating to the U.S. in 2014, the Company had issued Joint Share Ownership Plan ("JSOP") awards to employees and entered into agreements to issue common stock in exchange for services provided by non-employees.

Share-based expense is based on the estimated fair value of the option or calculated using the Black-Scholes option pricing model. Determining the appropriate fair value model and related assumptions requires judgment, including estimating share price volatility and expected terms of the awards. The expected volatility rates are estimated based on the historical volatility of the Company. To the extent Company data is not available for the full expected term of the awards the Company uses a weighted-average of the historical volatility of the Company and of a peer group of comparable publicly traded companies over the expected term of the option. The expected term represents the time that options are expected to be outstanding. The Company accounts for forfeitures as they occur and not at the time of grant. The Company has not paid dividends and does not anticipate paying cash dividends in the foreseeable future and, accordingly, uses an expected dividend yield of zero. The risk-free interest rate is based on the rate of U.S. Treasury securities with maturities consistent with the estimated expected term of the awards. Upon exercise, stock options are redeemed for newly issued shares of common stock. RSUs are redeemed for newly issued shares of common stock as the vesting and settlement provisions of the grant are met.

For employee options that vest based solely on service conditions, the fair value measurement date is generally on the date of grant and the related compensation expense is recognized on a straight-line basis over the requisite vesting period of the awards. For non-employee options issued in exchange for goods or services consumed in the Company's operations, the fair value measurement date is the earlier of the date the performance of services is complete or the date the performance commitment has been reached. The Company generally determines that the fair value of the stock options is more reliably measurable than the fair value of the services received. Compensation expense related to stock options granted to non-employees is recognized on a straight-line basis over requisite vesting periods of the awards.

***Warrants***

In connection with certain financing, consulting and collaboration arrangements, the Company has issued warrants to purchase shares of its common stock. The outstanding warrants are standalone instruments that are not puttable or mandatorily redeemable by the holder and are classified as equity awards. The Company measures the fair value of the awards using the Black-Scholes option pricing model as of the measurement date. Warrants issued to collaboration partners in conjunction with the issuance of common stock are initially recorded at fair value as a reduction in additional paid-in capital of the common stock issued. All other warrants are recorded at fair value as expense on a straight-line basis over the requisite service period or at the date of issuance if there is not a service period or if service has already been rendered. Warrant arrangements are more fully described in Note 9, *Stockholders' Equity*.

***Income Taxes***

The Company accounts for income taxes using the asset and liability method. Under this method, deferred tax assets and liabilities are determined based on temporary differences resulting from the different treatment of items for tax and financial reporting purposes. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to reverse. Additionally, the Company must assess the likelihood that deferred tax assets will be recovered as deductions from future taxable income. The Company evaluates the recoverability of its deferred tax assets on a quarterly basis.

***Basic and Diluted Net Loss per Share***

The Company computes basic net loss per share by dividing net loss applicable to common stockholders by the weighted-average number of shares of the Company's common stock outstanding during the period. The Company computes diluted net loss per share after giving consideration to the dilutive effect of stock options that are outstanding during the period, except where such non-participating securities would be anti-dilutive. The Company's JSOP awards, prior to exercise, are considered treasury shares by the Company and thus do not impact the Company's net loss per share calculation.

For the years ended December 31, 2024 and 2023, basic and diluted net loss per share are the same for each year due to the Company's net loss position. Potentially dilutive, non-participating securities have not been included in the calculations of diluted net loss per share, as their inclusion would be anti-dilutive. As of December 31, 2024 and 2023, approximately 3,000 and 5,000 potentially dilutive securities were deemed anti-dilutive for each period.

***Segment Information***

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2023-07, to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant expenses. Under this ASU, a company is required to enhance its segment disclosures to include significant segment expenses that are regularly provided to the chief operating decision maker (CODM), a description of other segment items by reportable segment, and any additional measures of a segment's profit or loss used by the CODM when deciding how to allocate resources. This ASU was adopted effective for the Company's fiscal year ending December 31, 2024 and the adoption did not have a material impact on the Company's consolidated financial statements.

The Company is principally engaged in pre-clinical research and development activities to advance its DNase technology. Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the CODM, who is the Company's Chief Executive Officer, in making decisions on how to allocate resources and assess performance. The Company views its operations and manages its business as a single operating segment. The Company's measure of segment profit or loss is net loss. The CODM manages and allocates to the operations of the Company on a total company basis. Managing and allocating resources on a consolidated basis enables the CODM to assess the overall level of resources available and how best to deploy these resources across functions, therapeutic areas and research and development projects that are in line with the Company's long-term company-wide strategic goals. Consistent with this decision-making process, the CODM uses consolidated financial information for purposes of evaluating performance, forecasting future period financial results, allocating resources and setting incentive targets. The following table is representative of the significant expense categories regularly provided to the CODM when managing the Company's single reporting segment. A reconciliation to the consolidated net loss for the years ended December 31, 2024 and 2023 is as follows:

| | Year Ended December 31, | |
|---|---|---|
| | **2024** | **2023** |
| Revenue | $ 2,500,284 | $ 2,539,986 |
| Program expenses[(1)] | 1,898,121 | 2,886,985 |
| Non-program expenses[(2)] | 2,754,895 | 2,386,508 |
| Salaries and wages | 1,879,882 | 1,499,123 |
| Other segment items[(3)] | (72,339) | (98,052) |
| Net loss | $ (3,960,275) | $ (4,134,578) |

(1) Includes external research and development.
(2) Includes information technology, legal, intellectual property and other general and administrative expenses.
(3) Includes stock-based compensation expense, interest income and other expense (income).

***Leases***

The Company leases administrative facilities under operating leases. The Company recognizes a lease liability and a right-of-use asset for all leases, with the exception of short-term leases, at the commencement date. See Note 12, *Commitments and Contingencies* for further information.

***Recent Accounting Standards***

*Income Taxes - Improvements to Income Tax Disclosures (Topic 740)*. In December 2023, the FASB issued ASU No. 2023-09, to improve income tax disclosure requirements, primarily through enhanced disclosures related to the income tax rate reconciliation and income taxes paid. This ASU is effective for fiscal 2025, with early adoption permitted, and may be applied retrospectively. The Company is currently evaluating the effects that the adoption of this ASU will have on its consolidated financial statements.

**4. Significant Strategic Collaborations**

***Takeda Pharmaceutical Co. Ltd. ( together with its wholly-owned subsidiaries, "Takeda")***

In October 2017, the Company granted to Takeda the right to grant a non-exclusive sublicense to certain patents related to the Company's PolyXen technology that were previously exclusively licensed to Takeda in connection with products related to the treatment of blood and bleeding disorders. Royalty payments of approximately $2.5 million were recorded as revenue for each year by the Company during the years ended December 31, 2024 and 2023 and are based on single digit royalties on net sales of certain covered products. The Company's policy is to recognize royalty payments as revenue when they are reliably measurable, which is upon receipt of reports from Takeda. The Company receives these reports in the quarter subsequent to the actual sublicensee sales. At the time the revenue was received, there were no remaining performance obligations and all other revenue recognition criteria were met.

***Belgian Volition SARL Limited ("Volition") Collaboration***

On August 2, 2022, the Company announced a research and development collaboration with Volition to develop NETs-targeted adoptive cell therapies for the treatment of cancer. The collaboration is an early exploratory program to evaluate the potential combination of Volition's Nu.Q® Technology Test and the Company's DNase-Armored CAR T platform to develop proprietary adoptive cell therapies potentially targeting multiple types of solid cancers. Under the terms of the collaboration agreement, Volition will fund a research program and the two parties will share proceeds from commercialization or licensing of any products arising from the collaboration. To date, Volition has funded $26,000 under this agreement.

***Catalent Pharma Solutions LLC ("Catalent")***

On June 30, 2022, the Company entered into a Statement of Work (the "SOW") with 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 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. The Company has paid Catalent approximately $2.5 million through December 31, 2024, of which $28,000 and $0.1 million has been recognized as an advance payment and is included in prepaid expenses and other current assets as of December 31, 2024 and 2023, respectively, and approximately $0.1 million has been recognized as a liability and is included in accrued expenses and other current liabilities as of December 31, 2024. There was no accrual as of December 31, 2023. In addition, approximately $0.3 million has been recognized within other assets as of both December 31, 2024 and 2023.

***Scripps Research***

On March 17, 2023, the Company and Scripps Research entered into a Research Funding and Option Agreement (the "Agreement"), pursuant to which the Company has agreed to provide Scripps Research an aggregate of up to $0.9 million to fund research relating to advancing the pre-clinical development of the Company's DNase technology. Under the Agreement, the Company has the option to acquire a worldwide exclusive license to Scripps Research's rights in the Technology or Patent Rights (as defined in the Agreement), as well as a non-exclusive, royalty-free, non-transferrable license to make and use TSRI Technology (as defined in the Agreement) solely for the Company's internal research purposes during the performance of the research program contemplated by the Agreement. During the second quarter of 2024, the Company amended the Agreement to extend the term to October 31, 2024 with no additional funding required.

On November 1, 2024, the Company and Scripps Research entered into a Second Amendment to the Agreement (the "Second Amendment") extending the term of the Agreement for an additional twelve (12) month period and to provide Scripps Research additional funding in an aggregate amount of up to approximately $400,000 to fund continuing research. The research funding is payable by the Company to Scripps Research on a monthly basis in accordance with a negotiated budget, which provides for an initial payment of approximately $65,000 on the date of the Amendment and subsequent monthly payments of approximately $65,000 over a 5-month period. All other terms of the Original Agreement remain unchanged.

The Company paid Scripps Research approximately $0.9 million under the Agreement through December 31, 2024, of which approximately $0.4 million had been recognized as an advance payment and was included in prepaid expenses and other current assets as of December 31, 2023. There was no amount prepaid as of December 31, 2024.

***University of Virginia ("UVA")***

On December 21, 2023, the Company entered into a Research Funding and Material Transfer Agreement with UVA (the "UVA Agreement") to advance the development of our systemic DNase program. Under the terms of the UVA Agreement, in addition to advancing our existing intellectual property, the Company has an option to acquire an exclusive license to any new intellectual property arising from the DNase research program. Allan Tsung, MD, a member of the Company's Scientific Advisory Board and Chair of the Department of Surgery at the UVA School of Medicine, will oversee the research conducted under the UVA Agreement. In November 2024, the Company and UVA entered into an amendment to extend the UVA Agreement through December 2025. Pursuant to the UVA agreement, as amended, UVA will build on the preclinical and translational data produced to date and continue to investigate combinations of DNase I with immunotherapies in models of primary and metastatic colorectal cancer. The Company paid UVA approximately $0.4 million under the UVA Agreement through December 31, 2024, of which $0.1 million has been recognized as an advance payment and is included within prepaid expenses and other current assets as of December 31, 2024. There were no amounts incurred as of December 31, 2023.

***PJSC Pharmsynthez***

In November 2009, the Company entered into a collaborative research and development license agreement with Pharmsynthez (the "Pharmsynthez Arrangement") pursuant to which the Company granted an exclusive license to Pharmsynthez to develop, commercialize and market six product candidates based on the Company's PolyXen and ImuXen technology in certain territories. In exchange, Pharmsynthez granted an exclusive license to the Company to use any preclinical and clinical data developed by Pharmsynthez, within the scope of the Pharmsynthez Arrangement, and to engage in further research, development and commercialization of drug candidates outside of certain territories at the Company's own expense.

Pharmsynthez directly, and indirectly through its wholly-owned subsidiary, SynBio, LLC ("SynBio"), had a share ownership in the Company of approximately 3.4% of the total outstanding common stock as of both December 31, 2024 and 2023, respectively. In addition to its common stock ownership, Pharmsynthez owns approximately 1.5 million shares of our outstanding Series B Preferred Stock (as defined in Note 9, *Stockholders' Equity*.)

In August 2011, SynBio and the Company entered into a stock subscription and collaborative development agreement (the "Co-Development Agreement"). The Company granted an exclusive license to SynBio to develop, market and commercialize certain drug candidates utilizing molecules based on SynBio's technology and the Company's proprietary technologies (PolyXen, OncoHist and ImuXen) in Russia and Commonwealth of Independent States, collectively referred to herein as the SynBio Market. In return, SynBio granted an exclusive license to the Company to use the preclinical and clinical data generated by SynBio in certain agreed products and to engage in the development of commercial candidates in any territory outside of the SynBio Market.

SynBio is solely responsible for funding and conducting their own research and clinical development activities. There are no milestone or other research-related payments provided for under the Co-Development Agreement other than fees for the supply of each company's respective research supplies based on their technology, which, when provided, are due to mutual convenience and not representative of an ongoing or recurring obligation to supply research supplies. Upon successful commercialization of any resultant products, the Company is entitled to receive a 10% royalty on sales in certain territories and pay royalties to SynBio for sales outside those certain territories, subject to the terms of the Co-Development Agreement. Effective December 20, 2021, SynBio assigned the Co-Development Agreement to Pharmsynthez.

Through December 31, 2024, Pharmsynthez continued to engage in research and development activities with no resultant commercial products. In December 2020, Pharmsynthez reported positive data from its Phase 3 clinical study of Epolong, a treatment for anemia in patients with chronic kidney disease leveraging the Company's PolyXen technology. Pharmsynthez filed a registration dossier to obtain approval in Russia and informed the Company that it has received a response letter indicating certain deficiencies in the dossier. Pharmsynthez further informed the Company that it developed a gap mitigation strategy and is currently determining next steps. The Company did not recognize revenue in connection with the Co-Development Agreement during the years ended December 31, 2024 and 2023.

***Serum Institute of India Limited***

In August 2011, the Company entered into a collaborative research and development agreement with Serum Institute of India Limited ("Serum Institute") providing Serum Institute an exclusive license to use the Company's PolyXen technology to research and develop one potential commercial product, Polysialylated Erythropoietin. Serum Institute is responsible for conducting all preclinical and clinical trials required to achieve regulatory approvals within the certain predetermined territories at Serum Institute's own expense. Royalty payments are payable by Serum Institute to the Company for net sales to certain customers in the Serum Institute sales territory. There are no milestone or other research-related payments due under the collaborative arrangement. Serum Institute has informed the Company that it is not actively pursuing this program but may seek to leverage Pharmsynthez' trial data and potential Russian marketing authorization to request a waiver for a Phase III clinical trial in India, subject to local regulatory authority approval. Through December 31, 2024, no commercial products were developed and no royalty revenue or expense was recognized by the Company related to the arrangement. Serum Institute had a share ownership of less than 1% of the total outstanding common stock of the Company as of each of December 31, 2024 and 2023.

## 5. Other Assets

In 2016, the Company entered into an agreement with Serum Institute for the prepayment of clinical polysialic acid ("PSA') supply in exchange for the Company's common stock. As of December 31, 2023 the Company had classified $0.7 million of prepaid clinical supply as long-term as it did not anticipate utilizing the majority of the PSA supply within the next 12 months. No clinical supply was utilized during the years ended December 31, 2024 and 2023. Long-lived assets to be held and used are tested for impairment whenever events or changes in circumstances indicate that the carrying value may not be recoverable. While the prepayment remains a valid claim for future PSA supply, the Company concluded that the following factors indicated that the long-lived asset was impaired: the failure to identify potential third-party partners to develop, sell or license the PSA technology; a change in both the Company's management and the Board of Directors (the "Board"); and a decision by the Company and the Board to no longer pursue development of the PSA supply and allow current patent protection for the PSA technology to lapse. During the year ended December 31, 2024, the Company recorded an asset impairment charge of $0.7 million, which is presented within research and development expenses in the consolidated statements of operations, representing the excess of the long-lived asset's carrying value over its estimated fair value. As a result, there was no clinical supply recorded as of December 31, 2024. No long-lived asset impairment was recorded during the year ended December 31, 2023.

## 6. Accrued Expenses and other current liabilities

Accrued expenses and other current liabilities consist of the following:

| | December 31, 2024 | December 31, 2023 |
|---|---|---|
| Accrued payroll and benefits | $ 243,396 | $ 216,547 |
| Accrued professional fees | 143,661 | 233,950 |
| Accrued research costs | 189,388 | 70,000 |
| Other | 34,203 | 48,256 |
| | $ 610,648 | $ 568,753 |

On June 19, 2024, the Company entered into a confidential separation agreement and general release with each of Jeffrey F. Eisenberg, the Company's former Chief Executive Officer (the "Eisenberg Separation Agreement"), and Curtis Lockshin, the Company's former Chief Scientific Officer (together, the "Separation Agreements") pursuant to which Messrs. Eisenberg and Lockshin were each eligible for certain severance payments and benefits consistent with the terms of their existing employment agreements as described under "Employment Agreements with our Named Executive Officers" in our Proxy Statement on Schedule 14A filed by the Company with the SEC on October 31, 2024. In addition, the Eisenberg Separation Agreement provided for accelerated vesting of all of the unvested stock options held by Mr. Eisenberg as of May 16, 2024. During the year ended December 31, 2024, the Company expensed approximately $0.8 million of accrued payroll and benefits related to the Separation Agreements. In addition, the Company recorded approximately $13,000 of share-based expense for the accelerated vesting of unvested stock options. As of December 31, 2024, approximately $0.2 million was accrued within accrued expenses and other current liabilities related to these obligations.

## 7. Fair Value Measurements

ASC Topic 820, *Fair Value Measurement,* defines fair value as the price that would be received to sell an asset or be paid to transfer a liability in an orderly transaction between market participants at the measurement date. The Company applies the following fair value hierarchy, which prioritizes the inputs used to measure fair value into three levels and bases the categorization within the hierarchy upon the lowest level of input that is available and significant to the fair value measurement. Level 1 inputs are quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date. Level 2 utilizes quoted market prices in markets that are not active, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency. Level 3 inputs are unobservable inputs for the asset or liability in which there is little, if any, market activity for the asset or liability at the measurement date. As of December 31, 2024 and December 31, 2023, the carrying amounts of the Company's financial instruments approximate fair value due to their short maturities. There were no financial instruments classified as Level 3 in the fair value hierarchy during the years ended December 31, 2024 and 2023.

## 8. Income Taxes

Deferred tax assets and liabilities are determined based on temporary differences resulting from the different treatment of items for tax and financial reporting purposes. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to reverse. Additionally, the Company must assess the likelihood that deferred tax assets will be recovered as deductions from future taxable income. The Company has provided a full valuation allowance on the Company's deferred tax assets because the Company believes it is more likely than not that its deferred tax assets will not be realized. The Company evaluates the recoverability of its deferred tax assets on a quarterly basis. There was no income tax provision (benefit) for the years ended December 31, 2024 and 2023, as the Company has incurred losses to date.

