

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2024

or

☐ TRANSITION REPORT 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
(State or other jurisdiction of
incorporation or organization)

45-2952962
(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 Stock Market

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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act): Yes ☐ No ☒

As of November 8, 2024, the number of outstanding shares of the registrant's common stock was 1,542,139.

XENETIC BIOSCIENCES, INC.
FORM 10-Q
QUARTERLY PERIOD ENDED SEPTEMBER 30, 2024

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PART I – FINANCIAL INFORMATION

ITEM 1 – FINANCIAL STATEMENTS

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

	September 30, 2024 (Unaudited)	December 31, 2023
ASSETS		
Current assets:		
Cash	\$ 6,839,560	\$ 8,983,046
Prepaid expenses and other	188,088	603,828
Total current assets	7,027,648	9,586,874
Other assets	1,018,352	1,018,352
Total assets	\$ 8,046,000	\$ 10,605,226
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 243,343	\$ 240,832
Accrued expenses and other current liabilities	766,064	568,753
Total current liabilities	1,009,407	809,585
Total liabilities	1,009,407	809,585
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, 10,000,000 shares authorized		
Series B, \$0.001 par value: 1,804,394 shares issued and outstanding as of September 30, 2024 and December 31, 2023	1,804	1,804
Common stock, \$0.001 par value; 10,000,000 shares authorized as of September 30, 2024 and December 31, 2023; 1,544,840 and 1,543,385 shares issued as of September 30, 2024 and December 31, 2023, respectively; 1,542,139 and 1,540,684 shares outstanding as of September 30, 2024 and December 31, 2023, respectively	1,545	1,544
Additional paid in capital	208,200,640	208,053,935
Accumulated deficit	(196,139,950)	(193,234,196)
Accumulated other comprehensive income	253,734	253,734
Treasury stock	(5,281,180)	(5,281,180)
Total stockholders' equity	7,036,593	9,795,641
Total liabilities and stockholders' equity	\$ 8,046,000	\$ 10,605,226

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

XENETIC BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2024	2023	2024	2023
Revenue:				
Royalty revenue	\$ 614,243	\$ 611,174	\$ 1,851,464	\$ 1,868,023
Total revenue	<u>614,243</u>	<u>611,174</u>	<u>1,851,464</u>	<u>1,868,023</u>
Operating costs and expenses:				
Research and development	(367,985)	(1,020,618)	(2,246,077)	(2,519,137)
General and administrative	(745,731)	(737,241)	(2,710,670)	(2,608,934)
Total operating costs and expenses	<u>(1,113,716)</u>	<u>(1,757,859)</u>	<u>(4,956,747)</u>	<u>(5,128,071)</u>
Loss from operations	<u>(499,473)</u>	<u>(1,146,685)</u>	<u>(3,105,283)</u>	<u>(3,260,048)</u>
Other income (expense):				
Other income (expense)	1,504	(666)	1,535	24,976
Interest income, net	61,298	91,796	197,994	272,000
Total other income, net	<u>62,802</u>	<u>91,130</u>	<u>199,529</u>	<u>296,976</u>
Net loss	<u>\$ (436,671)</u>	<u>\$ (1,055,555)</u>	<u>\$ (2,905,754)</u>	<u>\$ (2,963,072)</u>
Basic and diluted net loss per share	<u>\$ (0.28)</u>	<u>\$ (0.69)</u>	<u>\$ (1.89)</u>	<u>\$ (1.94)</u>
Weighted-average shares of common stock outstanding, basic and diluted	<u>1,541,722</u>	<u>1,532,600</u>	<u>1,541,070</u>	<u>1,524,717</u>

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

XENETIC BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(Unaudited)

THREE MONTHS ENDED SEPTEMBER 30, 2024

	Preferred Stock		Common Stock		Additional		Accumulated		Total
	Number of Shares	Par Value (\$0.001)	Number of Shares	Par Value (\$0.001)	Paid in Capital	Accumulated Deficit	Other Comprehensive Income	Treasury Stock	Stockholders' Equity
Balance as of July 1, 2024	1,804,394	\$ 1,804	1,543,802	\$ 1,544	\$ 208,173,105	\$ (195,703,279)	\$ 253,734	\$ (5,281,180)	\$ 7,445,728
Exercise of purchase warrants	—	—	1,038	1	(1)	—	—	—	—
Share-based expense	—	—	—	—	27,536	—	—	—	27,536
Net loss	—	—	—	—	—	(436,671)	—	—	(436,671)
Balance as of September 30, 2024	1,804,394	\$ 1,804	1,544,840	\$ 1,545	\$ 208,200,640	\$ (196,139,950)	\$ 253,734	\$ (5,281,180)	\$ 7,036,593

NINE MONTHS ENDED SEPTEMBER 30, 2024

	Preferred Stock		Common Stock		Additional		Accumulated		Total
	Number of Shares	Par Value (\$0.001)	Number of Shares	Par Value (\$0.001)	Paid in Capital	Accumulated Deficit	Other Comprehensive Income	Treasury Stock	Stockholders' Equity
Balance as of January 1, 2024	1,804,394	\$ 1,804	1,543,385	\$ 1,544	\$ 208,053,935	\$ (193,234,196)	\$ 253,734	\$ (5,281,180)	\$ 9,795,641
Exercise of purchase warrants	—	—	1,038	1	(1)	—	—	—	—
Issuance of common stock in connection with restricted stock	—	—	417	—	—	—	—	—	—
Share-based expense	—	—	—	—	146,706	—	—	—	146,706
Net loss	—	—	—	—	—	(2,905,754)	—	—	(2,905,754)
Balance as of September 30, 2024	1,804,394	\$ 1,804	1,544,840	\$ 1,545	\$ 208,200,640	\$ (196,139,950)	\$ 253,734	\$ (5,281,180)	\$ 7,036,593

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

XENETIC BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(Unaudited)

THREE MONTHS ENDED SEPTEMBER 30, 2023

	Preferred Stock		Common Stock		Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Treasury Stock	Total Stockholders' Equity
	Number of Shares	Par Value (\$0.001)	Number of Shares	Par Value (\$0.001)					
Balance as of July 1, 2023	2,774,394	\$ 2,774	1,535,301	\$ 1,536	\$ 207,908,129	\$ (191,007,135)	\$ 253,734	\$ (5,281,180)	\$ 11,877,858
Share-based expense	—	—	—	—	70,266	—	—	—	70,266
Net loss	—	—	—	—	—	(1,055,555)	—	—	(1,055,555)
Balance as of September 30, 2023	<u>2,774,394</u>	<u>\$ 2,774</u>	<u>1,535,301</u>	<u>\$ 1,536</u>	<u>\$ 207,978,395</u>	<u>\$ (192,062,690)</u>	<u>\$ 253,734</u>	<u>\$ (5,281,180)</u>	<u>\$ 10,892,569</u>

NINE MONTHS ENDED SEPTEMBER 30, 2023

	Preferred Stock		Common Stock		Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Treasury Stock	Total Stockholders' Equity
	Number of Shares	Par Value (\$0.001)	Number of Shares	Par Value (\$0.001)					
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)	—	—	—	—
Share-based expense	—	—	—	—	208,507	—	—	—	208,507
Net loss	—	—	—	—	—	(2,963,072)	—	—	(2,963,072)
Balance as of September 30, 2023	<u>2,774,394</u>	<u>\$ 2,774</u>	<u>1,535,301</u>	<u>\$ 1,536</u>	<u>\$ 207,978,395</u>	<u>\$ (192,062,690)</u>	<u>\$ 253,734</u>	<u>\$ (5,281,180)</u>	<u>\$ 10,892,569</u>