The components of loss before income taxes are as follows:

| | Year ended December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Domestic (U.S.) | $ (6,251,785) | $ (6,424,969) |
| Foreign (U.K.) | 2,460,945 | 2,440,857 |
| Foreign (Germany) | (153,332) | (136,977) |
| Foreign (Switzerland) | (16,103) | (13,489) |
| Loss before income taxes | $ (3,960,275) | $ (4,134,578) |

The reconciliation of income tax benefit at the U.S. corporation tax rate, being the rate applicable to the country of domicile of the Company to net income tax benefit, is as follows:

| | Year ended December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Federal | $ (831,658) | $ (868,261) |
| State | (311,694) | (373,684) |
| Change in valuation allowance | 1,463,230 | 1,116,036 |
| Permanent differences, net | 122,683 | 271,546 |
| Foreign rate differential | 80,187 | 81,227 |
| Share-based expense, net | 6,495 | 7,213 |
| Enhanced research and development tax credits | (139,259) | (238,631) |
| Other items | (389,984) | 4,554 |
| Net benefit for income taxes | $ – | $ – |

Deferred tax assets and liabilities reflect the net tax effect of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets are as follows:

| | Year ended December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Deferred tax assets: | | |
| U.K. net operating loss carryforwards | $ 21,938,273 | $ 14,664,858 |
| U.K. capital loss carryforwards | 1,745,821 | 1,545,934 |
| U.S. federal net operating loss carryforwards | 7,518,011 | 6,573,614 |
| Switzerland net operating loss carryforwards | 13,392 | 23,868 |
| IPR&D | 586,746 | 8,066,098 |
| Share-based expense | 1,979,372 | 2,235,214 |
| Enhanced research and development tax credits | 2,165,119 | 2,038,421 |
| Germany net operating loss carryforwards | 700,617 | 693,007 |
| Capitalized research and experimental expenditure | 1,804,979 | 1,473,049 |
| U.S. state net operating loss carryforwards | 2,468,919 | 2,142,380 |
| Other | 208,288 | 250,669 |
| Total deferred tax assets before valuation allowance | 41,129,537 | 39,707,112 |
| Valuation allowance for deferred tax assets | (41,129,537) | (39,707,112) |
| Net deferred tax assets | – | – |
| Deferred tax liabilities: | | |
| Total deferred tax liabilities | – | – |
| Net deferred liability | $ – | $ – |

For the years ended December 31, 2024 and 2023, the Company had U.K. net operating loss carryforwards of approximately $89.6 million and $61.3 million, respectively, U.S. federal net operating loss carryforwards of approximately $35.8 million and $31.3 million, respectively, U.S. state net operating loss carryforwards of approximately $39.1 million and $33.9 million, respectively, Germany net operating loss carryforwards of approximately $2.2 million and $2.2 million, respectively, and Switzerland net operating loss carryforwards of approximately $0.2 million and $0.3 million, respectively. The U.K. and Germany net operating loss carryforwards can be carried forward indefinitely. $22.4 million of the U.S. federal net operating loss carryforwards can be carried forward indefinitely, and the remaining U.S. federal and state net operating loss carryforwards begin to expire in 2031. The Switzerland net operating loss carryforwards begin to expire in 2026.

The Company's ability to use its operating loss carryforwards and tax credits generated in the U.S. to offset future taxable income is subject to restrictions under Section 382 of the U.S. Internal Revenue Code (the "Code"). These restrictions may limit the future use of the operating loss carryforwards and tax credits if certain ownership changes described in the Code occur. Future changes in stock ownership may occur that would create further limitations on the Company's use of the operating loss carryforwards and tax credits. In such a situation, the Company may be required to pay income taxes, even though significant operating loss carryforwards and tax credits exist.

The Company's ability to use its operating loss carryforwards and tax credits generated in the U.K. are subject to restrictions under U.K. tax legislation. These regulations may limit the future use of operating loss carryforwards (i) if there is a change in ownership and a change in the nature or conduct of the business carried on by the Company, and (ii) in certain circumstances where there is a change in the nature or conduct of the business only. In such cases the carryforwards would cease to be available to set against future income.

The Company's ability to use its operating loss carryforwards and tax credits generated in Germany and Switzerland are also subject to restrictions under German and Swiss tax legislation. These regulations may limit the future use of operating loss carryforwards if there is a change in ownership. In such cases the carryforwards would cease to be available to set against future income.

As of December 31, 2024 and 2023, the Company did not record any uncertain tax positions.

The Company files income tax returns in the U.S. federal tax jurisdiction, Massachusetts state tax jurisdiction, and certain foreign tax jurisdictions. The Company is subject to examination by the U.S. federal, state, foreign, and local income tax authorities for calendar tax years through 2024 due to available net operating loss carryforwards and research and development tax credits arising in those years. The Company has not been notified of any examinations by the Internal Revenue Service or any other tax authorities as of December 31, 2024. The Company has not recorded any interest or penalties for unrecognized tax benefits since its inception.

***Potential 382 Limitation***

The Company's net operating loss and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service. The Company's ability to utilize its net operating loss ("NOL") and research and development credit ("R&D") carryforwards may be substantially limited due to ownership changes that may have occurred or that could occur in the future, as required by Section 382 of the Code, as well as similar state provisions. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an ownership change, as defined in Section 382 of the Code, results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50% of the outstanding stock of a company by certain stockholders or public groups.

The Company has not completed a study to assess whether one or more ownership changes have occurred since it became a loss corporation as defined in Section 382 of the Code, but the Company believes that it is likely that an ownership change has occurred. If the Company has experienced an ownership change, utilization of the NOL and R&D credit carryforwards would be subject to an annual limitation, which is determined by first multiplying the value of the Company's common stock at the time of the ownership change by the applicable long-term, tax-exempt rate, and then could be subject to additional adjustments, as required. Any such limitation may result in the expiration of a portion of the NOL or R&D credit carryforwards before utilization. Until a study is completed, and any limitation known, no amounts are being considered as an uncertain tax position or disclosed as an unrecognized tax benefit. Any carryforwards that expire prior to utilization as a result of such limitations will be removed from deferred tax assets with a corresponding adjustment to the valuation allowance. Due to the existence of the valuation allowance, it is not expected that any potential limitation will have a material impact on the Company's operating results.

From time to time the Company may be assessed interest or penalties by major tax jurisdictions, namely the Commonwealth of Massachusetts. As of December 31, 2024, the Company had no material unrecognized tax benefits and no adjustments to liabilities or operations were required. No interest and penalties have been recognized by the Company to date.

## 9. Stockholders' Equity

***Common Stock***

Each share of the Company's common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to dividends when and if declared by the Board of Directors. In the event of any voluntary or involuntary liquidation, dissolution or winding-up of the Company, the holders of common stock are entitled to share ratably in the assets of the Company available for distribution.

On May 11, 2023, the Company filed a Certificate of Change to the Company's Articles of Incorporation with the Secretary of State of Nevada to effect the Reverse Stock Split. The Reverse Stock Split was effective at 12:01 a.m., Eastern Time, on May 15, 2023. No fractional shares were issued as a result of the Reverse Stock Split and any remaining share fractions were rounded up to the nearest whole share, resulting in 15,941 new shares of common stock being issued to existing holders of the Company's common stock.

***At the Market ("ATM") Offering***

On November 19, 2021, the Company entered into an ATM Offering Agreement (the "ATM Agreement") with H.C. Wainwright & Co., LLC, as the exclusive sales agent ("Wainwright"), pursuant to which the Company may offer and sell, from time to time through Wainwright, shares of its common stock, par value $0.001 per share. The offer and sale of the shares will be made pursuant to a shelf registration statement on Form S-3 and the related prospectus, and is limited to a number of securities the Company can sell pursuant to General Instruction I.B.6 of Form S-3. In October 2024, the Company filed a new shelf registration statement on Form S-3 (the "2024 Shelf Registration") replacing the previously filed shelf registration statement. The ATM Offering was not updated in connection the 2024 Shelf Registration and, as a result, is not currently effective.

No shares were sold under the ATM Agreement during the years ended December 31, 2024 and 2023. The Company incurred approximately $0.2 million of costs associated with the ATM offering which were expensed during the year ended December 31, 2023.

***Series A Preferred Stock***

The Company has designated 1,000,000 shares as Series A preferred stock with each share having a par value of $0.001 and stated value of $4.80 (the "Series A Preferred Stock"). During 2023, the holder of the Series A Preferred Stock converted all of their shares into 8,084 shares of Company common stock. As a result, there was no Series A Preferred Stock outstanding as of both December 31, 2024 and 2023.

***Series B Preferred Stock***

The Company has designated 2,500,000 shares as Series B preferred stock with each share having a stated value of $4.00 per share (the "Series B Preferred Stock"). The following is a summary of the material terms of the Company's Series B Preferred Stock.

*Liquidation*. Upon any dissolution, liquidation or winding up, whether voluntary or involuntary, holders of Series B Preferred Stock will be entitled to receive distributions out of the Company's assets of an amount equal to the stated value per share of Series B Preferred Stock (as adjusted for stock splits, combinations, reorganizations and the like) plus any accrued and unpaid dividends thereon and any other fees or liquidated damages then due and owing thereon under the amended and restated certificate of designation before any distributions shall be made on the common stock or any series of preferred stock ranked junior to the Series B Preferred Stock. A fundamental transaction or change of control under the amended and restated certificate of designation shall constitute a liquidation for purposes of this right. Xenetic will give each holder of Series B Preferred Stock written notice of any liquidation at least 30 days before any meeting of stockholders to approve such liquidation or at least 45 days before the date of such liquidation if no meeting is to be held.

*Dividends*. Subject to any preferential rights of any outstanding series of preferred stock created by the Company's Board from time to time, the holders of shares of the Company's Series B Preferred Stock will be entitled to such cash dividends, non-cumulative, as may be declared from time to time by the Company's Board on shares of the Company's common stock (on an as-converted basis) from funds available therefore. The Company shall not directly or indirectly pay or declare any dividend or make any distribution upon, nor shall any distribution be made in respect of, any junior securities as long as any dividends due on the Series B Preferred Stock remain unpaid, nor shall any monies be set aside for or applied to the purchase or redemption of any junior securities or shares pari passu with the Series B Preferred Stock.

*Conversion*. Series B Preferred Stock is convertible, at any time and from time to time at the option of the holder thereof, at a rate of one preferred share to approximately 0.033 common share basis, subject to an issuable maximum and the adjustments described below. There were no Series B Preferred Stock conversions during the years ended December 31, 2024 and 2023.

*Subsequent Equity Sales*. The Series B Preferred Stock has ratchet price based anti-dilution protection, subject to customary carve outs, in the event of a down-round financing at a price per share below the stated value of the Series B Preferred Stock. There is no bifurcation of the embedded conversion option being clearly and closely related to the host instrument.

The Series B Preferred Stock has additional terms covering stock dividends and splits, voting rights, fractional shares and fundamental transactions. As of December 31, 2024 and 2023, there were approximately 1.8 million shares of Series B Preferred Stock issued and outstanding which are convertible into approximately 60,000 shares of common stock in each year, which represents the issuable maximum that can be issued upon the conversion of the currently outstanding Series B Preferred Stock.

***Warrants Related to Financing Arrangements***

The Company has warrants to purchase approximately 462,963 shares of the Company's common stock (the "Series A Warrants") outstanding as of both December 31, 2024 and December 31, 2023. The Series A Warrants are immediately exercisable at a price of $33.00 per share of common stock and expire on February 23, 2025. No Series A Warrants were exercised or forfeited during the year ended December 31, 2024 and 2023.

The Company also has warrants to purchase approximately 800 shares of the Company's common stock outstanding as of both December 31, 2024 and December 31, 2023. These warrants have an exercise price of $29.09 per share of common stock and expire on July 3, 2026. None of these warrants were exercised or forfeited during the years ended December 31, 2024 and 2023.

In addition, the Company had publicly traded warrants to purchase approximately 2,100 shares of common stock outstanding as of December 31, 2023. These warrants had an exercise price of $130.00 per share of common stock and expired on July 19, 2024. The warrants ceased trading on Nasdaq under the symbol "XBIOW" upon expiration. The warrants also provided that if the weighted-average price of common stock on any trading day on or after 30 days after issuance is lower than the then-applicable exercise price per share, each warrant may be exercised, at the option of the holder, on a cashless basis for one share of common stock, as adjusted for the Reverse Stock Split. Warrants to purchase approximately 1,038 shares of common stock were exercised on a cashless, one-for-one basis during the year ended December 31, 2024. None of these warrants were exercised or forfeited during the year ended December 31, 2023. All of the remaining public warrants outstanding as of July 19, 2024 expired, and no public warrants were outstanding at December 31, 2024.

## 10. Share-Based Expense

Total share-based expense related to stock options, RSUs and common stock awards was approximately $0.2 million and $0.3 million for the years ended December 31, 2024 and 2023, respectively. Share-based expense is classified in the consolidated statements of operations as follows:

| | Year Ended December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Research and development expenses | $ 11,433 | $ 56,112 |
| General and administrative expenses | 160,381 | 226,973 |
| | $ 171,814 | $ 283,085 |

***Stock Options***

The Company grants stock option awards and RSUs to employees and non-employees with varying vesting terms under the Xenetic Biosciences, Inc. Amended and Restated Equity Incentive Plan. The Company measures the fair value of stock option awards using the Black-Scholes option pricing model, which uses the assumptions noted in the tables below, including the risk-free interest rate, expected term, share price volatility, dividend yield and forfeiture rate. The risk-free interest rate is based upon the U.S. Treasury yield curve in effect at the time of grant, with a term that approximates the expected life of the option. For stock options issued in 2024 and 2023 that qualify as "plain vanilla" stock options, the expected term is based on the simplified method. The Company has a limited history of stock option exercises, which does not provide a reasonable basis for the Company to estimate the expected term of employee and non-employee stock options. For all other stock options, the Company estimates the expected life using judgment based on the anticipated research and development milestones of the Company's clinical projects and behavior of the Company's employees and non-employees. The expected life of non-employee options is the contractual life of the option.

***Employee Stock Options***

During the years ended December 31, 2024 and 2023, 30,000 and 57,500 total stock options to purchase shares of common stock were granted by the Company, respectively. The weighted average grant date fair value per option was $3.41 and $3.49, respectively. No employee stock options were exercised during the years ended December 31, 2024 and 2023. During the year ended December 31, 2024, 32,535 shares having a weighted average grant date fair value of $40.07 per option were forfeited. No employee stock options were forfeited or expired during the year ended December 31, 2023.

During the years ended December 31, 2024 and 2023, 53,750 and 33,333 total stock options vested, respectively, with total fair values of approximately $0.3 million in both periods. As of December 31, 2024, there was approximately $0.1 million of unrecognized share-based payments related to employee stock options that are expected to vest. The Company expects to recognize this expense over a weighted-average period of approximately 2.1 years.

Key assumptions used in the Black-Scholes option pricing model for options granted to employees during the years ending December 31, 2024 and 2023 are as follows:

| | Year Ended December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Weighted-average expected dividend yield (%) | – | – |
| Weighted-average expected volatility (%) | 111.50 | 121.50 |
| Weighted-average risk-free interest rate (%) | 4.20 | 4.21 |
| Weighted-average expected life of option (years) | 5.67 | 5.76 |
| Weighted-average exercise price ($) | 4.07 | 4.00 |

The following is a summary of employee stock option activity for the years ended December 31, 2024 and 2023:

| | Number of shares | Weighted-average exercise price | Weighted-average remaining life (years) | Aggregate intrinsic value |
|---|---|---|---|---|
| Outstanding as of January 1, 2023 | 143,888 | $ 49.43 | 7.78 | $ – |
| Granted | 57,500 | 4.00 | | |
| Expired | – | – | | |
| Outstanding as of December 31, 2023 | 201,388 | $ 36.46 | 7.69 | $ – |
| Granted | 30,000 | 4.07 | | |
| Expired | (32,535) | (61.90) | | |
| Outstanding as of December 31, 2024 | 198,853 | $ 27.41 | 4.28 | $ 3,300 |
| Vested or expected to vest as of December 31, 2024 | 198,853 | $ 27.41 | 4.28 | $ 3,300 |
| Exercisable as of December 31, 2023 | 133,888 | $ 52.10 | 6.69 | $ – |
| Exercisable as of December 31, 2024 | 166,770 | $ 31.84 | 3.28 | $ 2,567 |

A summary of the status of the Company's non-vested employee stock option shares as of December 31, 2024, and the changes during the year ended December 31, 2024, is as follows:

| | Number of shares | Weighted-average grant date fair value |
|---|---|---|
| Balance as of January 1, 2024 | 67,500 | $ 4.77 |
| Granted | 30,000 | 3.41 |
| Forfeited | (11,667) | (4.32) |
| Vested | (53,750) | (4.87) |
| Balance as of December 31, 2024 | 32,083 | $ 3.49 |

***Restricted Stock Units***

There were 417 RSUs outstanding as of December 31, 2023. The RSUs were fully vested and had a grant date fair value of $253.70 per share. No RSUs were granted or expired during the years ended December 31, 2024 and 2023. During the year ended December 31, 2024, the Company issued 417 shares of common stock representing the exercise of all outstanding RSUs. As a result, no RSUs were outstanding at December 31, 2024.

***Non-Employee Stock Options***

Share-based expense related to stock options granted to non-employees is recognized as the services are rendered on a straight-line basis. The Company determined that the fair value of the stock options is more reliably measurable than the fair value of the services received. No non-employee stock options to purchase shares of common stock were granted or exercised during the years ended December 31, 2024 and 2023. No compensation expense related to non-employee options during the years ended December 31, 2024 and December 31, 2023 as all non-employee stock options were fully vested as of December 31, 2020.

The following is a summary of non-employee stock option activity for the years ended December 31, 2024 and 2023:

| | Number of shares | Weighted-average exercise price | Weighted-average remaining life (years) | Aggregate intrinsic value |
|---|---|---|---|---|
| Outstanding as of January 1, 2023 | 2,009 | $ 120.83 | 1.83 | $ – |
| Granted | – | – | | |
| Expired | (84) | 231.60 | | |
| Outstanding as of December 31, 2023 | 1,925 | 115.99 | 0.91 | – |
| Granted | – | – | | |
| Expired | (1,672) | 50.20 | | |
| Outstanding as of December 31, 2024 | 253 | $ 550.80 | 0.68 | $ – |
| Vested or expected to vest as of December 31, 2024 | 253 | $ 550.80 | 0.68 | $ – |
| Exercisable as of December 31, 2023 | 1,925 | $ 115.99 | 0.91 | $ – |
| Exercisable as of December 31, 2024 | 253 | $ 550.80 | 0.68 | $ – |

***Common Stock Awards***

The Company has granted common stock awards to non-employees in exchange for services provided. The Company measures the fair value of these awards using the fair value of the services provided or the fair value of the awards granted, whichever is more reliably measurable. The fair value measurement date of these awards is generally the date the performance of services is complete. The fair value of the awards is recognized as services are rendered on a straight-line basis. No common stock awards were granted or issued during the years ended December 31, 2024 and 2023.

***Joint Share Ownership Plan***

As of December 31, 2024 and 2023, there were approximately 2,701 JSOP awards issued and outstanding to two former senior executives. Under the JSOP, shares in the Company are jointly purchased at fair market value by the participating executives and the trustees of the JSOP trust, with such shares held in the JSOP trust. For U.S. GAAP purposes the awards were valued as employee options and recorded as a reduction in equity as treasury shares until they are exercised by the employee. The JSOP awards are fully vested and have no expiration date. There were no compensation charges during the years ended December 31, 2024 and 2023.

## 11. Employee Benefit Plans

The Company has a defined contribution 401(k) savings plan (the "401(k) Plan"). The 401(k) Plan covers substantially all U.S. employees, and allows participants to defer a portion of their annual compensation on a pre-tax basis or make post-tax contributions. Company contributions to the 401(k) Plan may be made at the discretion of the Board of Directors. During the years ended December 31, 2024 and 2023, the Company made contributions of approximately $31,000 and $41,000 to the 401(k) Plan, respectively.

## 12. Commitments and Contingencies

***Leases***

The Company determines whether an arrangement is a lease at inception. The Company leases office space in a shared office location in Framingham, Massachusetts. As this lease had a term of 6 months at inception, the Company did not apply the provisions of ASU 2016-02 and will account for it as an operating lease. As of December 31, 2024, total minimum lease payments on this lease were approximately $3,000.

The Company did not apply the provisions of ASU 2016-02 to the lease of its office space in Miami, Florida as this lease had a term of 12 months at inception. As a result, the Company accounts for it as an operating lease. This lease was terminated in November 2024 and no further minimum lease payments are due.

***Letter of Credit***

As of December 31, 2024, the Company has an outstanding letter of credit of approximately $0.1 million in support of an intercompany loan with its Hesperix subsidiary. As the intercompany loan is eliminated in consolidation, the letter of credit has no effect on the consolidated financial statements.

## 13. Related Party Transactions

The Company has entered into various research, development, license and supply agreements with Serum Institute and Pharmsynthez, each a related party whose relationship, ownership, and nature of transactions is disclosed within other sections of these footnotes. Please refer to Note 4, *Significant Strategic Collaborations,* and Note 5, *Other Assets*, for details on arrangements with collaboration partners that are also related parties.

During the fourth quarter of 2019, the Company entered into a loan agreement with Pharmsynthez (the "Pharmsynthez Loan"), pursuant to which the Company advanced Pharmsynthez an aggregate principal amount of up to $500,000 to be used for the development of a specific product under the Company's Co-Development Agreement with Pharmsynthez. The Pharmsynthez Loan had an initial term of 15-months and accrued interest at a rate of 10% per annum. The Pharmsynthez Loan was guaranteed by all of the operating subsidiaries of Pharmsynthez, including SynBio and AS Kevelt, and was secured by all of the common and preferred stock of the Company owned by Pharmsynthez and SynBio.

Pharmsynthez paid all obligations due under the Pharmsynthez Loan in May 2023, and no further amounts are due under the Pharmsynthez Loan. As a result, no amounts were outstanding as of December 31, 2024 and December 31, 2023. The Company did not recognize any interest income related to the Pharmsynthez Loan during the year ended December 31, 2024. The Company recognized approximately $65,000 of income related to interest and fees associated with the Pharmsynthez Loan including approximately $40,000 related to interest income during the twelve months ended December 31, 2023.

During the fourth quarter of 2024, the Company entered into a clinical trial services agreement with PeriNess Ltd. ("PeriNess") to advance the Company's development program for its systemic DNase I technology in Israeli medical centers. One of our directors, Dr. Dmitry Genkin, is a significant shareholder of PeriNess and another of our directors, Mr. Moshe Mizrahy, is a majority shareholder and director of PeriNess. The Company expensed approximately $50,000 related to this agreement during the year ended December 31, 2024. As of December 31, 2024, approximately $45,000 was recorded as an advanced payment and included in Prepaid expenses and other on the December 31, 2024 consolidated balance sheet.

## 14. Subsequent Events

The Company performed a review of events subsequent to the balance sheet date through the date the financial statements were issued and determined that there were no such events requiring recognition or disclosure in the financial statements.

## ITEM 9 – CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

## ITEM 9A – CONTROLS AND PROCEDURES

### Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Interim Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of the end of the period covered by this Annual Report on Form 10-K.

Based on this evaluation our management, including our Interim Chief Executive Officer and Chief Financial Officer, concluded that, as of December 31, 2024, our disclosure controls and procedures are designed at a reasonable assurance level and are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure.

### Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) of the Exchange Act. Management, under the supervision and with the participation of our Interim Chief Executive Officer and Chief Financial Officer, conducted an assessment of the design and effectiveness of our internal control over financial reporting as of the end of the period covered by this Annual Report on Form 10-K. In making its assessment of internal control over financial reporting, management used the criteria set forth by the Committee of Sponsoring Organizations ("COSO") of the Treadway Commission in *Internal Control — Integrated Framework (2013 Framework)*. Based on this assessment, our management concluded that, as of the end of the period covered by this Annual Report on Form 10-K, our internal control over financial reporting was effective based on the criteria set forth by COSO of the Treadway Commission in *Internal Control — Integrated Framework.*

This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to an exemption for non-accelerated filers set forth in Section 989G of the Dodd-Frank Wall Street Reform and Consumer Protection Act.

### Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting that occurred during the quarterly period covered by this Annual Report on Form 10-K that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### Limitations on Effectiveness of Controls and Procedures

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. The Company's internal control over financial reporting includes those policies and procedures that:

(1) Pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the Company's assets;
(2) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that the Company's receipts and expenditures are being made only in accordance with authorizations of the Company's management and directors; and
(3) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the financial statements.

Management, including the Company's principal executive and principal financial officers, or persons performing similar functions, does not expect that the Company's internal controls will prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of internal controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Also, any evaluation of the effectiveness of controls in future periods are subject to the risk that those internal controls may become inadequate because of changes in business conditions, or that the degree of compliance with the policies or procedures may deteriorate.

**ITEM 9B – OTHER INFORMATION**

During the quarter ended December 31, 2024, no director or officer adopted or terminated any Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement, as each term is defined in Item 408(a) of Regulation S-K.

**ITEM 9C – DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS**

Not applicable.

## PART III

### ITEM 10 – DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item will be set forth in the Company's definitive proxy statement or information statement to be filed with the SEC in connection with the Company's 2025 Annual Meeting of Stockholders within 120 days of the end of the Company's fiscal year ended December 31, 2024 and is incorporated herein by reference, or will be included in an amendment to this Annual Report on Form 10-K.

### ITEM 11 – EXECUTIVE COMPENSATION

The information required by this Item will be set forth in the Company's definitive proxy statement or information statement to be filed with the SEC in connection with the Company's 2025 Annual Meeting of Stockholders within 120 days of the end of the Company's fiscal year ended December 31, 2024 and is incorporated herein by reference, or will be included in an amendment to this Annual Report on Form 10-K.

### ITEM 12 – SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item will be set forth in the Company's definitive proxy statement or information statement to be filed with the SEC in connection with the Company's 2025 Annual Meeting of Stockholders within 120 days of the end of the Company's fiscal year ended December 31, 2024 and is incorporated herein by reference, or will be included in an amendment to this Annual Report on Form 10-K.

### ITEM 13 – CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item will be set forth in the Company's definitive proxy statement or information statement to be filed with the SEC in connection with the Company's 2025 Annual Meeting of Stockholders within 120 days of the end of the Company's fiscal year ended December 31, 2024 and is incorporated herein by reference, or will be included in an amendment to this Annual Report on Form 10-K.

### ITEM 14 – PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item will be set forth in the Company's definitive proxy statement or information statement to be filed with the SEC in connection with the Company's 2025 Annual Meeting of Stockholders within 120 days of the end of the Company's fiscal year ended December 31, 2024 and is incorporated herein by reference, or will be included in an amendment to this Annual Report on Form 10-K.

## PART IV

### ITEM 15 – EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following is filed as part of this Annual Report on Form 10-K:

- *Consolidated Financial Statements:* The consolidated financial statements and report of independent registered public accounting firm required by this item are included in Part II, Item 8;
- *Financial Statement Schedules:* All schedules are omitted because they are not applicable or not required, or because the required information is shown either in the consolidated financial statements or in the notes thereto.

(b) **Exhibits:** The exhibits which are filed or furnished with this Annual Report on Form 10-K or which are incorporated herein by reference are set forth in the Exhibit Index beginning on page 60 which is incorporated herein by reference.

### ITEM 16 – FORM 10-K SUMMARY

Not applicable.

### EXHIBIT INDEX

| Exhibit No. | Exhibit Index | Form | Filing Date | Exhibit Number | Filed Herewith |
|---|---|---|---|---|---|
| 3.1 | Articles of Incorporation | S-1 | 11/21/2011 | 3.1 | |
| 3.2 | Certificate of Amendment to Articles of Incorporation | 8-K | 02/12/2013 | 3.1 | |
| 3.3 | Certificate of Amendment to Articles of Incorporation | 8-K | 02/27/2013 | 3.1 | |
| 3.4 | Certificate of Amendment to Articles of Incorporation | 10-Q | 01/10/2014 | 3.1 | |
| 3.5 | Certificate of Change Pursuant to NRS 78.209 | 10-Q | 01/10/2014 | 3.2 | |
| 3.6 | Certificate of Amendment to Articles of Incorporation | 8-K | 09/30/2015 | 3.1 | |
| 3.7 | Amended and Restated Bylaws | 8-K | 02/27/2017 | 3.1 | |
| 3.9 | Second Amended and Restated Certificate of Designation of Preferences, Rights and Limitations of Series B Preferred Stock | S-1/A | 10/31/2016 | 3.9 | |
| 3.10 | Certificate of Change Pursuant to NRS 78.209 | 8-K | 06/24/2019 | 3.1 | |
| 3.11 | Certificate of Amendment to Articles of Incorporation | 8-K | 06/24/2019 | 3.2 | |
| 3.12 | Certificate of Amendment to Articles of Incorporation | 10-K | 03/16/2021 | 3.12 | |
| 3.13 | Certificate of Amendment to Articles of Incorporation | 10-K | 03/16/2021 | 3.13 | |
| 3.14 | Certificate of Amendment to Articles of Incorporation | 10-K | 03/22/2023 | 3.14 | |
| 3.15 | Certificate of Change to Articles of Incorporation | 8-K | 05/12/2023 | 3.1 | |
| 4.1 | Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 | | | | X |
| 4.2 | Form of Common Stock Certificate of the Registrant | S-1/A | 07/14/2016 | 4.1 | |
| 4.3 | Form of Common Stock Purchase Warrant | 8-K | 06/25/2019 | 4.1 | |
| 4.5 | Form of Series A Warrant | 8-K | 07/28/2021 | 4.1 | |

| Exhibit No. | Exhibit Index | Form | Filing Date | Exhibit Number | Filed Herewith |
|---|---|---|---|---|---|
| 10.1† | Form of Amended and Restated Xenetic Biosciences, Inc. Equity Incentive Plan, as amended, effective as of December 7, 2021 | DEF14A | 10/15/2021 | Appendix A | |
| 10.2# | Agreement on Co-Development and the Terms of Exclusive License dated August 4, 2011 between Lipoxen plc, Lipoxen Technologies LTD and SynBio LLC | 10-K/A | 02/18/2015 | 10.18 | |
| 10.3 | Novation of Agreement on Co-Development and the Terms of Exclusive License, dated December 17, 2021, between Xenetic Biosciences (UK) Limited (formerly Lipoxen plc), Lipoxen Technologies Limited, SynBio LLC and Public Joint-Stock Company Pharmsynthez | 10-K | 03/22/2022 | 10.3 | |
| 10.4## | Exclusive License Agreement, dated December 20, 2021, between Lipoxen Technologies Limited and Public Joint-Stock Company Pharmsynthez | 10-K | 03/22/2022 | 10.4 | |
| 10.5# | Subscription Agreement in respect of ordinary shares in the capital of Lipoxen plc dated August 4, 2011 between SynBio LLC and Lipoxen plc | 10-K/A | 02/18/2015 | 10.19 | |
| 10.6# | Collaboration, License and Development Agreement, dated November 11, 2009, between Pharmsynthez ZAO and Lipoxen Technologies Ltd. | 10-K/A | 02/18/2015 | 10.20 | |
| 10.7# | Exclusive Patent and Know How License and Manufacturing Agreement, dated August 4, 2011, between Lipoxen plc, Lipoxen Technologies Ltd and Serum Institute of India Limited | 10-K/A | 02/18/2015 | 10.21 | |
| 10.8 | Intellectual Property Assignment between Dmitry Genkin, FDS Pharma, Lipoxen Technologies Limited and Xenetic Biosciences Inc. | 10-K | 04/15/2015 | 10.1 | |
| 10.9† | Employment Agreement, dated March 23, 2017 between Xenetic Biosciences, Inc. and James F. Parslow | 8-K | 04/04/2017 | 10.1 | |
| 10.10† | Amendment to Employment Agreement, dated June 18, 2024, between James F. Parslow and Xenetic Biosciences, Inc. | 10-Q | 08/13/2024 | 10.3 | |
| 10.11† | Form of Indemnity Agreement by and between Xenetic Biosciences, Inc. and each of its directors and executive officers | 10-Q | 08/14/2017 | 10.1 | |
| 10.12† | Confidential Separation Agreement and General Release, dated June 19, 2024, between Jeffrey Eisenberg and Xenetic Biosciences, Inc. | 10-Q | 08/13/2024 | 10.1 | |
| 10.13† | Confidential Separation Agreement and General Release, dated June 19, 2024, between Curtis Lockshin and Xenetic Biosciences, Inc. | 10-Q | 08/13/2024 | 10.2 | |
| 10.14# | Right to Sublicense Agreement, dated October 27, 2017, by and among Xenetic Biosciences, Inc., Baxalta Incorporated, Baxalta US Inc., and Baxalta GmbH | 10-K | 03/30/2018 | 10.46 | |
| 10.15 | Assignment Agreement between Xenetic Biosciences, Inc. and OPKO Pharmaceuticals, LLC, dated March 1, 2019 | 8-K/A | 05/20/2019 | 10.1 | |
| 10.16 | First Amendment to Assignment Agreement dated June 7, 2019 | 8-K | 06/13/2019 | 10.1 | |
| 10.17 | Second Amendment to Assignment Agreement dated June 24, 2019 | 8-K | 06/24/2019 | 10.1 | |
| 10.18 | Third Amendment to Assignment Agreement dated July 15, 2019 | 8-K | 07/16/2019 | 10.1 | |
| 10.19 | Form of Consent Agreement by and among Xenetic Biosciences, Inc. and certain purchasers dated June 24, 2019 | 8-K | 06/25/2019 | 10.1 | |
| 10.20 | Consent Agreement by and among Xenetic Biosciences, Inc. and certain purchasers dated July 16, 2019 | 8-K | 07/16/2019 | 10.1 | |
| 10.21† | Form of Letter Agreement re. Appointment of Non – Employee, Independent Director of Xenetic Biosciences, Inc. | 10-K | 03/26/2020 | 10.51 | |
| 10.22† | Form of Xenetic Biosciences, Inc. Stock Option Grant Notice | 10-K | 03/26/2020 | 10.52 | |
| 10.23† | Xenetic Biosciences, Inc. Stock Option Grant Notice, dated December 4, 2019, between Jeffrey Eisenberg and Xenetic Biosciences, Inc. | 10-K | 03/26/2020 | 10.53 | |

| Exhibit No. | Exhibit Index | Form | Filing Date | Exhibit Number | Filed Herewith |
|---|---|---|---|---|---|
| 10.24## | Exclusive Sublicense Agreement, dated April 26, 2022, between Xenetic Biosciences, Inc. and CLS Therapeutics LTD | 10-Q | 8/11/2022 | 10.1 | |
| 10.25## | Exclusive License Agreement, dated April 26, 2022, between Xenetic Biosciences, Inc. and CLS Therapeutics LTD | 10-Q | 8/11/2022 | 10.2 | |
| 10.26 | Form of Subscription Agreement, dated April 26, 2022, between Xenetic Biosciences, Inc. and CLS Therapeutics LTD | 10-Q | 8/11/2022 | 10.3 | |
| 10.27## | Statement of Work, dated June 30, 2022, between Xenetic Biosciences, Inc. and Catalent Pharma Solutions, LLC | 10-Q | 8/11/2022 | 10.4 | |
| 10.28## | Research Funding and Option Agreement, dated March 17, 2023, between the Company and the Scripps Research Institute | 10-Q | 5/11/2023 | 10.1 | |
| 10.29 | First Amendment to Research Funding and Option Agreement, dated June 1, 2024, between Xenetic Biosciences, Inc. and the Scripps Research Institute | | | | X |
| 10.30## | Second Amendment to Research Funding and Option Agreement, dated November 1, 2024, between Xenetic Biosciences, Inc. and the Scripps Research Institute | | | | X |
| 10.31## | Consulting Agreement, dated January 1, 2025, between Xenetic Biosciences, Inc. and Dmitry Genkin | | | | X |
| 19.1 | Insider Trading Policy and Procedures | | | | X |
| 21.1 | List of Subsidiaries | | | | X |
| 23.1 | Consent of Marcum LLP | | | | X |
| 24.1 | Power of Attorney (included on signature page) | | | | X |
| 31.1 | Certification of Principal Executive Officer, as required by Rule 13a-14(a) or Rule 15d-14(a) | | | | X |
| 31.2 | Certification of Principal Financial Officer, as required by Rule 13a-14(a) or Rule 15d-14(a) | | | | X |
| 32.1* | Certification of Principal Executive Officer and Principal Financial Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 36 of Title 18 of the United States Code (18 U.S.C. §1350) | | | | X |
| 97.1 | Policy Regarding the Mandatory Recovery of Compensation | 10-K | 3/21/2024 | 97.1 | |
| 101.INS | Inline XBRL Instance Document. | | | | X |
| 101.SCH | Inline XBRL Taxonomy Extension Schema Document. | | | | X |
| 101.CAL | Inline XBRL Taxonomy Extension Calculation Linkbase Document. | | | | X |
| 101.DEF | Inline XBRL Taxonomy Extension Definition Linkbase Document. | | | | X |
| 101.LAB | Inline XBRL Taxonomy Extension Label Linkbase Document. | | | | X |
| 101.PRE | Inline XRBL Taxonomy Extension Presentation Linkbase Document. | | | | X |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) | | | | X |

† Indicates a management contract or any compensatory plan, contract or arrangement.