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

XENETIC BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Nine Months Ended September 30,	
	2024	2023
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (2,905,754)	\$ (2,963,072)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based expense	146,706	208,507
Changes in operating assets and liabilities:		
Prepaid expenses and other	415,740	(924,468)
Other assets	—	362,500
Accounts payable, accrued expenses and other liabilities	199,822	(4,659)
Net cash used in operating activities	<u>(2,143,486)</u>	<u>(3,321,192)</u>
Net change in cash	(2,143,486)	(3,321,192)
Cash at beginning of period	<u>8,983,046</u>	<u>13,097,265</u>
Cash at end of period	<u><u>\$ 6,839,560</u></u>	<u><u>\$ 9,776,073</u></u>
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash paid for interest	<u><u>\$ —</u></u>	<u><u>\$ —</u></u>

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

XENETIC BIOSCIENCES, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

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 hard to treat cancers. The Company’s proprietary Deoxyribonuclease (“DNase”) platform is designed to improve outcomes of existing treatments, including immunotherapies, by targeting neutrophil extracellular traps (“NETs”), which have been implicated in cancer progression and resistance to cancer treatments. 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. Additionally, Xenetic has partnered with biotechnology and pharmaceutical companies to develop its proprietary drug delivery platform, PolyXen[®], and receives royalty payments under an exclusive license arrangement in the field of blood coagulation disorders.

As used in this Quarterly Report on Form 10-Q (“Quarterly Report”), unless otherwise indicated, all references herein to “Xenetic,” the “Company,” “we” or “us” refer to Xenetic Biosciences, Inc. and its wholly-owned subsidiaries.

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 may be used throughout this Quarterly 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 condensed consolidated financial statements. However, the Company anticipates it will need additional capital in the long-term to pursue its business initiatives. While the Company believes 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 Interim Financial Statements

The accompanying condensed consolidated interim financial statements were prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission (“SEC”) and, in the opinion of management, include all normal and recurring adjustments necessary to present fairly the results of the interim periods shown. Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. generally accepted accounting principles have been condensed or omitted pursuant to such SEC rules and regulations. Management believes that the disclosures made are adequate to make the information presented not misleading. The results for the interim periods are not necessarily indicative of results for the full year. The condensed consolidated financial statements contained herein should be read in conjunction with the consolidated financial statements and notes thereto included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2023 filed with the SEC on March 21, 2024, and amended on April 26, 2024.

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 Quarterly Report, on a retroactive basis, to reflect this 1-for-10 Reverse Stock Split.

Principles of Consolidation

The condensed 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.

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.

For the three and nine months ended September 30, 2024 and 2023, basic and diluted net loss per share are the same in each respective three and nine month period 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.

Recent Accounting Pronouncements Not Yet Adopted

Segment Reporting - Improving Reportable Segment Disclosures (Topic 280). 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 also requires all annual disclosures currently required by Topic 280 to be included in interim periods. This ASU is effective for the Company's fiscal year ending December 31, 2024, and interim periods beginning in fiscal 2025, with early adoption permitted, and requires retrospective application to all prior periods presented in the financial statements. The Company has one reportable segment and is currently evaluating the effects that the adoption of this ASU will have on its consolidated financial statements.

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 \$0.6 million and \$1.9 million were recorded as revenue by the Company during both the three and nine months ended September 30, 2024 and 2023, respectively. These payments 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 September 30, 2024, of which approximately \$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 September 30, 2024 and December 31, 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 September 30, 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 September 30, 2024 and December 31, 2023.

Scripps Research Institute (“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 oncology platform 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. The Company paid Scripps Research approximately \$0.9 million under the Agreement through September 30, 2024, of which approximately \$20,000 and \$0.4 million has been recognized as an advance payment and is included in prepaid expenses and other current assets as of September 30, 2024 and December 31, 2023, respectively.