# Application has been made with the Securities and Exchange Commission to seek confidential treatment of certain confidential material contained in this document. Omitted material for which confidential treatment has been requested has been filed separately with the Securities and Exchange Commission.

##Portions of this exhibit, marked by brackets and asterisks, have been omitted pursuant to Item 601(b)(10) of Regulation S-K under the Securities Act of 1933, as amended, because they are both (i) not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed. The registrant undertakes to promptly provide an unredacted copy of the exhibit on a supplemental basis, if requested by the Commission or its staff.

* This certification is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**XENETIC BIOSCIENCES, INC.**

Date: March 18, 2025

By: /s/ JAMES PARSLOW
James Parslow
*Interim Chief Executive Officer*

## POWER OF ATTORNEY AND SIGNATURES

We, the undersigned officers and directors of Xenetic Biosciences, Inc., hereby severally constitute and appoint James Parslow, our true and lawful attorney, with full power to him, to sign for us in our names in the capacities indicated below, all amendments to this report, and generally to do all things in our names and on our behalf in such capacities to enable Xenetic Biosciences, Inc. to comply with the provisions of the Securities Exchange Act of 1934, as amended, and all requirements of the Securities and Exchange Commission.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated below on the 18th day of March, 2025.

| **Signature** | **Title(s)** |
|---|---|
| /s/ JAMES PARSLOW<br>James Parslow<br>Date: March 18, 2025 | Interim Chief Executive Officer and Chief Financial Officer<br>*(Principal Executive Officer and Principal Financial Officer and Principal Accounting Officer*) |
| /s/ GRIGORY BORISENKO<br>Grigory Borisenko<br>Date: March 18, 2025 | Director |
| /s/ FIRDAUS JAL DASTOOR<br>Firdaus Jal Dastoor<br>Date: March 18, 2025 | Director |
| /s/ DMITRY GENKIN<br>Dmitry Genkin<br>Date: March 18, 2025 | Director |
| /s/ ROGER KORNBERG<br>Roger Kornberg<br>Date: March 18, 2025 | Director |
| /s/ MOSHE MIZRAHY<br>Moshe Mizrahy<br>Date: March 18, 2025 | Director |
| /s/ ALEXEY VINOGRADOV<br>Alexey Vinogradov<br>Date: March 18, 2025 | Director |

[This page intentionally left blank]

# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**Washington, D.C. 20549**

**Form 10-K/A**
**Amendment No. 1**

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.**
**For the fiscal year ended December 31, 2024**

☐ **TRANSITION REPORTS PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.**
**For the transition period from to**

**Commission File Number: 001-37937**

# XENETIC BIOSCIENCES, INC.
**(Exact name of registrant as specified in its charter)**

| **Nevada** | **45-2952962** |
|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(IRS Employer Identification No.)** |

**945 Concord Street**
**Framingham, Massachusetts 01701**
**(Address of principal executive offices (Zip code)**

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

**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 Capital Market |

**Securities registered pursuant to Section 12(g) of the Act:**
**None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act: Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act: Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files): Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer" "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

| | | | |
|---|---|---|---|
| Large accelerated filer | ☐ | Accelerated filer | ☐ |
| Non-accelerated filer | ☒ | Smaller reporting company | ☒ |
| | | 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. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive- based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Exchange Act Rule 12b-2): Yes ☐ No ☒

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant as of June 28, 2024, the last business day of the registrant's most recently completely second fiscal quarter, based upon the closing price of the registrant's common stock on the Nasdaq Capital Market on that date of $4.07, was approximately $5,301,818. For purposes of this computation, all officers, directors, and 10% beneficial owners of the registrant are deemed to be affiliates. Such determination should not be deemed to be an admission that such officers, directors or 10% beneficial owners are, in fact, affiliates of the registrant.

As of April 18, 2025, the number of outstanding shares of the registrant's common stock was 1,542,139.

**DOCUMENTS INCORPORATED BY REFERENCE**

None

## EXPLANATORY NOTE

The Registrant is filing this Amendment No. 1 on Form 10-K/A (this "Amendment") to amend its Annual Report on Form 10-K for the fiscal year ended December 31, 2024, originally filed with the Securities and Exchange Commission ("SEC") on March 18, 2025 (the "Original Filing"), to include the information required by Items 10 through 14 of Part III of Form 10-K. This information was previously omitted from the Original Filing in reliance on General Instruction G(3) to Form 10-K, which permits the information in the above-referenced items to be incorporated in the Form 10-K by reference from our definitive proxy statement if such statement is filed no later than 120 days after our fiscal year-end. We are filing this Amendment to include Part III information in our Form 10-K because our definitive proxy statement will be filed later this year.

Part III of the Original Filing (Items 10 through 14) is being amended and restated in its entirety by this Amendment. In addition, pursuant to Rule 12b-15 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), Part IV, Item 15 of the Original Filing is being amended to contain the currently dated certifications pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, which are attached hereto as Exhibit 31.3 and Exhibit 31.4, respectively. Because no financial statements are included in this Amendment and this Amendment does not contain or amend any disclosure with respect to Items 307 and 308 of Regulation S-K, paragraphs 3, 4, and 5 of the certifications have been omitted. Further, we are amending the cover page to update the number of shares of our stock outstanding and to remove the statement that information is being incorporated by reference from our definitive proxy statement.

Except as described above, this Amendment does not amend or otherwise update any other information in the Original Filing. Accordingly, this Amendment should be read in conjunction with the Original Filing. In addition, this Amendment does not reflect events that may have occurred subsequent to the date of the Original Filing.

As used in this Amendment, unless otherwise indicated, all references herein to "Xenetic," the "Company," "we" or "us" refer to Xenetic Biosciences, Inc. and its wholly owned subsidiaries.

**XENETIC BIOSCIENCES, INC.**
**2024 ANNUAL REPORT ON FORM 10-K**

**TABLE OF CONTENTS**


| | | |
|---|---|---|
| PART III | | 1 |
| Item 10 | Directors, Executive Officers and Corporate Governance | 1 |
| Item 11 | Executive Compensation | 5 |
| Item 12 | Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters | 12 |
| Item 13 | Certain Relationships and Related Transactions, and Director Independence | 14 |
| Item 14 | Principal Accounting Fees and Services | 16 |
| PART IV | | 17 |
| Item 15 | Exhibits and Financial Statement Schedules | 17 |

## PART III

## ITEM 10 – DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

### Directors and Executive Officers

Set forth below is the name, age, position and brief biographies of each of our executive officers and directors as of April 18, 2025.

| Name | Age | Position |
|---|---|---|
| Mr. James Parslow | 60 | Interim Chief Executive Officer, Chief Financial Officer and Corporate Secretary |
| Dr. Grigory Borisenko | 56 | Director[(1)] |
| Mr. Firdaus Jal Dastoor, FCS | 72 | Director [(1), (2), (3)] |
| Dr. Dmitry Genkin | 56 | Director |
| Dr. Roger Kornberg | 77 | Director [(3)] |
| Mr. Moshe Mizrahy | 72 | Director |
| Dr. Alexey Vinogradov | 54 | Director[(1), (2)] |

(1) Member of the Audit Committee
(2) Member of the Compensation Committee
(3) Member of the Nominating and Corporate Governance Committee

***James Parslow*** was appointed our interim Chief Executive Officer on May 16, 2024, and has served as our Chief Financial Officer since April 3, 2017. Mr. Parslow most recently served as Chief Financial Officer, Treasurer and Secretary of World Energy Solutions, Inc., a publicly-traded business-to-business e-commerce company brokering energy and environmental commodities, from 2006 until its acquisition by EnerNOC, Inc. in 2015. From 2015 until 2017, he served as an independent consultant providing interim chief financial officer services to multiple emerging technology companies. Mr. Parslow is a Certified Public Accountant with over 35 years of experience serving private and public companies in the biotech, clean tech, e-commerce, and high-tech manufacturing industries. He holds an A.B. in Economics and Accounting from the College of the Holy Cross and an M.B.A. with a concentration in Finance from Bentley University.

***Grigory Borisenko, PhD*** has served as a member of our Board since 2019. Dr. Borisenko has over 25 years of scientific, management and strategic experience in the life science field. Since April 2022, Dr. Borisenko has been an independent consultant for a number of companies. Prior to that time, Dr. Borisenko served as an Investment Director of an eastern European venture capital and private equity management fund, and has specialized in investment projects in life sciences for over ten years. Dr. Borisenko served on the board of directors of multiple biotechnology companies including Atea Pharmaceuticals, Inc. and Adastra Pharmaceuticals, Inc. Currently, Dr. Borisenko provides consulting and investment advising services in the biotech area. Prior to his investment career, Dr. Borisenko held academic appointments with the University of Pittsburgh and co-authored over fifty peer-reviewed publications in leading biochemistry and cell biology journals. Dr. Borisenko received his M.S. and Ph.D. from the Pirogov State Medical University, accomplished postdoctoral training at the University of Pittsburg and is a recipient of Fogarty International and International Fellowship Awards from NIH and WHO. We believe Dr. Borisenko's extensive background in the life sciences and biotechnology industries provide him with the appropriate set of skills to serve as a member of our Board.

***Firdaus Jal Dastoor, FCS*** has served as a member of our Board since January 2014 pursuant to terms of the agreement of our acquisition of Xenetic U.K. He has been employed by the Cyrus Poonawalla Group, a conglomerate in India with interests in horse breeding, biotech and life sciences, and financial services, in business development strategies and operational roles since October 1981. Mr. Dastoor is currently a Group Director in charge of Finance and Corporate Affairs and Company Secretary of the Serum Institute of India Private Limited at the Cyrus Poonawalla Group. He has been a Fellow Member of The Institute of Company Secretaries of India since 1990. Mr. Dastoor is on the board of several private companies operating in the fields of life sciences and biotech, international trade, financial services and quality standards certifications. Mr. Dastoor received a B.A. in Commerce from the University of Poona. We believe Mr. Dastoor's knowledge of investments in the life sciences and biotechnology industries, and his finance and business development background provide him with the appropriate set of skills to serve as a member of our Board.

***Dmitry Genkin, MD*** has served as a current member of our Board since December 2023. Dr. Genkin previously served on the Company's Board of Directors from 2017-2021. He studied drug delivery under Professor Gregory Gregoriadis at The School of Pharmacy, University of London, as well as at the Department of Clinical Pharmacology at Karolinska Hospital, Stockholm. Since 2005, Dr. Genkin has served as Executive Chairman of PJSC Pharmsynthez, a stockholder of Xenetic. Dr. Genkin is founder and board member of Santersus AG – a Swiss private therapeutic medical device company developing novel apheresis therapies for extracorporeal removal of NETs. Dr. Genkin is on the board of CLS Therapeutics Inc. and Peri-Ness Ltd. – private biotechnology companies developing anti-NETosis therapies. Dr. Genkin is the inventor of more than 20 patents and patent applications in the field of therapeutics targeting of NETosis and cell free DNA. We believe Dr. Genkin's significant life sciences, biotechnology and international background provide him with the appropriate set of skills to serve as a member of our Board.

***Roger Kornberg, PhD*** has served as a member of our Board since February 2016. Dr. Kornberg is a member of the U.S. National Academy of Sciences and the Winzer Professor of Medicine in the Department of Structural Biology at Stanford University. He earned his B.S. in chemistry from Harvard University in 1967 and his Ph.D. in chemical physics from Stanford in 1972. He became a postdoctoral fellow at the Laboratory of Molecular Biology in Cambridge, England and then an assistant professor of biological chemistry at Harvard Medical School in 1976, before moving to his present position as professor of structural biology at Stanford Medical School in 1978. In 2006, Dr. Kornberg was awarded the Nobel Prize in Chemistry in recognition for his studies of the molecular basis of Eukaryotic Transcription, the process by which DNA is copied to RNA. Dr. Kornberg is also the recipient of several awards, including the 2001 Welch Prize, the highest award granted in the field of chemistry in the United States, and the 2002 Leopald Mayer Prize, the highest award granted in the field of biomedical sciences from the French Academy of Sciences. Dr. Kornberg has served as a director of Cocrystal Pharma, Inc. (NasdaqCM: COCP) since April 2020. We believe Dr. Kornberg's prior experience serving on the boards of directors of large organizations as well as his scientific background provides him with the appropriate set of skills to serve as a member of our Board.

***Moshe Mizrahy*** has served as a member of our Board since December 2023. Mr. Mizrahy is co-founder of InMode Ltd. (NASDAQ: INMD) and has served as its Chief Executive Officer and Chairman of its board of directors since its inception in 2008. Prior to that, Mr. Mizrahy was co-founder and chief executive officer of Syneron Medical Ltd. Mr. Mizrahy was also the former chief executive officer of Home Skinovations Ltd., and is currently chairman of its board. In addition to Home Skinovations Ltd., Mr. Mizrahy currently sits on the board of directors of SipNose Ltd., Pet Novations Ltd., Peri-Ness Technologies Ltd., Santersus AG, Easy-Lap Ltd., O.B.-Tools Ltd., Urifer Ltd., Easy Notes Ltd., Escape Rescue Systems Ltd., M.N. Business Strategy Ltd., Silk'n Cure Ltd., Himalaya Family Office Advising Ltd. and Polimer Logistics (Israel) Ltd. Mr. Mizrahy is co-founder and general partner of Nitzanim AVX Kyocera Venture Capital Fund and First Israel Mezzeine Investors Fund. Mr. Mizrahy has expertise in value creation for medical technologies, fundraising, public offerings, marketing and regulatory affairs. Mr. Mizrahy has a B.S. in Engineering from the Tel Aviv University and an MBA from Pace University, New York. We believe Dr. Mizrahy's executive leadership background provide him with the appropriate set of skills to serve as a member of our Board.

***Alexey Vinogradov*** has served as a member of our Board since July 2019. Dr. Vinogradov currently works as Business Development Manager at Mag. Peter G. Wahl's Law Firm in Vienna, Austria, which focuses on corporate, property and commercial law. Dr. Vinogradov has extensive experience in business development. From 2017 to 2022 he worked as a Business Development Director and Operations Director at Cantreva LLC, providing services in the field of renewable energy sources (solar, wind, hydropower). Previously, from 2015 to 2017, Dr. Vinogradov held the executive position at Togas Middle East LLC in Dubai, UAE. Dr. Vinogradov is a member of the board of PJSC Pharmsynthez a shareholder of Xenetic. We believe Mr. Vinogradov's experience in business communication, international business development and financial analytics provides him with the appropriate set of skills to serve as a member of our Board.

There are no family relationships among any of our directors and executive officers and, to the best of our knowledge, none of our directors or executive officers has, during the past ten years, been involved in any legal proceedings which are required to be disclosed pursuant to the rules and regulations of the SEC.

**Board Role in Risk Oversight and Board Leadership**

Our management is principally responsible for defining the various risks facing the Company, formulating risk management policies and procedures, and managing our risk exposures on a day-to-day basis. The Board's principal responsibility in this area is to ensure that sufficient resources, with appropriate technical and managerial skills, are provided throughout the Company to identify, assess and facilitate processes and practices to address material risk and to monitor our risk management processes by informing itself concerning our material risks and evaluating whether management has reasonable controls in place to address the material risks. The involvement of the Board in reviewing our business strategy is an integral aspect of the Board's assessment of management's tolerance for risk and its determination of what constitutes an appropriate level of risk for the Company.

We separate the roles of Chief Executive Officer and Board Chair in recognition of the differences between the two roles. The Board of Directors is currently chaired by director, Dmitry Genkin, and our Interim Chief Executive Officer, James Parslow, is not a member of our Board of Directors. Prior to December 11, 2024 the Board of Directors was chaired by independent director, Adam Logal, and, prior to May 17, 2024, our Chief Executive Officer was Jeffrey Eisenberg, our only employee-director. The Chief Executive Officer is responsible for setting the strategic direction for the Company and the day to day leadership and performance of the Company, while the Board Chair is responsible for leading the Board in the execution of its fiduciary duties. The Board Chair presides over meetings of the full Board. While we recognize that different board leadership structures may be appropriate for companies in different situations, we believe our current leadership structure is the optimal structure for the Company at this time.

**Our Board of Directors**

During fiscal year 2024, the following served as a member of the Company's Board of Directors: Jeffrey Eisenberg, Dr. Grigory Borisenko, Dr. James Callaway, Firdaus Jal Dastoor, Dr. Dmitry Genkin, Dr. Roger Kornberg, Adam Logal, Mr. Moshe Mizrahy and Alexey Vinogradov. On May 16, 2024, Mr. Eisenberg resigned as a member of the Board. On October 29, 2024, the Directors voted to set the size of the Board to six members. On December 11, 2024, Dr. Callaway and Mr. Logal were not re-elected to the Board of Directors at the Company's annual shareholder meeting. Directors shall hold office for a one-year term or until their successors have been duly elected and qualified. Vacancies on the Board resulting from death, resignation, disqualification, removal, or other causes can be filled by the affirmative vote of a majority of the directors then in office. Any director so elected, shall hold office for the remainder of the full term of the director for which the vacancy was created or occurred and until such director's successor shall have been duly elected and qualified.

**Committees of the Board**

The Board has three standing committees: an Audit Committee, a Compensation Committee, and a Nominating and Corporate Governance Committee. The Board also has two special committees: the Special Committee, which was formed on January 16, 2024, and the Financing Committee, which was formed in August 2020. The Company has adopted charters to govern the conduct, authority and responsibilities of each of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee, which are available to stockholders on the Company's website at http://ir.xeneticbio.com/. The information on our website is not incorporated by reference into, or a part of, this Amendment or the Original Filing.

**Audit Committee**

The Audit Committee of the Board of Directors was established by the Board in accordance with Section 3(a)(58)(A) of the Exchange Act to oversee the Company's corporate accounting and financial reporting processes and audits of its financial statements. For this purpose, the Audit Committee performs several functions. The Audit Committee evaluates the performance of and assesses the qualifications of the independent auditors; determines and approves the engagement of the independent auditors; determines whether to retain or terminate the existing independent auditors or to appoint and engage new independent auditors; reviews and approves the retention of the independent auditors to perform any proposed permissible non-audit services; monitors the rotation of partners of the independent auditors on the Company's audit engagement team as required by law; reviews and approves or rejects transactions between the Company and any related persons; confers with management and the independent auditors regarding the effectiveness of internal control over financial reporting; establishes procedures, as required under applicable law, for the receipt, retention and treatment of complaints received by the Company regarding accounting, internal accounting controls or auditing matters and the confidential and anonymous submission by employees of concerns regarding questionable accounting or auditing matters; and meets to review the Company's annual audited financial statements and quarterly financial statements with management and the independent auditor, including a review of the Company's disclosures under the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of the Company's Annual Report to Stockholders on Form 10-K.

For the fiscal year 2024, the Audit Committee was composed of three directors. Prior to December 11, 2024, the Audit Committee was composed of Mr. Dastoor, Dr. Callaway, and Mr. Logal (chair). Subsequent to December 11, 2024, the Audit Committee was composed of Mr. Dastoor (chair), Dr. Borisenko and Dr. Vinogradov. The Audit Committee met seven times during fiscal year 2024. The Board has adopted a written Audit Committee charter that is available to stockholders on the Company's website at http://ir.xeneticbio.com/. The information on our website is not incorporated by reference into, or a part of, this Amendment or the Original Filing.

The Board of Directors reviews the Nasdaq Stock Market LLC ("Nasdaq") listing standards definition of independence for Audit Committee members on an annual basis and has determined that all current members of our Audit Committee are independent (as independence is currently defined in Rule 5605(c)(2)(A)(i) and (ii) of the Nasdaq listing standards).

The Board of Directors determined that Mr. Dastoor qualifies as an "audit committee financial expert," as defined in applicable SEC rules. The Board made a qualitative assessment of Mr. Dastoor's level of knowledge and experience based on a number of factors, including his formal education and experience as group director-finance.

**Director Nominations**

No material changes have been made to the procedures by which stockholders may recommend nominees to our Board.

**Code of Business Conduct and Ethics**

We have adopted the Xenetic Biosciences, Inc. Code of Business Conduct and Ethics that applies to all of our employees, officers and directors, including our principal executive officer, principal financial officer and principal accounting officer. The Code of Business Conduct and Ethics is available on our website, www.xeneticbio.com, under "Investors" at "Corporate Governance." If we make any substantive amendments to the Code of Business Conduct and Ethics or grant any waiver from a provision of the Code of Business Conduct and Ethics to any executive officer or director, we intend to promptly disclose the nature of the amendment or waiver on our website, to the extent required by the applicable rules and exchange requirements. The information on our website is not incorporated by reference into, or a part of, this Amendment or the Original Filing.

**Delinquent Section 16(a) Reports**

Section 16(a) of the Exchange Act requires our directors and executive officers, and persons who own more than ten percent of a registered class of our equity securities, to file with the SEC initial reports of ownership and reports of changes in ownership of our ordinary shares and other equity securities. Such persons are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file.

To our knowledge, based solely on a review of the copies of such reports furnished to us and written representations that no other reports were required, during the fiscal year ended December 31, 2024, we believe that all Section 16(a) filing requirements applicable to our executive officers, directors and greater than 10% beneficial owners were complied with, except for the following: Dr. Genkin has not yet filed the initial Form 3 since his election to the Board.

**Insider Trading Policy**

We have adopted an insider trading policy and procedures governing the purchase, sale and other dispositions of the Company's securities that applies to all of the Company's directors, officers, employees and certain designated consultants. We believe our insider trading policy is reasonably designed to promote compliance with insider trading laws, rules and regulations, and listing standards applicable to the Company. A copy of Xenetic's insider trading policy and procedures was filed as Exhibit 19.1 to the Original Filing.

## ITEM 11 – EXECUTIVE COMPENSATION

### Summary Compensation Table – 2023 - 2024

The following table sets forth, for the years ended December 31, 2024 and 2023, the compensation information for James Parslow, our Interim Chief Executive Officer and Chief Financial Officer, Jeffrey Eisenberg, our former Chief Executive Officer and Dr. Curtis Lockshin, our former Chief Scientific Officer. We refer to Messrs. Parslow, Eisenberg, and Lockshin herein, collectively, as our "named executive officers."

| Name and Principal Position | Year | Salary ($) | Option Awards [1] ($) | Non-Equity Incentive Plan Compensation [2] ($) | All Other Compensation ($) | Total ($) |
|---|---|---|---|---|---|---|
| James Parslow, | 2024 | $378,378 | $67,280 | $ – | $ 35,510[3] | $481,168 |
| *Interim Chief Executive Officer & Chief Financial Officer* | 2023 | $329,175 | $33,932 | $ 33,411 | $ 37,214 | $433,732 |
| Jeffrey F. Eisenberg, | 2024 | $201,843 | $ – | $ – | $ 471,300[4] | $673,143 |
| *Former Chief Executive Officer* | 2023 | $404,250 | $67,863 | $ 58,617 | $ 32,764 | $563,494 |
| Dr. Curtis Lockshin, | 2024 | $166,992 | $ – | $ – | $ 387,091[5] | $554,083 |
| *Former Chief Scientific Officer* | 2023 | $329,175 | $33,932 | $ 33,411 | $ 39,298 | $435,816 |

(1) The amounts represent the aggregate grant date fair value of stock options granted in the applicable fiscal year, computed in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 718, excluding the effect of estimated forfeitures. Assumptions used in the calculation of this amount are set forth in Note 10 to our audited consolidated financial statements included in Item 8 of the Original Filing. Mr. Parslow was granted options to purchase 20,000 shares during 2024.

(2) Represents incentive compensation payments earned.

(3) Includes $21,710 for health and welfare plans and $13,800 employer matching 401(k) contribution. Does not include a retention bonus earned in 2025 as further described within *"Employment Agreements with our Named Executive Officers"* below.

(4) Includes $454,559 of severance related to salary and benefit continuation as further described within *"Employment Agreements with our Named Executive Officers"* below, $8,090 for health and welfare plans and $8,651 employer matching 401(k) contribution.

(5) Includes $369,994 of severance related to salary and benefit continuation as further described within *"Employment Agreements with our Named Executive Officers"* below, $10,625 for health and welfare plans and $6,472 employer matching 401(k) contribution.

***401(k) Plan***

The Company provides all full-time employees, including our named executive officers, with the opportunity to participate in a defined contribution 401(k) plan. Our 401(k) plan is intended to qualify under Section 401 of the Internal Revenue Code so that employee pre-tax contributions and income earned on such contributions are not taxable to employees until withdrawn. Employees may elect to defer up to 80 percent of their eligible compensation (not to exceed the statutorily prescribed annual limit) in the form of elective deferral contributions to our 401(k) plan. Our 401(k) plan also has a "catch-up contribution" feature for employees aged 50 or older (including those who qualify as "highly compensated" employees) who can defer amounts over the statutory limit that applies to all other employees. The 401(k) plan matches 100% of employee contributions up to a maximum of 4% of employees' salary. Matching contributions are fully vested at the time of contribution.

**Outstanding Equity Awards at Fiscal Year-End – 2024**

The following table sets forth certain information with respect to outstanding equity awards held by our named executive officers at December 31, 2024.

| | Option Awards | | | | Stock Awards | |
|---|---|---|---|---|---|---|
| Name | Number of Securities Underlying Unexercised Options, Exercisable | Number of Securities Underlying Unexercised Options, Unexercisable | Option Exercise Price ($) | Option Expiration Date | Number of Shares or Units of Stock That Have Not Vested | Market Value of Shares or Units of Stock That Have Not Vested ($) |
| James Parslow | 1,459[1] | – | 548.40 | 4/3/2027 | – | – |
| | 8,000[2] | – | 13.10 | 12/4/2029 | – | – |
| | 5,000[3] | – | 26.00 | 3/18/2031 | – | – |
| | 4,583[4] | 417[4] | 11.20 | 3/24/2032 | – | – |
| | 3,333[5] | 6,667[5] | 3.88 | 12/11/2033 | – | – |
| | 5,000[6] | 15,000[6] | 3.99 | 6/18/2034 | – | – |
| Jeffrey F. Eisenberg | 1,042[7] | – | 253.20 | 5/16/2025 | – | – |
| | 23,000[8] | – | 13.10 | 5/16/2025 | – | – |
| | 10,000[9] | – | 26.00 | 5/16/2025 | – | – |
| | 10,000[10] | – | 11.20 | 5/16/2025 | – | – |
| | 20,000[11] | – | 3.88 | 5/16/2025 | – | – |
| Curtis Lockshin | 127[12] | – | 550.80 | 9/6/2025 | – | – |

(1) Vested one-third upon the first anniversary of the grant date, one-third upon the second anniversary of the grant date and one-third upon the third anniversary of the grant date.

(2) Vested one-third upon the first anniversary of the grant date, one-third upon the second anniversary of the grant date and one-third upon the third anniversary of the grant date.

(3) Vested one-third upon the first anniversary of the grant date and the remaining two-thirds over eight equal quarterly installments commencing June 18, 2022 and ending on March 18, 2024.

(4) Vests one-third upon the first anniversary of the grant date and the remaining two-thirds over eight equal quarterly installments commencing June 24, 2023 and ending on March 24, 2025.

(5) Vests one-third upon the first anniversary of the grant date and the remaining two-thirds over eight equal quarterly installments commencing March 11, 2025 and ending on December 11, 2026.

(6) Vests one-fourth upon grant date, one-fourth on the first anniversary of the grant date, one-fourth upon the second anniversary of the grant date and one-fourth upon the third anniversary of the grant date.

(7) Vested one-third upon the first anniversary of the grant date, one-third upon the second anniversary of the grant date and one-third upon the third anniversary of the grant date.

(8) Vested one-third upon the first anniversary of the grant date, one-third upon the second anniversary of the grant date and one-third upon the third anniversary of the grant date.

(9) Vested one-third upon the first anniversary of the grant date and the remaining two-thirds over eight equal quarterly installments commencing June 18, 2022 and ending on March 18, 2024.

(10) Fully vested upon termination of employment.

(11) Fully vested upon termination of employment.

(12) Vested one-third upon the first anniversary of the grant date, one-third upon the second anniversary of the grant date and one-third upon the third anniversary of the grant date.

**Pay Versus Performance Disclosure**

The following tables and related disclosures provide information about (i) the "total compensation" of our CEO, and our other named executive officers (the "Other NEOs" or the "Non-CEO NEOs") as presented in the Summary Compensation Table within this proxy statement, (ii) the "compensation actually paid" to our CEO and our Other NEOs, as calculated pursuant to the SEC's pay-versus-performance rules, (iii) certain financial performance measures, and (iv) the relationship of the "compensation actually paid" to those financial performance measures.

This disclosure has been prepared in accordance with Item 402(v) of Regulation S-K under the Securities Exchange Act of 1934, as amended, and does not necessarily reflect value actually realized by the executives or how our compensation committee evaluates compensation decisions in light of company or individual performance.

| Year | Summary Compensation Table Total for CEO [1] ($) | Compensation Actually Paid to CEO [1][2][3] ($) | Summary Compensation Table Total for Former CEO [1] ($) | Compensation Actually Paid to Former CEO [1][2][3] ($) | Value of Initial Fixed $100 Investment Based on Total Shareholder Return[4] ($) | Net Loss ($) |
|---|---|---|---|---|---|---|
| 2024 | $ 481,168 | $ 469,659 | $ 673,144 | $ 622,644 | $ 30.93 | $ (3,960,275) |
| 2023 | $ – | – | $ 563,494 | $ 560,385 | $ 16.91 | $ (4,134,578) |
| 2022 | $ – | – | $ 632,827 | $ 425,619 | $ 13.98 | $ (6,552,353) |

| Year | Average Summary Compensation Table for Non-CEO NEOs [1] ($) | Average Compensation Actually Paid to Non-CEO NEOs[1][2][3] ($) | Value of Initial Fixed $100 Investment Based on Total Shareholder Return[4] ($) | Net Loss ($) |
|---|---|---|---|---|
| 2024 | $ 554,083 | $ 521,224 | $ 30.93 | $ (3,960,275) |
| 2023 | $ 434,774 | $ 433,219 | $ 16.91 | $ (4,134,578) |
| 2022 | $ 472,180 | $ 377,162 | $ 13.98 | $ (6,552,353) |

---

(1) Effective May 16, 2024, James Parslow was appointed Interim CEO. Prior to that time, Jeffrey Eisenberg was the CEO for 2024, 2023 and 2022. The Non-CEO NEOs for whom average compensation is presented in this table for 2024 is Dr. Curtis Lockshin. The Non-CEO NEOs for whom average compensation is presented in this table for 2023 and 2022 are James Parslow and Dr. Curtis Lockshin.

(2) The amounts shown as Compensation Actually Paid have been calculated in accordance with Item 402(v) of Regulation S-K and do not reflect compensation actually realized or received by the Company's NEOs. These amounts reflect total compensation as set forth in the Summary Compensation Table for each year, adjusted as described in footnote 3 below.

(3) Compensation Actually Paid reflects the exclusions and inclusions for the CEO and the Non-CEO NEOs set forth below. Amounts excluded, which are set forth in the table below in the "Minus Stock and Option Awards from Summ. Comp. Table" columns below, represent the Stock Awards and Option Awards reported in the Stock Awards and Option Awards columns of the Summary Compensation Table for each applicable year. Amounts added back to determine Compensation Actually Paid are made up of the following components as applicable: (i) the fair value as of the end of the fiscal year of outstanding and unvested equity awards granted in that year; (ii) the change in fair value during the year of equity awards granted in prior years that remained outstanding and unvested at the end of the year; (iii) the fair value as of the vesting date of equity awards that were granted and vested in that year, if any and (iv) the change in fair value during the year through the vesting date of equity awards granted in prior years that vested during that year. The fair value at the end of the prior year of awards granted in any prior year that failed to meet applicable vesting conditions during the covered year are subtracted in 2024. There were no such awards that failed to meet applicable vesting conditions for the CEOs or the Non-CEO NEOs in 2022 or 2023. Equity values are calculated in accordance with ASC Topic 718.

| Year | Summary Comp. Table Total for CEO | *Minus* Stock and Option Awards from Summ. Comp. Table | *Plus* Year-End Equity Value of Unvested Awards Granted During Year | *Plus* Change in Value of Unvested Awards Granted in Prior Years | *Plus* Change in Value of Unvested Awards Granted in Prior Years | *Plus* Change in Value of Prior Years' Awards Vested During Year | Comp. Actually Paid to CEO |
|---|---|---|---|---|---|---|---|
| 2024 | $ 481,168 | $ 67,280 | $ 49,007 | $ (1,622) | $ 16,193 | $ (7,807) | $ 469,659 |

| Year | Summary Comp. Table Total for Former CEO | *Minus* Stock and Option Awards from Summ. Comp. Table | *Plus* Year-End Equity Value of Unvested Awards Granted During Year | *Plus* Change in Value of Unvested Awards Granted in Prior Years | *Plus* Change in Value of Prior Years' Awards Vested During Year | Comp. Actually Paid to Former CEO |
|---|---|---|---|---|---|---|
| 2024 | $ 673,144 | $ – | $ – | $ (64,967) | $ 14,467 | $ 622,644 |
| 2023 | $ 563,494 | $ 67,863 | $ 59,661 | $ 1,103 | $ 3,990 | $ 560,385 |
| 2022 | $ 632,827 | $ 98,882 | $ 20,922 | $ (37,387) | $ (91,861) | $ 425,619 |

| Year | Avg. Summary Comp. Table Total for Other NEOs | *Minus* Avg. Stock and Option Awards from Summ. Comp. Table | *Plus* Avg. Year-End Equity Value of Unvested Awards Granted During Year | *Plus* Avg. Change in Value of Unvested Awards Granted in Prior Years | *Plus* Avg. Change in Value of Prior Year's Awards Vested During Year | Average Comp. Actually Paid to Other NEOs |
|---|---|---|---|---|---|---|
| 2024 | $ 554,083 | $ – | $ – | $ (33,544) | $ 685 | $ 521,224 |
| 2023 | $ 434,774 | $ 33,932 | $ 29,830 | $ 552 | $ 1,995 | $ 433,219 |
| 2022 | $ 472,180 | $ 49,441 | $ 10,461 | $ (18,693) | $ (37,345) | $ 377,162 |

For the equity values included in the above tables, the valuation assumptions used to calculate fair values of stock options were materially different from those disclosed at the time of the grant of the stock options. The assumptions used in determining fair value of the stock options that vested during 2022, 2023 and 2024, or that were outstanding as of December 31, 2022, December 31, 2023 or December 31, 2024, as applicable, are as follows:

| | Options Vested During Year or Outstanding on December 31 of: | | |
|---|---|---|---|
| | 2024 | 2023 | 2022 |
| Expected Volatility | 74.42% - 112.22% | 105.80% - 121.52% | 123.60% - 135.86% |
| Risk-Free Interest Rate | 3.45% - 5.41% | 3.54% - 4.80% | 2.15% - 4.05% |
| Expected Dividend Yield | 0% | 0% | 0% |
| Expected Term (in years) | 0.5 - 5.46 | 3.63 - 5.82 | 3.5 - 5.12 |

(4) Total Shareholder Return illustrates the value, as of the last day of the indicated fiscal year of an investment of $100 in Xenetic common stock on December 31, 2021.

***Description of Relationship Between NEO Compensation Actually Paid and Company Total Shareholder Return ("TSR") and Net Loss***

The Compensation Actually Paid to our CEO and the average of Compensation Actually Paid to our Non-CEO NEOs increased in 2024, which corresponded to the increase in the Company's TSR and decrease in Net Loss in 2024. The Compensation Actually Paid for both our former CEO and Non-CEO NEOs in 2024 increased primarily due to severance commitments incurred in 2024. The CEO and Non-CEO NEOs Non-Equity Incentive Plan Compensation is determined based on our strategic, financial and operating performance objectives that have been established by the Compensation Committee. While not directly tied to stock price performance and/or net loss, these performance objectives have been established as core drivers of TSR.