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, 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, will oversee the research conducted under the UVA Agreement. The Company paid UVA approximately \$0.2 million under the UVA Agreement through September 30, 2024, which was expensed during the nine months ended September 30, 2024. There were no amounts incurred as of December 31, 2023.

Other Agreements

The Company has also entered into various research, development, license and supply agreements with Serum Institute of India (“Serum Institute”), PJSC Pharmsynthez (“Pharmsynthez”) and SynBio LLC (“SynBio”), a wholly owned subsidiary of Pharmsynthez. The Company and its collaborative partners continue to engage in research and development activities with no resultant commercial products through September 30, 2024. No amounts were recognized as revenue related to the Serum Institute, Pharmsynthez or SynBio agreements during the three and nine months ended September 30, 2024 and 2023, respectively.

5. Accrued Expenses and Other Current Liabilities

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 the Amendment No. 1 to Annual Report on Form 10-K/A filed by the Company with the Securities and Exchange Commission on April 26, 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 nine months ended September 30, 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 September 30, 2024, approximately \$0.3 million was accrued within accrued expenses and other current liabilities related to these obligations.

6. Fair Value Measurements

Accounting Standards Codification 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 unadjusted 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 September 30, 2024 and December 31, 2023, the carrying amounts of the Company’s financial instruments approximates fair value due to their short maturities. There were no financial instruments classified as Level 3 in the fair value hierarchy during the three and nine months ended September 30, 2024 and 2023.

7. 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.

Warrants

The Company has warrants to purchase approximately 462,963 shares of the Company's common stock (the "Series A Warrants") outstanding as of both September 30, 2024 and December 31, 2023, which expire on February 23, 2025. The Series A Warrants are immediately exercisable at a price of \$33.00 per share of common stock. No Series A Warrants were exercised or forfeited during the three and nine months ended September 30, 2024 and 2023.

The Company also has warrants to purchase approximately 800 shares of the Company's common stock outstanding as of both September 30, 2024 and December 31, 2023, which expire on July 3, 2026. These warrants have an exercise price of \$29.09 per share of common stock. None of these warrants were exercised or forfeited during the three and nine months ended September 30, 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 three and nine months ended September 30, 2024. All of the public warrants remaining outstanding as of July 19, 2024 expired, and no public warrants were outstanding at September 30, 2024. None of these warrants were exercised or forfeited during the three and nine months ended September 30, 2023.

8. Share-Based Expense

Total share-based expense related to stock options and RSUs was approximately \$28,000 and \$0.1 million for the three months ended September 30, 2024 and 2023, respectively, and approximately \$0.1 million and \$0.2 million for each of the nine months ended September 30, 2024 and 2023.

Share-based expense is classified in the condensed consolidated statements of operations as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development expenses	\$ —	\$ 13,961	\$ 11,433	\$ 41,427
General and administrative expenses	27,536	56,305	135,273	167,080
	<u>\$ 27,536</u>	<u>\$ 70,266</u>	<u>\$ 146,706</u>	<u>\$ 208,507</u>

Employee Stock Options and RSUs

During the nine months ended September 30, 2024, 20,000 stock options to purchase shares of common stock were granted by the Company. No stock options to purchase shares of common stock were granted during the three months ended September 30, 2024. No stock option awards to purchase shares of common stock were granted during the three and nine months ended September 30, 2023. No RSUs were granted during each of the three and nine months ended September 30, 2024 and 2023. The Company recognized a total of approximately \$28,000 and \$0.1 million of share-based expense related to employee stock options during the three months ended September 30, 2024 and 2023, respectively, and \$0.1 million and \$0.2 million during the nine months ended September 30, 2024 and 2023, respectively. The Company issued 417 shares of common stock during the nine months ended September 30, 2024 related to RSUs representing all the RSUs outstanding. As a result, no RSUs were outstanding at September 30, 2024. No employee stock options were exercised during the three and nine months ended September 30, 2024 and 2023. During each of the three and nine months ended September 30, 2024 stock options to purchase 20,847 shares of common stock were cancelled and, during the nine months ended September 30, 2024, stock options to purchase 11,667 shares of common stock were forfeited. No employee stock options expired during the three and nine months ended September 30, 2023.