**Employment Agreements with our Named Executive Officers**

***Employment Agreement with Mr. Parslow***

We entered into an employment agreement with Mr. Parslow effective as of April 3, 2017 (the "Parslow Employment Agreement"). The Parslow Employment Agreement does not provide for a specified term of employment and Mr. Parslow's employment will be on an at-will basis. Mr. Parslow received an initial annual base salary of $265,000 and is eligible to earn an annual cash incentive bonus, which is set at a target aggregate bonus amount of 35% of Mr. Parslow's base salary, upon achievement of certain individual and/or Company performance goals set by the Compensation Committee. Mr. Parslow is also eligible to participate in the Company's employee benefit, welfare and other plans, as may be maintained by the Company from time to time, on a basis no less favorable than those provided to other similarly-situated executives of the Company. Mr. Parslow is also subject to certain customary confidentiality, non-solicitation and non-competition provisions.

If Mr. Parslow's employment is terminated by the Company without "cause" (as defined in the Parslow Employment Agreement) or Mr. Parslow resigns for "good reason" (as defined in the Parslow Employment Agreement), he will be entitled to receive (i) one year of his then current base salary, paid over time in accordance with the Company's payroll practices then in effect and (ii) payment of premiums for continued health benefits under COBRA for up to one year.

On May 16, 2024, the Board appointed Mr. Parslow to the position of Interim Chief Executive Officer, in addition to his role as the Company's Chief Financial Officer. In connection with the foregoing, on June 18, 2024, the Company and Mr. Parslow entered into an amendment (the "Parslow Employment Amendment") to the Parslow Employment Agreement, to provide for, effective as of May 16, 2024: (i) certain changes to Mr. Parslow's title and responsibilities; (ii) an increase in Mr. Parslow's base salary to $400,000; (iii) a $100,000 cash retention bonus if Mr. Parslow remains employed with the Company for a ten month period; and (iv) a stock option grant to Mr. Parslow to purchase 20,000 shares of common stock of the Company with an exercise price equal to the fair market value of the Company's common stock on the effective date of the Parslow Employment Amendment. Such option grant shall be issued pursuant to the terms and conditions of the Company's Amended and Restated Equity Incentive Plan, and shall vest one-fourth on the grant date and one-fourth upon the first, second and third anniversaries of the grant date, provided Mr. Parslow remains employed with the Company on the applicable vesting date. All other terms of the Parslow Employment Agreement remain in full force and effect.

***Employment Agreement with Mr. Eisenberg***

The Company entered into an employment agreement with Mr. Eisenberg effective as of December 1, 2016, which agreement was amended and restated on October 26, 2017 (as amended, the "Amended Agreement") pursuant to which Mr. Eisenberg was previously employed as the Chief Executive Officer of the Company. The Amended Agreement was for an initial term of one year, and automatically renewed for successive one year periods unless either party gave notice to the other no later than 90 days prior to the expiration of the then-applicable term; provided, however, that we could terminate the Amended Agreement at any time. Mr. Eisenberg's annual salary under the Amended Agreement was $300,000, and was subject to annual review and upward adjustment only by the Compensation Committee of the Board. Mr. Eisenberg was eligible to receive a bonus equal to 50% of his annual salary based on the attainment of certain individual and/or Company goals established by the Board or a committee thereto, and if Mr. Eisenberg's employment was terminated by us without "Cause" (as defined in the Amended Agreement) or if he resigned for "Good Reason" (as defined in the Amended Agreement), he would be entitled to receive (i) within thirty days following the date of termination, an amount equal to one times his then current base salary, (ii) a pro-rated annual bonus and (iii) payment of premiums for continued health benefits under COBRA for up to twelve months. Mr. Eisenberg was also eligible to participate in our employee benefit, welfare and other plans, as may be maintained by us from time to time, on a basis no less favorable than those provided to other similarly situated executives of the Company. Mr. Eisenberg was also subject to certain customary confidentiality, non-solicitation and non-competition provisions.

The Company entered into a confidential separation agreement and release with Mr. Eisenberg on June 19, 2024 in connection with his separation of employment from the Company that was effective as of May 16, 2024 pursuant to which Mr. Eisenberg became eligible to receive the payments and benefits described above in connection with a termination without "Cause" and also received full vesting of all outstanding unvested options to purchase shares of common stock of the Company.

***Employment Agreement with Dr. Lockshin***

The Company previously entered into an employment agreement with Dr. Lockshin effective as of January 1, 2017 (the "Lockshin Employment Agreement") pursuant to which Dr. Lockshin was previously employed as the Chief Scientific Officer of the Company. The Lockshin Employment Agreement did not provide for a specified term of employment and Dr. Lockshin's employment was on an at-will basis. Dr. Lockshin received an initial annual base salary of $250,000 and was eligible to earn an annual performance-based cash incentive bonus, which was set at a target aggregate bonus amount of 35% of Dr. Lockshin's base salary, upon achievement of certain individual and/or Company performance goals established by the Board or a committee thereto. Dr. Lockshin was also eligible to participate in the Company's employee benefit, welfare and other plans, as may be maintained by the Company from time to time, on a basis no less favorable than those provided to other similarly-situated executives of the Company. Dr. Lockshin was also subject to certain customary confidentiality, non-solicitation and non-competition provisions.

If Dr. Lockshin's employment was terminated by the Company without "Cause" (as defined in the Lockshin Employment Agreement) or Dr. Lockshin terminated his employment for "Good Reason" (as defined in the Lockshin Employment Agreement) and Dr. Lockshin executed and did not revoke a general release of claims against the Company, then he would be entitled to receive (i) one year of his then current base salary, paid over time in accordance with the Company's payroll practices then in effect and (ii) payment of premiums for continued health benefits under COBRA for up to twelve months.

The Company entered into a confidential separation agreement and release with Dr. Lockshin on June 19, 2024 in connection with his separation of employment from the Company that was effective as of May 16, 2024 pursuant to which Dr. Lockshin became eligible to receive the payments and benefits described above in connection with a termination without "Cause".

**Potential Payments Upon Termination or Change of Control**

Our named executive officers may be entitled to payments upon termination or change of control. The details of such payments are included in the description of their employment agreements above.

**Director Compensation**

Each of our non-employee, independent directors is currently entitled to receive an annual retainer of $43,000, payable in equal quarterly installments, an option to acquire 2,500 shares of the Company's common stock upon initial appointment to the Board, and an additional option to acquire 2,500 shares each year thereafter on the date of the Company's annual meeting of stockholders. All members of our Board are reimbursed for their usual and customary expenses incurred in connection with their service on the Board, including out-of-pocket expenses, transportation, and airfare on the Company's business.

**Director Compensation Table**

As an employee director during fiscal year 2024, Mr. Eisenberg did not receive any compensation for his Board service during the last completed year. The following table sets forth information for the year ended December 31, 2024 regarding the compensation awarded to, earned by or paid to our non-employee directors:

| Name | Fees Earned or Paid in Cash ($) | Stock Awards ($) | Option Awards[1][2] ($) | All Other Compensation ($) | Total ($) |
|---|---|---|---|---|---|
| Dr. Grigory Borisenko | 43,000 | – | 8,721 | – | 51,721 |
| Firdaus Jal Dastoor | 43,000 | – | 8,721 | – | 51,721 |
| Dr. Dmitry Genkin[3] | – | – | – | – | – |
| Dr. Roger Kornberg | 43,000 | – | 8,721 | – | 51,721 |
| Mr. Moshe Mizrahy[3] | – | – | – | – | – |
| Dr. Alexey Vinogradov | 43,000 | – | 8,721 | – | 51,721 |

(1) The amounts represent the aggregate grant date fair value of stock options granted during 2024, computed in accordance with FASB ASC Topic 718. For a discussion of the assumptions and methodology used to calculate the value of our stock options, see Note 10 to our audited financial statements included in Item 8 of the Original Filing.

(2) The table below shows the aggregate number of option awards outstanding for each of our non-employee directors as of December 31, 2024:

| Name | Option Awards (#) |
|---|---|
| Dr. Grigory Borisenko | 7,500 |
| Firdaus Jal Dastoor | 15,796 |
| Dr. Dmitry Genkin | – |
| Dr. Roger Kornberg | 15,626 |
| Mr. Moshe Mizrahy | 2,500 |
| Dr. Alexey Vinogradov | 15,000 |

(3) The Board determined that Dr. Genkin and Mr. Mizrahy are not independent directors, and as such, neither were eligible for compensation during fiscal year 2024.

See “Certain Related Person Transactions” below for compensation arrangements involving specific members of the Board.

**ITEM 12 – SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

The following table and footnotes set forth certain information known to us regarding beneficial ownership of our capital stock as of March 31, 2025 for:

- each person known by us to be the beneficial owner of more than 5% of our capital stock;
- our named executive officers;
- each of our directors; and
- all executive officers and directors as a group.

The number of shares beneficially owned by each entity, person, director or executive officer is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to acquire within 60 days through the exercise of any stock option, warrants or other rights. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock held by that person or entity.

The percentage of shares beneficially owned is computed on the basis of 1,542,139 shares of our common stock outstanding as of March 31, 2025, on an as-converted basis. Shares of our common stock that a person has the right to acquire within 60 days after March 31, 2025 are deemed outstanding for purposes of computing the percentage ownership of the person or entity holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all directors and executive officers as a group. Unless otherwise indicated below, the address for each beneficial owner listed is c/o Xenetic Biosciences, Inc., at 945 Concord Street, Framingham, Massachusetts 01701.

| Name of Beneficial Owner | Number of Shares Beneficially Owned [1] | Percentage of Class Beneficially Owned |
|---|---|---|
| **Fiscal Year 2024 Named Executive Officers and Current Directors** | | |
| James Parslow | 28,626[2] | 1.8% |
| Jeffrey Eisenberg | 64,459[3] | 4.0% |
| Dr. Curtis Lockshin | 127[4] | * |
| Dr. Grigory Borisenko[5] | 5,000[6] | * |
| Firdaus Jal Dastoor | 13,296[7] | * |
| Dr. Dmitry Genkin[5] | 215,964[8] | 14.0% |
| Dr. Roger Kornberg | 13,126[9] | * |
| Moshe Mizrahy | 2,500[10] | * |
| Alexey Vinogradov | 31,179[11] | 2.0% |
| All current executive officers and directors as a group (7 persons) | 162,191[12] | 10.0% |
| **5% Current Stockholders** | | |
| CLS Therapeutics Ltd. | 147,500[8] | 9.6% |
| PJSC Pharmsynthez [5] | 97,922[13] | 6.2% |

* Represents beneficial ownership of less than one percent (1%).

(1) Unless otherwise indicated below, this table is based upon corporate records, information supplied by officers, directors and, in the case of principal stockholders, information provided by our transfer agent.

(2) The total beneficial ownership consists of 28,626 shares issuable upon exercise of options that are exercisable within 60 days of March 31, 2025.

(3) The total beneficial ownership consists of 417 shares of common stock owned directly and 64,042 shares issuable upon exercise of options that are exercisable within 60 days of March 31, 2025.

(4) The total beneficial ownership consists of 127 shares issuable upon exercise of options that are exercisable within 60 days of March 31, 2025.

(5) Dr. Borisenko was employed by Rusnano LLC, an entity affiliated with Pharmsynthez, through March 31, 2022. Dr. Dmitry Genkin and Dr. Alexey Vinogradov are on the board of directors of Pharmsynthez, with Dr. Genkin serving as Executive Chairman. Refer to the "Transactions with Related Persons" section below for additional information with respect to certain related party transactions involving Dr. Genkin, Dr. Vinogradov and Pharmsynthez (including its wholly owned subsidiaries).

(6) The total beneficial ownership consists of 5,000 shares issuable upon exercise of options that are exercisable within 60 days of March 31, 2025.

(7) The total beneficial ownership consists of 13,296 shares issuable upon exercise of options that are exercisable within 60 days of March 31, 2025.

(8) Based on the Schedule 13D/A filed with the SEC on March 18, 2024 by CLS Therapeutics Ltd., a limited company organized under the laws of Guernsey, United Kingdom ("CLS"), CLS Therapeutics, LLC, a Delaware limited liability company and subsidiary of CLS ("CLS LLC"), Dmitry Genkin ("Genkin"), Victor Tets ("VT"), Georgy Tets ("GT") and M. Scott Maguire ("Maguire") (the "CLS 13D"): CLS has sole voting and dispositive power as to 147,500 shares of common stock, which includes 85,000 shares of common stock owned by CLS LLC; CLS LLC has sole voting and dispositive power as to 85,000 shares of common stock; Genkin has sole voting and dispositive power as to 68,464 shares of common stock and shared voting and dispositive power as to 147,500 shares of common stock; VT and GT each have shared voting and dispositive power as to 147,500 shares of common stock; and Maguire has sole voting and dispositive power as to 3,800 shares of common stock, and shared voting and dispositive power as to 2,202 shares of common stock. CLS, as the ultimate parent of CLS LLC, may exercise voting and dispositive power over the shares owned by CLS LLC, and as such, may be deemed the beneficial owner of such shares. Genkin, VT and GT may exercise voting and dispositive power over the shares owned by CLS and CLS LLC, and as such, may be deemed to be the beneficial owner of such shares. According to the 13D, the address of Genkin is Pazzale Baracca 2, Milan, Italy; the address of CLS and CLS LLC is PO Box 175, Frances House, Sir William Place, St. Peter Port Guernsey, Channel Islands GY1 4HQ; and the address of VT and GT is 180 Varick Street, New York, NY 10014.

(9) The total beneficial ownership consists of 13,126 shares issuable upon exercise of options that are exercisable within 60 days of March 31, 2025.

(10) The total beneficial ownership consists of 2,500 shares issuable upon exercise of options that are exercisable within 60 days of March 31, 2025.

(11) The total beneficial ownership consists of 18,679 shares of common stock owned directly and 12,500 shares issuable upon exercise of options that are exercisable within 60 days of March 31, 2025.

(12) The total beneficial ownership consists of 87,143 shares of common stock owned directly and 75,048 shares issuable upon exercise of options that are exercisable within 60 days of March 31, 2025.

(13) The total beneficial ownership consists of 52,797 shares of common stock owned directly or indirectly through SynBio and 45,125 shares issuable upon the conversion of Series B Preferred Stock that are exercisable within 60 days of March 31, 2025. SynBio is a wholly-owned subsidiary of Pharmsynthez. Pharmsynthez may be deemed to have shared voting and shared dispositive power with respect to all the shares owned by SynBio and therefore, Pharmsynthez may be deemed to be the beneficial owner of such shares. The address of PJSC Pharmsynthez is 9 Korpusnaya Street, Letter A 1st Floor, St. Petersburg, 197110, Russia. Refer to the "Certain Related Person Transactions" section below for additional information with respect to certain related party transactions involving Pharmsynthez.

**Equity Compensation Plan Information**

The following table sets forth information as of December 31, 2024 with respect to compensation plans under which equity securities are authorized for issuance:

| Plan Category | Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights (a) | Weighted Average Exercise Price of Outstanding Options, Warrants and Rights (b) | Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a)) (c) |
|---|---|---|---|
| Equity compensation plans approved by security holders | 197,647(1) | $ 24.24 | 54,503 |
| Equity compensation plans not approved by security holders | 1,459(2) | 548.40 | – |
| Total | 199,106 | $ 28.08 | 54,503 |

(1) Consists of 197,647 shares of our common stock to be issued upon the exercise of outstanding stock options under the Xenetic Biosciences, Inc. Amended and Restated Equity Incentive Plan ("Equity Plan.")

(2) Represents inducement award granted to Mr. Parslow in 2017 in connection with his employment with the Company that was not covered under the Equity Plan in accordance with Nasdaq Listing Rule 5635(c)(4). The option has a ten-year term and is fully vested.

## ITEM 13 – CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

During the fiscal years ended December 31, 2024 and December 31, 2023, there was not, nor is there any currently proposed transaction or series of similar transactions to which Xenetic was or is to be a party in which the amount involved exceeded or exceeds the lesser of $120,000 or 1% of the average of our total assets at year end for the last two completed fiscal years and in which any executive officer, director or holder of more than 5% of any class of voting securities of Xenetic and members of that person's immediate family had, has or will have a direct or indirect material interest, other than as set forth in "Executive Compensation" and "Director Compensation Table" above and as disclosed below.

### Policy Regarding Related Party Transactions

Our Board adopted an amended written related party transaction policy on August 27, 2020 to set forth the policies and procedures for the review and approval or ratification of related party transactions by our audit committee, which replaced the policy previously adopted in November 1, 2016. Any transaction between the Company and its officers, directors, principal stockholders or affiliates is required to be on terms no less favorable to us than could be reasonably obtained in arms-length transactions with independent third-parties. Transactions described in this section that occurred prior to November 1, 2016 were not covered by the Company's related party transaction policy.

### Certain Related Person Transactions

#### *PJSC Pharmsynthez*

Pharmsynthez directly, and indirectly through its wholly-owned subsidiary SynBio LLC ("SynBio"), had a share ownership in the Company of approximately 3% of the total outstanding common stock at March 31, 2025. In addition to its common stock ownership, Pharmsynthez holds approximately 1.5 million shares of our outstanding Series B Preferred Stock at March 31, 2025. In addition, two of our current directors, Dr. Dmitry Genkin and Dr. Alexey Vinogradov serve on the board of directors of Pharmsynthez, with Dr. Genkin serving as Executive Chairman, and, prior to March 31, 2022, Dr. Grigory Borisenko, one of our current directors, was employed as the Investment Director of Rusnano LLC, an entity affiliated with Pharmsynthez.

In November 2009, the Company entered into a collaborative research and development license agreement with Pharmsynthez (the "Pharmsynthez Arrangement") pursuant to which the Company granted an exclusive license to Pharmsynthez to develop, commercialize and market six product candidates based on the Company's PolyXen and ImuXen technology in certain territories. In exchange, Pharmsynthez granted an exclusive license to the Company to use any preclinical and clinical data developed by Pharmsynthez, within the scope of the Pharmsynthez Arrangement, and to engage in further research, development and commercialization of drug candidates outside of certain territories at the Company's own expense.

In August 2011, SynBio and the Company entered into a stock subscription and collaborative development agreement (the "Co-Development Agreement"). The Company granted an exclusive license to SynBio to develop, market and commercialize certain drug candidates utilizing molecules based on SynBio's technology and the Company's proprietary technologies (PolyXen, OncoHist and ImuXen) in Russia and Commonwealth of Independent States ("CIS"), collectively referred to herein as the SynBio Market. In return, SynBio granted an exclusive license to the Company to use the preclinical and clinical data generated by SynBio in certain agreed products and to engage in the development of commercial candidates in any territory outside of the SynBio Market.

SynBio is solely responsible for funding and conducting their own research and clinical development activities. There are no milestone or other research-related payments provided for under the Co-Development Agreement other than fees for the supply of each company's respective research supplies based on their technology, which, when provided, are due to mutual convenience and not representative of an ongoing or recurring obligation to supply research supplies. Upon successful commercialization of any resultant products, the Company is entitled to receive a 10% royalty on sales in certain territories and pay royalties to SynBio for sales outside those certain territories, subject to the terms of the Co-Development Agreement. Effective December 20, 2021, SynBio assigned the Co-Development Agreement to Pharmsynthez.

Through December 31, 2024, Pharmsynthez informed the Company that it continued to engage in research and development activities with no resultant commercial products. In December 2020, Pharmsynthez reported positive data from its Phase 3 clinical study of Epolong, a treatment for anemia in patients with chronic kidney disease leveraging the Company's PolyXen technology. Pharmsynthez filed a registration dossier to obtain approval in Russia and informed the Company that it has received a response letter indicating certain deficiencies in the dossier. Pharmsynthez further informed the Company that it developed a gap mitigation strategy and is currently determining next steps. The Company did not recognize revenue in connection with the Co-Development Agreement during the years ended December 31, 2024 and 2023.

During the fourth quarter of 2019, the Company entered into a loan agreement with Pharmsynthez (the "Pharmsynthez Loan"), pursuant to which the Company advanced Pharmsynthez an aggregate principal amount of up to $500,000 to be used for the development of a specific product under the Company's Co-Development Agreement with Pharmsynthez. The Pharmsynthez Loan had an initial term of 15-months and accrued interest at a rate of 10% per annum. The Pharmsynthez Loan was guaranteed by all of the operating subsidiaries of Pharmsynthez, including SynBio and AS Kevelt, and was secured by all of the common and preferred stock of the Company owned by Pharmsynthez and SynBio.

Pharmsynthez paid all obligations due under the Pharmsynthez Loan in May 2023, and no further amounts are due under the Pharmsynthez Loan. As a result, no amounts were outstanding as of December 31, 2024 and December 31, 2023. The Company did not recognize any interest income related to the Pharmsynthez Loan during the year ended December 31, 2024. The Company recognized approximately $65,000 of income related to interest and fees associated with the Pharmsynthez Loan including approximately $40,000 related to interest income during the twelve months ended December 31, 2023.

***Peri-Ness Technologies Ltd.***

During the fourth quarter of 2024, the Company entered into a clinical trial services agreement with PeriNess Ltd. ("PeriNess") to advance the Company's development program for its systemic DNase I technology in Israeli medical centers. One of our directors, Dr. Dmitry Genkin, is a significant shareholder of PeriNess and another of our directors, Mr. Moshe Mizrahy, is a majority shareholder and director of PeriNess. The services to be provided under this agreement are estimated to be approximately $0.3 million.

***Consulting Services Agreement with Dr. Dmitry Genkin***

During the first quarter of 2025, the Company entered into a Consulting Agreement with Dr. Genkin, Chairman of our Board Directors, to provide consulting services to the Company's DNase-based oncology program. The agreement was effective January 1, 2025 and the Company paid Dr. Genkin approximately $90,000 during the three months ended March 31, 2025, of which approximately $30,000 was reflected in current liabilities as of March 31, 2025. Dr. Genkin does not receive any fees for his service as a member of the Board of Directors.

**Director Independence**

As required under the Nasdaq Stock Market LLC ("Nasdaq") listing standards, a majority of the members of a listed company's board of directors must qualify as "independent," as affirmatively determined by the Board of Directors. The Board consults with advisors to ensure that the Board's determinations are consistent with relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in pertinent listing standards of Nasdaq, as in effect from time to time.

Consistent with these considerations, after review of all relevant identified transactions or relationships between each director, or any of his or her family members, and the Company, its senior management and its independent auditors, the Board affirmatively determined that the following directors are independent directors within the meaning of the applicable Nasdaq listing standards (and were for the period during which they served as a member of the Board during fiscal year 2024): Dr. Callaway, Mr. Dastoor, Dr. Kornberg, Mr. Logal, Mr. Mizrahy (until October 2024 in connection with the approval of a proposed transaction with Peri-Ness, as described in the "Certain Related Person Transactions" section of this Form 10-K/A), Dr. Vinogradov and Dr. Borisenko. In making these determinations, the Board considered the current and prior relationships that each non-employee director had with the Company and all other facts and circumstances our Board deemed relevant in determining independence, including those transactions set forth in the "Certain Related Person Transactions" section of this Form 10-K/A, as previously disclosed with the SEC.

During fiscal year 2024, all members of our Audit Committee, Nominating and Corporate Governance Committee, and Compensation Committee were independent (as independence is currently defined in Rule 5605 of the Nasdaq listing standards).

## ITEM 14 – PRINCIPAL ACCOUNTING FEES AND SERVICES

The following table represents aggregate fees billed to the Company for the fiscal years ended December 31, 2024 and December 31, 2023, by Marcum LLP, the Company's principal accountant.

| | 2024 | 2023 |
|---|---|---|
| Audit Fees | $ 160,000 | $ 168,228 |
| Audit-Related Fees | 5,000 | 20,342 |
| Tax Fees | – | – |
| All Other Fees | – | – |
| | $ 165,000 | $ 188,570 |

**Audit Fees**

Audit fees include the total fees incurred in connection with the audit of our annual consolidated financial statements for each of the years ended December 31, 2024 and 2023.

**Audit-Related Fees**

Audit related fees during the year ended December 31, 2024 include fees incurred in connection with our S-3 registration statement. Audit related fees during the year ended December 31, 2023 include fees incurred in connection with comfort letters issued in connection with our At-The-Market program under our S-3 registration statement.

**Audit and Non-Audit Services Pre-Approval Policy**

The Audit Committee pre-approves all audit and non-audit accounting services provided by our independent, registered accounting firm. All audit and non-audit fee services described above were pre-approved by the Audit Committee.

Pursuant to the Board of Directors' policy, to help ensure the independence of our independent registered public accounting firm, all auditing services and permitted non-audit services (including the terms thereof) to be performed for us by our independent registered public accounting firm must be pre-approved by the Audit Committee, subject to the de-minimus exceptions for non-audit services described in Section 10A(i)(1)(B) of the Exchange Act, which are approved by the Audit Committee prior to the commencement of services.

Our Audit Committee approved and retained Marcum LLP to audit our consolidated financial statements for 2024. Our Audit Committee reviewed all services provided by Marcum LLP in 2024 and concluded that the services provided were compatible with maintaining its independence.

## PART IV

## ITEM 15 – EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following financial statements, schedules and exhibits are filed as part of this report:

*Consolidated Financial Statements:* The consolidated financial statements and report of independent registered public accounting firm required by this item are included in Part II, Item 8 of the Original Filing;

*Financial Statement Schedules:* All schedules were omitted because they are not applicable or not required, or because the required information is shown in the consolidated financial statements or in the notes thereto.

(b) **Exhibits:** The exhibits required to be filed by Item 15 are set forth in, and filed with or incorporated by reference in, the "Exhibit Index" of the Original Filing. The attached list of exhibits in the "Exhibit Index" sets forth the additional exhibits required to be filed with this Amendment and is incorporated herein by reference in response to this item.

## EXHIBIT INDEX

| Exhibit No. | Exhibit Index | Form | Filing Date | Exhibit Number | Filed Herewith |
|---|---|---|---|---|---|
| 31.3 | Certification of Principal Executive Officer, as required by Rule 13a-14(a) and Rule 15d-14(a) | | | | X |
| 31.4 | Certification of Principal Financial Officer, as required by Rule 13a-14(a) and Rule 15d-14(a) | | | | X |
| 101.INS | Inline XBRL Instance Document | | | | X |
| 101.SCH | Inline XBRL Taxonomy Extension Schema Document | | | | X |
| 101.DEF | Inline XBRL Taxonomy Extension Definition Linkbase Document. | | | | X |
| 101.LAB | Inline XBRL Taxonomy Extension Label Linkbase Document. | | | | X |
| 104 | Cover Page Interactive Data File (embedded within the inline document and included in Exhibit 101) | | | | X |

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**XENETIC BIOSCIENCES, INC.**

Date: April 29, 2025

By: /s/ JAMES PARSLOW
James Parslow
*Interim Chief Executive Officer*

# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**Washington, D.C. 20549**

**Form 10-K/A**
**Amendment No. 2**

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.**
**For the fiscal year ended December 31, 2024**

☐ **TRANSITION REPORTS PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.**
**For the transition period from to**

**Commission File Number: 001-37937**

# XENETIC BIOSCIENCES, INC.
**(Exact name of registrant as specified in its charter)**

| **Nevada** | **45-2952962** |
|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(IRS Employer Identification No.)** |

**945 Concord Street**
**Framingham, Massachusetts 01701**
**(Address of principal executive offices (Zip code)**

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

**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 Capital Market |

**Securities registered pursuant to Section 12(g) of the Act:**
**None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act: Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act: Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files): Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer" "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

| | | | |
|---|---|---|---|
| Large accelerated filer | ☐ | Accelerated filer | ☐ |
| Non-accelerated filer | ☒ | Smaller reporting company | ☒ |
| | | 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. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive- based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Exchange Act Rule 12b-2): Yes ☐ No ☒

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant as of June 28, 2024, the last business day of the registrant's most recently completely second fiscal quarter, based upon the closing price of the registrant's common stock on the Nasdaq Capital Market on that date of $4.07, was approximately $5,301,818. For purposes of this computation, all officers, directors, and 10% beneficial owners of the registrant are deemed to be affiliates. Such determination should not be deemed to be an admission that such officers, directors or 10% beneficial owners are, in fact, affiliates of the registrant.

As of April 18, 2025, the number of outstanding shares of the registrant's common stock was 1,542,139.

**DOCUMENTS INCORPORATED BY REFERENCE**

None

## EXPLANATORY NOTE

The Registrant is filing this Amendment No. 2 on Form 10-K/A (this "Amendment") to amend its Annual Report on Form 10-K for the fiscal year ended December 31, 2024, originally filed with the Securities and Exchange Commission ("SEC") on March 18, 2025, as amended by that Amendment No. 1 on Form 10-K/A filed with the SEC on April 29, 2025 (as amended, the "Original Filing"). We are filing this Amendment solely to add a new paragraph under the heading "Equity Award Grant Practices" in Item 11 of Part III and to include certain required XBRL tagging with respect thereto, which was inadvertently omitted in the Original Filing.

Part III, Item 11 of the Original Filing is being amended and restated in its entirety by this Amendment. In addition, pursuant to Rule 12b-15 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), Part IV, Item 15 of the Original Filing is being amended to contain the currently dated certifications pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, which are attached hereto as Exhibit 31.5 and Exhibit 31.6, respectively. Because no financial statements are included in this Amendment and this Amendment does not contain or amend any disclosure with respect to Items 307 and 308 of Regulation S-K, paragraphs 3, 4, and 5 of the certifications have been omitted.

Except as described above, this Amendment does not amend or otherwise update any other information in the Original Filing. Accordingly, this Amendment should be read in conjunction with the Original Filing. In addition, this Amendment does not reflect events that may have occurred subsequent to the date of the Original Filing.

As used in this Amendment, unless otherwise indicated, all references herein to "Xenetic," the "Company," "we" or "us" refer to Xenetic Biosciences, Inc. and its wholly owned subsidiaries.

**XENETIC BIOSCIENCES, INC.**
**2024 ANNUAL REPORT ON FORM 10-K**

**TABLE OF CONTENTS**

**PART III**

Item 11 Executive Compensation..... 1

**PART IV**

Item 15 Exhibits and Financial Statement Schedules..... 8

## PART III

### ITEM 11 – EXECUTIVE COMPENSATION

**Summary Compensation Table – 2023 - 2024**

The following table sets forth, for the years ended December 31, 2024 and 2023, the compensation information for James Parslow, our Interim Chief Executive Officer and Chief Financial Officer, Jeffrey Eisenberg, our former Chief Executive Officer and Dr. Curtis Lockshin, our former Chief Scientific Officer. We refer to Messrs. Parslow, Eisenberg, and Lockshin herein, collectively, as our "named executive officers."

| Name and Principal Position | Year | Salary ($) | Option Awards [1] ($) | Non-Equity Incentive Plan Compensation [2] ($) | All Other Compensation ($) | Total ($) |
|---|---|---|---|---|---|---|
| James Parslow, | 2024 | $378,378 | $67,280 | $ – | $ 35,510[3] | $481,168 |
| *Interim Chief Executive Officer & Chief Financial Officer* | 2023 | $329,175 | $33,932 | $ 33,411 | $ 37,214 | $433,732 |
| Jeffrey F. Eisenberg, | 2024 | $201,843 | $ – | $ – | $ 471,300[4] | $673,143 |
| *Former Chief Executive Officer* | 2023 | $404,250 | $67,863 | $ 58,617 | $ 32,764 | $563,494 |
| Dr. Curtis Lockshin, | 2024 | $166,992 | $ – | $ – | $ 387,091[5] | $554,083 |
| *Former Chief Scientific Officer* | 2023 | $329,175 | $33,932 | $ 33,411 | $ 39,298 | $435,816 |

(1) The amounts represent the aggregate grant date fair value of stock options granted in the applicable fiscal year, computed in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 718, excluding the effect of estimated forfeitures. Assumptions used in the calculation of this amount are set forth in Note 10 to our audited consolidated financial statements included in Item 8 of the Original Filing. Mr. Parslow was granted options to purchase 20,000 shares during 2024.

(2) Represents incentive compensation payments earned.

(3) Includes $21,710 for health and welfare plans and $13,800 employer matching 401(k) contribution. Does not include a retention bonus earned in 2025 as further described within *"Employment Agreements with our Named Executive Officers"* below.

(4) Includes $454,559 of severance related to salary and benefit continuation as further described within *"Employment Agreements with our Named Executive Officers"* below, $8,090 for health and welfare plans and $8,651 employer matching 401(k) contribution.

(5) Includes $369,994 of severance related to salary and benefit continuation as further described within *"Employment Agreements with our Named Executive Officers"* below, $10,625 for health and welfare plans and $6,472 employer matching 401(k) contribution.

***401(k) Plan***

The Company provides all full-time employees, including our named executive officers, with the opportunity to participate in a defined contribution 401(k) plan. Our 401(k) plan is intended to qualify under Section 401 of the Internal Revenue Code so that employee pre-tax contributions and income earned on such contributions are not taxable to employees until withdrawn. Employees may elect to defer up to 80 percent of their eligible compensation (not to exceed the statutorily prescribed annual limit) in the form of elective deferral contributions to our 401(k) plan. Our 401(k) plan also has a "catch-up contribution" feature for employees aged 50 or older (including those who qualify as "highly compensated" employees) who can defer amounts over the statutory limit that applies to all other employees. The 401(k) plan matches 100% of employee contributions up to a maximum of 4% of employees' salary. Matching contributions are fully vested at the time of contribution.

**Outstanding Equity Awards at Fiscal Year-End – 2024**

The following table sets forth certain information with respect to outstanding equity awards held by our named executive officers at December 31, 2024.

| | Option Awards | | | | Stock Awards | |
|---|---|---|---|---|---|---|
| Name | Number of Securities Underlying Unexercised Options, Exercisable | Number of Securities Underlying Unexercised Options, Unexercisable | Option Exercise Price ($) | Option Expiration Date | Number of Shares or Units of Stock That Have Not Vested | Market Value of Shares or Units of Stock That Have Not Vested ($) |
| James Parslow | 1,459[1] | – | 548.40 | 4/3/2027 | – | – |
| | 8,000[2] | – | 13.10 | 12/4/2029 | – | – |
| | 5,000[3] | – | 26.00 | 3/18/2031 | – | – |
| | 4,583[4] | 417[4] | 11.20 | 3/24/2032 | – | – |
| | 3,333[5] | 6,667[5] | 3.88 | 12/11/2033 | – | – |
| | 5,000[6] | 15,000[6] | 3.99 | 6/18/2034 | – | – |
| Jeffrey F. Eisenberg | 1,042[7] | – | 253.20 | 5/16/2025 | – | – |
| | 23,000[8] | – | 13.10 | 5/16/2025 | – | – |
| | 10,000[9] | – | 26.00 | 5/16/2025 | – | – |
| | 10,000[10] | – | 11.20 | 5/16/2025 | – | – |
| | 20,000[11] | – | 3.88 | 5/16/2025 | – | – |
| Curtis Lockshin | 127[12] | – | 550.80 | 9/6/2025 | – | – |

(1) Vested one-third upon the first anniversary of the grant date, one-third upon the second anniversary of the grant date and one-third upon the third anniversary of the grant date.

(2) Vested one-third upon the first anniversary of the grant date, one-third upon the second anniversary of the grant date and one-third upon the third anniversary of the grant date.

(3) Vested one-third upon the first anniversary of the grant date and the remaining two-thirds over eight equal quarterly installments commencing June 18, 2022 and ending on March 18, 2024.

(4) Vests one-third upon the first anniversary of the grant date and the remaining two-thirds over eight equal quarterly installments commencing June 24, 2023 and ending on March 24, 2025.

(5) Vests one-third upon the first anniversary of the grant date and the remaining two-thirds over eight equal quarterly installments commencing March 11, 2025 and ending on December 11, 2026.

(6) Vests one-fourth upon grant date, one-fourth on the first anniversary of the grant date, one-fourth upon the second anniversary of the grant date and one-fourth upon the third anniversary of the grant date.

(7) Vested one-third upon the first anniversary of the grant date, one-third upon the second anniversary of the grant date and one-third upon the third anniversary of the grant date.

(8) Vested one-third upon the first anniversary of the grant date, one-third upon the second anniversary of the grant date and one-third upon the third anniversary of the grant date.

(9) Vested one-third upon the first anniversary of the grant date and the remaining two-thirds over eight equal quarterly installments commencing June 18, 2022 and ending on March 18, 2024.

(10) Fully vested upon termination of employment.

(11) Fully vested upon termination of employment.

(12) Vested one-third upon the first anniversary of the grant date, one-third upon the second anniversary of the grant date and one-third upon the third anniversary of the grant date.

**Pay Versus Performance Disclosure**

The following tables and related disclosures provide information about (i) the "total compensation" of our CEO, and our other named executive officers (the "Other NEOs" or the "Non-CEO NEOs") as presented in the Summary Compensation Table within this proxy statement, (ii) the "compensation actually paid" to our CEO and our Other NEOs, as calculated pursuant to the SEC's pay-versus-performance rules, (iii) certain financial performance measures, and (iv) the relationship of the "compensation actually paid" to those financial performance measures.