Non-Employee Stock Options

There were no non-employee stock options granted or exercised during the three and nine months ended September 30, 2024 and 2023, respectively. No non-employee stock option grants expired during the three and nine months ended September 30, 2024. During the nine months ended September 30, 2023, non-employee stock option grants to purchase approximately 100 shares of common stock expired. The Company did not recognize any expense related to non-employee stock options during the three and nine months ended September 30, 2024 and 2023, respectively.

9. Income Taxes

During the three and nine months ended September 30, 2024 and 2023, there was no provision for income taxes as the Company incurred losses during both periods. 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. The Company records a valuation allowance against its deferred tax assets as the Company believes it is more likely than not the deferred tax assets will not be realized. The valuation allowance against deferred tax assets was approximately \$40.6 million and \$39.7 million as of September 30, 2024 and December 31, 2023, respectively.

As of September 30, 2024 and December 31, 2023, the Company did not record any unrecognized tax positions.

10. 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 has not materially changed from that disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2023 filed with the SEC on March 21, 2024, as amended on April 26, 2024.

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 September 30, 2024 and December 31, 2023. The Company did not recognize any interest income related to the Pharmsynthez Loan during the three and nine months ended September 30, 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 nine months ended September 30, 2023.

11. 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 except as described below.

Scripps Research

On November 1, 2024, the Company and Scripps entered into a Second Amendment to Research Funding and Option Agreement (the "Amendment"), pursuant to which the Company amended that certain Research Funding and Option Agreement, dated March 17, 2023, by and between the Company and Scripps (the "Original Agreement"), in order to extend the term of the Original 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 relating to advancing the pre-clinical development of the Company's DNase oncology platform technology. 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.

ITEM 2 – MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This 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 Quarterly 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 U.S. and other countries in response; our plans to develop our proposed drug candidates; 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 hard to treat oncology indications; expectations regarding our Deoxyribonuclease (“DNase”) platform, such as regarding the DNase platform 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 platform into the clinic as an adjunctive therapy for pancreatic carcinoma and locally advanced or metastatic solid tumors; and our expectations regarding our PolyXen[®] platform and any partnerships with respect thereto.

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,” 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.

The Management’s Discussion and Analysis of Financial Condition and Results of Operations (the “MD&A”) should be read together with our condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report. This Quarterly Report, including the MD&A, contains trend analysis and other forward-looking statements. Any statements in this Quarterly Report that are not statements of historical facts are forward-looking statements. These forward-looking statements made herein are based on our current expectations, involve a number of risks and uncertainties and should not be considered as guarantees of future performance.

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 or PolyXen technologies;
- our ability to implement our business strategy;
- our failure to maintain compliance with the continued listing requirements of the Nasdaq Stock Market (“Nasdaq”);
- 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 we 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 Quarterly 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 Quarterly Report are made only as of the date of this Quarterly 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.

BUSINESS OVERVIEW

We are a biopharmaceutical company focused on advancing innovative immune-oncology technologies addressing hard to treat cancers. Our DNase platform is designed to improve outcomes of existing treatments, including immunotherapies, by targeting NETs, which have been implicated in cancer progression and resistance to cancer treatments. 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. 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.

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 have committed 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 nor in any other countries or territories by any applicable agencies. 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 during the three and nine months ended September 30, 2024, was on the advancement of our DNase technology.