This disclosure has been prepared in accordance with Item 402(v) of Regulation S-K under the Securities Exchange Act of 1934, as amended, and does not necessarily reflect value actually realized by the executives or how our compensation committee evaluates compensation decisions in light of company or individual performance.

| Year | Summary Compensation Table Total for CEO [1] ($) | Compensation Actually Paid to CEO [1][2][3] ($) | Summary Compensation Table Total for Former CEO [1] ($) | Compensation Actually Paid to Former CEO [1][2][3] ($) | Value of Initial Fixed $100 Investment Based on Total Shareholder Return[4] ($) | Net Loss ($) |
|---|---|---|---|---|---|---|
| 2024 | $ 481,168 | $ 469,659 | $ 673,144 | $ 622,644 | $ 30.93 | $ (3,960,275) |
| 2023 | $ – | – | $ 563,494 | $ 560,385 | $ 16.91 | $ (4,134,578) |
| 2022 | $ – | – | $ 632,827 | $ 425,619 | $ 13.98 | $ (6,552,353) |

| Year | Average Summary Compensation Table for Non-CEO NEOs [1] ($) | Average Compensation Actually Paid to Non-CEO NEOs[1][2][3] ($) | Value of Initial Fixed $100 Investment Based on Total Shareholder Return[4] ($) | Net Loss ($) |
|---|---|---|---|---|
| 2024 | $ 554,083 | $ 521,224 | $ 30.93 | $ (3,960,275) |
| 2023 | $ 434,774 | $ 433,219 | $ 16.91 | $ (4,134,578) |
| 2022 | $ 472,180 | $ 377,162 | $ 13.98 | $ (6,552,353) |

---

(1) Effective May 16, 2024, James Parslow was appointed Interim CEO. Prior to that time, Jeffrey Eisenberg was the CEO for 2024, 2023 and 2022. The Non-CEO NEOs for whom average compensation is presented in this table for 2024 is Dr. Curtis Lockshin. The Non-CEO NEOs for whom average compensation is presented in this table for 2023 and 2022 are James Parslow and Dr. Curtis Lockshin.

(2) The amounts shown as Compensation Actually Paid have been calculated in accordance with Item 402(v) of Regulation S-K and do not reflect compensation actually realized or received by the Company's NEOs. These amounts reflect total compensation as set forth in the Summary Compensation Table for each year, adjusted as described in footnote 3 below.

(3) Compensation Actually Paid reflects the exclusions and inclusions for the CEO and the Non-CEO NEOs set forth below. Amounts excluded, which are set forth in the table below in the "Minus Stock and Option Awards from Summ. Comp. Table" columns below, represent the Stock Awards and Option Awards reported in the Stock Awards and Option Awards columns of the Summary Compensation Table for each applicable year. Amounts added back to determine Compensation Actually Paid are made up of the following components as applicable: (i) the fair value as of the end of the fiscal year of outstanding and unvested equity awards granted in that year; (ii) the change in fair value during the year of equity awards granted in prior years that remained outstanding and unvested at the end of the year; (iii) the fair value as of the vesting date of equity awards that were granted and vested in that year, if any and (iv) the change in fair value during the year through the vesting date of equity awards granted in prior years that vested during that year. The fair value at the end of the prior year of awards granted in any prior year that failed to meet applicable vesting conditions during the covered year are subtracted in 2024. There were no such awards that failed to meet applicable vesting conditions for the CEOs or the Non-CEO NEOs in 2022 or 2023. Equity values are calculated in accordance with ASC Topic 718.

| Year | Summary Comp. Table Total for CEO | *Minus* Stock and Option Awards from Summ. Comp. Table | *Plus* Year-End Equity Value of Unvested Awards Granted During Year | *Plus* Change in Value of Unvested Awards Granted in Prior Years | *Plus* Change in Value of Unvested Awards Granted in Prior Years | *Plus* Change in Value of Prior Years' Awards Vested During Year | Comp. Actually Paid to CEO |
|---|---|---|---|---|---|---|---|
| 2024 | $ 481,168 | $ 67,280 | $ 49,007 | $ (1,622) | $ 16,193 | $ (7,807) | $ 469,659 |

| Year | Summary Comp. Table Total for Former CEO | *Minus* Stock and Option Awards from Summ. Comp. Table | *Plus* Year-End Equity Value of Unvested Awards Granted During Year | *Plus* Change in Value of Unvested Awards Granted in Prior Years | *Plus* Change in Value of Prior Years' Awards Vested During Year | Comp. Actually Paid to Former CEO |
|---|---|---|---|---|---|---|
| 2024 | $ 673,144 | $ – | $ – | $ (64,967) | $ 14,467 | $ 622,644 |
| 2023 | $ 563,494 | $ 67,863 | $ 59,661 | $ 1,103 | $ 3,990 | $ 560,385 |
| 2022 | $ 632,827 | $ 98,882 | $ 20,922 | $ (37,387) | $ (91,861) | $ 425,619 |

| Year | Avg. Summary Comp. Table Total for Other NEOs | *Minus* Avg. Stock and Option Awards from Summ. Comp. Table | *Plus* Avg. Year-End Equity Value of Unvested Awards Granted During Year | *Plus* Avg. Change in Value of Unvested Awards Granted in Prior Years | *Plus* Avg. Change in Value of Prior Year's Awards Vested During Year | Average Comp. Actually Paid to Other NEOs |
|---|---|---|---|---|---|---|
| 2024 | $ 554,083 | $ – | $ – | $ (33,544) | $ 685 | $ 521,224 |
| 2023 | $ 434,774 | $ 33,932 | $ 29,830 | $ 552 | $ 1,995 | $ 433,219 |
| 2022 | $ 472,180 | $ 49,441 | $ 10,461 | $ (18,693) | $ (37,345) | $ 377,162 |

For the equity values included in the above tables, the valuation assumptions used to calculate fair values of stock options were materially different from those disclosed at the time of the grant of the stock options. The assumptions used in determining fair value of the stock options that vested during 2022, 2023 and 2024, or that were outstanding as of December 31, 2022, December 31, 2023 or December 31, 2024, as applicable, are as follows:

| | Options Vested During Year or Outstanding on December 31 of: | | |
|---|---|---|---|
| | 2024 | 2023 | 2022 |
| Expected Volatility | 74.42% - 112.22% | 105.80% - 121.52% | 123.60% - 135.86% |
| Risk-Free Interest Rate | 3.45% - 5.41% | 3.54% - 4.80% | 2.15% - 4.05% |
| Expected Dividend Yield | 0% | 0% | 0% |
| Expected Term (in years) | 0.5 - 5.46 | 3.63 - 5.82 | 3.5 - 5.12 |

(4) Total Shareholder Return illustrates the value, as of the last day of the indicated fiscal year of an investment of $100 in Xenetic common stock on December 31, 2021.

***Description of Relationship Between NEO Compensation Actually Paid and Company Total Shareholder Return ("TSR") and Net Loss***

The Compensation Actually Paid to our CEO and the average of Compensation Actually Paid to our Non-CEO NEOs increased in 2024, which corresponded to the increase in the Company's TSR and decrease in Net Loss in 2024. The Compensation Actually Paid for both our former CEO and Non-CEO NEOs in 2024 increased primarily due to severance commitments incurred in 2024. The CEO and Non-CEO NEOs Non-Equity Incentive Plan Compensation is determined based on our strategic, financial and operating performance objectives that have been established by the Compensation Committee. While not directly tied to stock price performance and/or net loss, these performance objectives have been established as core drivers of TSR.

**Employment Agreements with our Named Executive Officers**

***Employment Agreement with Mr. Parslow***

We entered into an employment agreement with Mr. Parslow effective as of April 3, 2017 (the "Parslow Employment Agreement"). The Parslow Employment Agreement does not provide for a specified term of employment and Mr. Parslow's employment will be on an at-will basis. Mr. Parslow received an initial annual base salary of $265,000 and is eligible to earn an annual cash incentive bonus, which is set at a target aggregate bonus amount of 35% of Mr. Parslow's base salary, upon achievement of certain individual and/or Company performance goals set by the Compensation Committee. Mr. Parslow is also eligible to participate in the Company's employee benefit, welfare and other plans, as may be maintained by the Company from time to time, on a basis no less favorable than those provided to other similarly-situated executives of the Company. Mr. Parslow is also subject to certain customary confidentiality, non-solicitation and non-competition provisions.

If Mr. Parslow's employment is terminated by the Company without "cause" (as defined in the Parslow Employment Agreement) or Mr. Parslow resigns for "good reason" (as defined in the Parslow Employment Agreement), he will be entitled to receive (i) one year of his then current base salary, paid over time in accordance with the Company's payroll practices then in effect and (ii) payment of premiums for continued health benefits under COBRA for up to one year.

On May 16, 2024, the Board appointed Mr. Parslow to the position of Interim Chief Executive Officer, in addition to his role as the Company's Chief Financial Officer. In connection with the foregoing, on June 18, 2024, the Company and Mr. Parslow entered into an amendment (the "Parslow Employment Amendment") to the Parslow Employment Agreement, to provide for, effective as of May 16, 2024: (i) certain changes to Mr. Parslow's title and responsibilities; (ii) an increase in Mr. Parslow's base salary to $400,000; (iii) a $100,000 cash retention bonus if Mr. Parslow remains employed with the Company for a ten month period; and (iv) a stock option grant to Mr. Parslow to purchase 20,000 shares of common stock of the Company with an exercise price equal to the fair market value of the Company's common stock on the effective date of the Parslow Employment Amendment. Such option grant shall be issued pursuant to the terms and conditions of the Company's Amended and Restated Equity Incentive Plan, and shall vest one-fourth on the grant date and one-fourth upon the first, second and third anniversaries of the grant date, provided Mr. Parslow remains employed with the Company on the applicable vesting date. All other terms of the Parslow Employment Agreement remain in full force and effect.

***Employment Agreement with Mr. Eisenberg***

The Company entered into an employment agreement with Mr. Eisenberg effective as of December 1, 2016, which agreement was amended and restated on October 26, 2017 (as amended, the "Amended Agreement") pursuant to which Mr. Eisenberg was previously employed as the Chief Executive Officer of the Company. The Amended Agreement was for an initial term of one year, and automatically renewed for successive one year periods unless either party gave notice to the other no later than 90 days prior to the expiration of the then-applicable term; provided, however, that we could terminate the Amended Agreement at any time. Mr. Eisenberg's annual salary under the Amended Agreement was $300,000, and was subject to annual review and upward adjustment only by the Compensation Committee of the Board. Mr. Eisenberg was eligible to receive a bonus equal to 50% of his annual salary based on the attainment of certain individual and/or Company goals established by the Board or a committee thereto, and if Mr. Eisenberg's employment was terminated by us without "Cause" (as defined in the Amended Agreement) or if he resigned for "Good Reason" (as defined in the Amended Agreement), he would be entitled to receive (i) within thirty days following the date of termination, an amount equal to one times his then current base salary, (ii) a pro-rated annual bonus and (iii) payment of premiums for continued health benefits under COBRA for up to twelve months. Mr. Eisenberg was also eligible to participate in our employee benefit, welfare and other plans, as may be maintained by us from time to time, on a basis no less favorable than those provided to other similarly situated executives of the Company. Mr. Eisenberg was also subject to certain customary confidentiality, non-solicitation and non-competition provisions.

The Company entered into a confidential separation agreement and release with Mr. Eisenberg on June 19, 2024 in connection with his separation of employment from the Company that was effective as of May 16, 2024 pursuant to which Mr. Eisenberg became eligible to receive the payments and benefits described above in connection with a termination without "Cause" and also received full vesting of all outstanding unvested options to purchase shares of common stock of the Company.

***Employment Agreement with Dr. Lockshin***

The Company previously entered into an employment agreement with Dr. Lockshin effective as of January 1, 2017 (the "Lockshin Employment Agreement") pursuant to which Dr. Lockshin was previously employed as the Chief Scientific Officer of the Company. The Lockshin Employment Agreement did not provide for a specified term of employment and Dr. Lockshin's employment was on an at-will basis. Dr. Lockshin received an initial annual base salary of $250,000 and was eligible to earn an annual performance-based cash incentive bonus, which was set at a target aggregate bonus amount of 35% of Dr. Lockshin's base salary, upon achievement of certain individual and/or Company performance goals established by the Board or a committee thereto. Dr. Lockshin was also eligible to participate in the Company's employee benefit, welfare and other plans, as may be maintained by the Company from time to time, on a basis no less favorable than those provided to other similarly-situated executives of the Company. Dr. Lockshin was also subject to certain customary confidentiality, non-solicitation and non-competition provisions.

If Dr. Lockshin's employment was terminated by the Company without "Cause" (as defined in the Lockshin Employment Agreement) or Dr. Lockshin terminated his employment for "Good Reason" (as defined in the Lockshin Employment Agreement) and Dr. Lockshin executed and did not revoke a general release of claims against the Company, then he would be entitled to receive (i) one year of his then current base salary, paid over time in accordance with the Company's payroll practices then in effect and (ii) payment of premiums for continued health benefits under COBRA for up to twelve months.

The Company entered into a confidential separation agreement and release with Dr. Lockshin on June 19, 2024 in connection with his separation of employment from the Company that was effective as of May 16, 2024 pursuant to which Dr. Lockshin became eligible to receive the payments and benefits described above in connection with a termination without "Cause".

**Potential Payments Upon Termination or Change of Control**

Our named executive officers may be entitled to payments upon termination or change of control. The details of such payments are included in the description of their employment agreements above.

**Equity Award Grant Practices**

We do not currently have any policies or procedures that require us to grant equity awards, including stock options, to executive officers on specified dates. Equity awards to executive officers are granted at such times as determined in the discretion of the Compensation Committee. Neither the Compensation Committee nor the Board of Directors takes material nonpublic information into account when determining the timing and terms of equity awards, including stock options, and we do not time the disclosure of material nonpublic information for the purpose of affecting the value of executive compensation. During 2024, we did not grant any equity awards to any of our NEOs within four business days prior to or one business day after making any filing on Forms 10-K, 10-Q or 8-K (other than a current report on Form 8-K disclosing a new material option award grant under Item 5.02(e) of that form) that disclosed any material non-public information.

**Director Compensation**

Each of our non-employee, independent directors is currently entitled to receive an annual retainer of $43,000, payable in equal quarterly installments, an option to acquire 2,500 shares of the Company's common stock upon initial appointment to the Board, and an additional option to acquire 2,500 shares each year thereafter on the date of the Company's annual meeting of stockholders. All members of our Board are reimbursed for their usual and customary expenses incurred in connection with their service on the Board, including out-of-pocket expenses, transportation, and airfare on the Company's business.

**Director Compensation Table**

As an employee director during fiscal year 2024, Mr. Eisenberg did not receive any compensation for his Board service during the last completed year. The following table sets forth information for the year ended December 31, 2024 regarding the compensation awarded to, earned by or paid to our non-employee directors:

| Name | Fees Earned or Paid in Cash ($) | Stock Awards ($) | Option Awards[1][2] ($) | All Other Compensation ($) | Total ($) |
|---|---|---|---|---|---|
| Dr. Grigory Borisenko | 43,000 | – | 8,721 | – | 51,721 |
| Firdaus Jal Dastoor | 43,000 | – | 8,721 | – | 51,721 |
| Dr. Dmitry Genkin[3] | – | – | – | – | – |
| Dr. Roger Kornberg | 43,000 | – | 8,721 | – | 51,721 |
| Mr. Moshe Mizrahy[3] | – | – | – | – | – |
| Dr. Alexey Vinogradov | 43,000 | – | 8,721 | – | 51,721 |

(1) The amounts represent the aggregate grant date fair value of stock options granted during 2024, computed in accordance with FASB ASC Topic 718. For a discussion of the assumptions and methodology used to calculate the value of our stock options, see Note 10 to our audited financial statements included in Item 8 of the Original Filing.

(2) The table below shows the aggregate number of option awards outstanding for each of our non-employee directors as of December 31, 2024:

| Name | Option Awards (#) |
|---|---|
| Dr. Grigory Borisenko | 7,500 |
| Firdaus Jal Dastoor | 15,796 |
| Dr. Dmitry Genkin | – |
| Dr. Roger Kornberg | 15,626 |
| Mr. Moshe Mizrahy | 2,500 |
| Dr. Alexey Vinogradov | 15,000 |

(3) The Board determined that Dr. Genkin and Mr. Mizrahy are not independent directors, and as such, neither were eligible for compensation during fiscal year 2024.

See “Certain Related Person Transactions” in the Original Filing for compensation arrangements involving specific members of the Board.

## PART IV

## ITEM 15 – EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following financial statements, schedules and exhibits are filed as part of this report:

*Consolidated Financial Statements:* The consolidated financial statements and report of independent registered public accounting firm required by this item are included in Part II, Item 8 of the Original Filing;

*Financial Statement Schedules:* All schedules were omitted because they are not applicable or not required, or because the required information is shown in the consolidated financial statements or in the notes thereto.

(b) **Exhibits:** The exhibits required to be filed by Item 15 are set forth in, and filed with or incorporated by reference in, the "Exhibit Index" of the Original Filing. The attached list of exhibits in the "Exhibit Index" sets forth the additional exhibits required to be filed with this Amendment and is incorporated herein by reference in response to this item.

### EXHIBIT INDEX

| Exhibit No. | Exhibit Index | Form | Filing Date | Exhibit Number | Filed Herewith |
|---|---|---|---|---|---|
| 31.5 | Certification of Principal Executive Officer, as required by Rule 13a-14(a) and Rule 15d-14(a) | | | | X |
| 31.6 | Certification of Principal Financial Officer, as required by Rule 13a-14(a) and Rule 15d-14(a) | | | | X |
| 101.INS | Inline XBRL Instance Document | | | | X |
| 101.SCH | Inline XBRL Taxonomy Extension Schema Document | | | | X |
| 101.DEF | Inline XBRL Taxonomy Extension Definition Linkbase Document. | | | | X |
| 101.LAB | Inline XBRL Taxonomy Extension Label Linkbase Document. | | | | X |
| 104 | Cover Page Interactive Data File (embedded within the inline document and included in Exhibit 101) | | | | X |

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**XENETIC BIOSCIENCES, INC.**

Date: May 13, 2025

By: /s/ JAMES PARSLOW
James Parslow
*Interim Chief Executive Officer*