Impact of the Global Conflicts on Our Operations

The short and long-term implications of conflicts in the Ukraine and 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

Comparison of Quarter Ended September 30, 2024 and 2023

The comparison of our historical results of operations for the fiscal quarter ended September 30, 2024 to the fiscal quarter ended September 30, 2023 is as follows:

Description	Quarter Ended September 30, 2024	Quarter Ended September 30, 2023	Increase (Decrease)	Percentage Change
Revenues:				
Royalty revenue	\$ 614,243	\$ 611,174	\$ 3,069	0.5
Operating costs and expenses:				
Research and development	(367,985)	(1,020,618)	(652,633)	(63.9)
General and administrative	(745,731)	(737,241)	8,490	1.2
Total operating costs and expenses	(1,113,716)	(1,757,859)	(644,143)	(36.6)
Loss from operations	(499,473)	(1,146,685)	(647,212)	(56.4)
Total other income, net:				
Other income (expense)	1,504	(666)	2,170	325.8
Interest income, net	61,298	91,796	(30,498)	(33.2)
Net loss	<u>\$ (436,671)</u>	<u>\$ (1,055,555)</u>	<u>\$ (618,884)</u>	<u>(58.6)</u>

Revenue

Revenue for the three months ended September 30, 2024 was relatively flat with that of the three months ended September 30, 2023.

Research and Development Expenses

Research & development (“R&D”) expenses for the three months ended September 30, 2024 decreased by approximately \$0.7 million, or 63.9%, to approximately \$0.4 million from approximately \$1.0 million in the comparable quarter in 2023. The table below sets forth the R&D costs incurred by the Company by category of expense for the quarters ended September 30, 2024 and 2023:

Category of Expense	Quarter Ended,	
	September 30, 2024	September 30, 2023
Outside services and contract research organizations	\$ 360,549	\$ 877,647
Personnel costs	–	88,557
Share-based expense	–	13,961
Other	7,436	40,453
Total research and development expense	<u>\$ 367,985</u>	<u>\$ 1,020,618</u>

The decrease in outside services and contract research organizations expense was primarily due to decreased spending in connection with our process development efforts related to our DNase platform. The decrease in personnel costs during the three months ended September 30, 2024 as compared to the three months ending September 30, 2023 is due to the departure of our former Chief Scientific Officer during the second quarter of 2024.

General and Administrative Expenses

General and administrative expenses for the three months ended September 30, 2024 was relatively flat with that of the three months ended September 30, 2023. Increases in legal fees during the three months ended September 30, 2024 compared to the same period in 2023 were offset by decreases in personnel costs during the third quarter of 2024 due to the departure of our former Chief Executive Officer in the second quarter of 2024.

Other Income (Expense)

Other income was approximately \$1,500 for the three months ended September 30, 2024 compared to approximately \$700 of other expense for the comparable quarter in 2023. This increase in other income was primarily related to favorable changes in foreign currency exchange rates during the three months ended September 30, 2024 as compared to the same period in 2023.

Interest Income

Interest income, net decreased to approximately \$61,000 during the three months ended September 30, 2024 from approximately \$92,000 for the same period in the prior year. This decrease was primarily due to lower average invested funds during the three months ended September 30, 2024 compared to the same period in 2023.

Comparison of Nine Months Ended September 30, 2024 and 2023

The comparison of our historical results of operations for the nine months ended September 30, 2024 to the nine months ended September 30, 2023 is as follows:

Description	Nine Months Ended September 30, 2024	Nine Months Ended September 30, 2023	Increase (Decrease)	Percentage Change
Revenues:				
Royalty revenue	\$ 1,851,464	\$ 1,868,023	\$ (16,559)	(0.9)
Operating costs and expenses:				
Research and development	(2,246,077)	(2,519,137)	(273,060)	(10.8)
General and administrative	(2,710,670)	(2,608,934)	101,736	3.9
Total operating costs and expenses	(4,956,747)	(5,128,071)	(171,324)	(3.3)
Loss from operations	(3,105,283)	(3,260,048)	(154,765)	(4.7)
Total other income, net:				
Other income	1,535	24,976	(23,441)	(93.9)
Interest income, net	197,994	272,000	(74,006)	(27.2)
Net loss	<u>\$ (2,905,754)</u>	<u>\$ (2,963,072)</u>	<u>\$ (57,318)</u>	(1.9)

Revenue

Revenue for the nine months ended September 30, 2024 was relatively flat with that of the nine months ended September 30, 2023.

Research and Development Expenses

R&D expenses for the nine months ended September 30, 2024 decreased by approximately \$0.3 million, or 10.8%, to approximately \$2.2 million from approximately \$2.5 million in the comparable period in 2023. The table below sets forth the R&D costs incurred by the Company by category of expense for the nine months ended September 30, 2024 and 2023:

Category of Expense	Nine Months Ended,	
	September 30, 2024	September 30, 2023
Outside services and contract research organizations	\$ 1,581,070	\$ 2,034,601
Personnel costs	561,612	340,307
Share-based expense	11,433	41,427
Other	91,962	102,802
Total research and development expense	<u>\$ 2,246,077</u>	<u>\$ 2,519,137</u>

The decrease in outside services and contract research organizations expense was primarily due to decreased spending in connection with our process development efforts, partially offset by increased pre-clinical development efforts related to our DNase platform. 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 Expenses

General and administrative expenses for the nine months ended September 30, 2024 increased by approximately \$0.1 million, or 3.9%, to approximately \$2.7 million from approximately \$2.6 million in the comparable period in 2023. The increase was primarily 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 Executive Officer. This increase was partially offset by general decreases in accounting fees during the nine months ended September 30, 2024 compared to the same period in 2023.

Other Income

Other income was approximately \$1,500 for the nine months ended September 30, 2024 compared to approximately \$25,000 of other income for the nine months ended September 30, 2023. This decrease in other income was primarily related to fees associated with the Pharmsynthez Loan recognized during the nine months ended September 30, 2023 for which there was no similar fees received in the same period in 2024.

Interest Income

Interest income decreased to approximately \$198,000 during the nine months ended September 30, 2024 as compared to approximately \$272,000 for the same period in the prior year. This decrease was primarily due to lower average invested funds during the nine months ended September 30, 2024 compared to the same period in 2023, as well as a decrease in interest income received on the Pharmsynthez Loan.

Liquidity and Capital Resources

We incurred a net loss of approximately \$2.9 million for the nine months ended September 30, 2024. We had an accumulated deficit of approximately \$196.1 million at September 30, 2024, as compared to an accumulated deficit of approximately \$193.2 million at December 31, 2023. Working capital was approximately \$6.0 million at September 30, 2024, and approximately \$8.8 million at December 31, 2023. During the nine months ended September 30, 2024, our working capital decreased by approximately \$2.8 million primarily due to our net loss for the nine months ended September 30, 2024.

Our principal source of liquidity consists of cash. At September 30, 2024, we had approximately \$6.8 million in cash and approximately \$1.0 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. 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, we anticipate we will need additional capital in the long-term to pursue our business initiatives. While the Company believes 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 our clinical development programs, our ability to identify and enter into licensing or other strategic arrangements, our continued listing on 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 nine months ended September 30, 2024 totaled approximately \$2.1 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 \$0.4 million and current liabilities increased approximately \$0.2 million during the period. Cash flows used in operating activities for the nine months ended September 30, 2023 totaled approximately \$3.3 million, which was primarily due to our net loss for the period as well as advance payments made in accordance with our statement of work with Catalent, partially offset by cash received from the repayment of the Pharmsynthez Loan.

Cash Flows from Investing Activities

There were no cash flows from investing activities for the nine months ended September 30, 2024 and 2023.

Cash Flow from Financing Activities

There were no cash flows from financing activities for the nine months ended September 30, 2024 and 2023.

Contractual Obligations and Commitments

As of September 30, 2024, there were no material changes in our contractual obligations and commitments from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on March 21, 2024, as amended on April 26, 2024.

Off Balance Sheet Arrangements

We do not have any off-balance sheet financing arrangements that have or are reasonably likely to have a current or future material effect on our financial condition, change in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures, or capital resources.

Recent Accounting Standards

See Note 3 in our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on March 21, 2024, as amended on April 26, 2024, for a discussion of recent accounting standards.

Critical Accounting Estimates

Our condensed consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles. The preparation of our condensed consolidated financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenue, costs and expenses. We base our estimates and assumptions on historical experience and other factors that we believe to be reasonable under the circumstances. We evaluate our estimates and assumptions on an ongoing basis. 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. There have been no material changes in our critical accounting estimates from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on March 21, 2024, as amended on April 26, 2024.

ITEM 3 – 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 4 – CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Interim Chief Executive Officer (principal executive officer) and Chief Financial Officer (principal financial officer), evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) or 15d-15(e) under the Exchange Act, as of the end of the period covered by this Quarterly Report.

Based on this evaluation, our management, including our Interim Chief Executive Officer and Chief Financial Officer, concluded that as of the end of the period covered by this Quarterly Report, 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 Interim Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the period covered by this Quarterly Report that would have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1 – LEGAL PROCEEDINGS

We are not currently subject to any material legal proceedings, nor, to our knowledge, is any material legal proceeding threatened against us. From time to time, we may be a party to certain legal proceedings, incidental to the normal course of our business. While the outcome of these legal proceedings cannot be predicted with certainty, we do not expect that these proceedings will have a material effect upon our financial condition or results of operations.

ITEM 1A – RISK FACTORS

There have been no material changes to the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2023 filed with the SEC on March 21, 2024, as amended on April 26, 2024.

ITEM 2 – UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3 – DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4 – MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5 – OTHER INFORMATION

During the quarter ended September 30, 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 6 – EXHIBITS

The following exhibits are incorporated herein by reference or filed as part of this report.

EXHIBIT NUMBER	DESCRIPTION
31.1*	Certification of James Parslow, Interim Principal Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of James Parslow, Principal Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification of James Parslow, Interim Principal Executive Officer and Principal Financial Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101*	The following financial statements from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, formatted in inline XBRL, include: (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statements of Changes in Stockholders' Equity, (iv) Condensed Consolidated Statements of Cash Flows and (v) the Notes to the Condensed Consolidated Financial Statements.
104*	Cover Page Interactive Data File (formatted in inline XBRL and included in Exhibit 101)
*	Filed herewith.
**	Exhibit 32.1 is being furnished and shall not be deemed to be "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 such exhibits be deemed to be incorporated by reference in any registration statement or other document filed under the Securities Act of 1933, as amended or the Securities Exchange Act of 1934, as amended, except as otherwise stated in such filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

XENETIC BIOSCIENCES, INC.

November 12, 2024

By: /S/ JAMES PARSLow

James Parslow

Interim Chief Executive Officer and Chief Financial Officer

(Principal Executive, Principal Financial Officer and Principal Accounting Officer)

I, James Parslow, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Xenetic Biosciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2024

By: /s/ JAMES PARSLOW
James Parslow
Interim Chief Executive Officer
(Principal Executive Officer)

I, James Parslow, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Xenetic Biosciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2024

By: /s/ JAMES PARSLow
 James Parslow
 Chief Financial Officer
 (Principal Financial and Principal Accounting Officer)

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the “Exchange Act”) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), James Parslow, Interim Chief Executive Officer and Chief Financial Officer of the Xenetic Biosciences, Inc. (the “Company”) hereby certifies that, to the best of his knowledge:

The Company’s Quarterly Report on Form 10-Q for the period ended September 30, 2024, to which this Certification is attached as Exhibit 32.1 (the “Periodic Report”), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 12, 2024

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 12th day of November 2024.

/s/James Parslow

James Parslow

Interim Chief Executive Officer and Chief Financial Officer

(Principal Executive Officer and Principal Financial Officer)

“This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Xenetic Biosciences, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.”