

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, 2023

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
Purchase Warrants	XBIOW	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 3, 2023, the number of outstanding shares of the registrant's common stock was 1,540,684.

**XENETIC BIOSCIENCES, INC.**  
**FORM 10-Q**  
**QUARTERLY PERIOD ENDED SEPTEMBER 30, 2023**

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**PART I – FINANCIAL INFORMATION**

**ITEM 1 – FINANCIAL STATEMENTS**

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

	<b>September 30, 2023</b>	<b>December 31, 2022</b>
	<b>(Unaudited)</b>	
<b>ASSETS</b>		
Current assets:		
Cash	\$ 9,776,073	\$ 13,097,265
Prepaid expenses and other	1,480,562	556,094
Total current assets	11,256,635	13,653,359
Other assets	704,431	1,066,931
Total assets	\$ 11,961,066	\$ 14,720,290
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 448,558	\$ 287,360
Accrued expenses and other current liabilities	619,939	785,796
Total current liabilities	1,068,497	1,073,156
Total liabilities	1,068,497	1,073,156
Commitments and contingencies (Note 9)		
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, 2023 and December 31, 2022	1,804	1,804
Series A, \$0.001 par value: 970,000 shares issued and outstanding as of September 30, 2023 and December 31, 2022	970	970
Common stock, \$0.001 par value; 10,000,000 shares authorized as of September 30, 2023 and December 31, 2022; 1,535,301 and 1,519,360 shares issued as of September 30, 2023 and December 31, 2022, respectively; 1,532,600 and 1,516,659 shares outstanding as of September 30, 2023 and December 31, 2022, respectively	1,536	1,520
Additional paid in capital	207,978,395	207,769,904
Accumulated deficit	(192,062,690)	(189,099,618)
Accumulated other comprehensive income	253,734	253,734
Treasury stock	(5,281,180)	(5,281,180)
Total stockholders' equity	10,892,569	13,647,134
Total liabilities and stockholders' equity	\$ 11,961,066	\$ 14,720,290

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

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

	<b>THREE MONTHS ENDED SEPTEMBER 30,</b>		<b>NINE MONTHS ENDED SEPTEMBER 30,</b>	
	<b>2023</b>	<b>2022</b>	<b>2023</b>	<b>2022</b>
Revenue:				
Royalty revenue	\$ 611,174	\$ 414,250	\$ 1,868,023	\$ 1,219,953
Total revenue	<u>611,174</u>	<u>414,250</u>	<u>1,868,023</u>	<u>1,219,953</u>
Operating costs and expenses:				
Research and development	(1,020,618)	(398,803)	(2,519,137)	(3,577,701)
General and administrative	(737,241)	(863,233)	(2,608,934)	(2,796,832)
Total operating costs and expenses	<u>(1,757,859)</u>	<u>(1,262,036)</u>	<u>(5,128,071)</u>	<u>(6,374,533)</u>
Loss from operations	<u>(1,146,685)</u>	<u>(847,786)</u>	<u>(3,260,048)</u>	<u>(5,154,580)</u>
Other income (expense):				
Other income (expense)	(666)	(1,706)	24,976	(2,583)
Interest income, net	91,796	45,475	272,000	87,345
Total other income	<u>91,130</u>	<u>43,769</u>	<u>296,976</u>	<u>84,762</u>
Net loss	<u>\$ (1,055,555)</u>	<u>\$ (804,017)</u>	<u>\$ (2,963,072)</u>	<u>\$ (5,069,818)</u>
Basic and diluted net loss per share	<u>\$ (0.69)</u>	<u>\$ (0.56)</u>	<u>\$ (1.94)</u>	<u>\$ (3.64)</u>
Weighted-average shares of common stock outstanding, basic and diluted	<u>1,532,600</u>	<u>1,431,659</u>	<u>1,524,717</u>	<u>1,394,429</u>

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

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

**THREE MONTHS ENDED SEPTEMBER 30, 2023**

	<b>Preferred Stock</b>		<b>Common Stock</b>		<b>Additional</b>		<b>Accumulated</b>	<b>Other</b>		<b>Total</b>
	<b>Number of</b>	<b>Par Value</b>	<b>Number of</b>	<b>Par Value</b>	<b>Paid in</b>	<b>Accumulated</b>	<b>Comprehensive</b>	<b>Treasury</b>		<b>Stockholders'</b>
	<b>Shares</b>	<b>(\$0.001)</b>	<b>Shares</b>	<b>(\$0.001)</b>	<b>Capital</b>	<b>Deficit</b>	<b>Income</b>	<b>Stock</b>		<b>Equity</b>
<b>Balance as of July 1, 2023</b>	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)
<b>Balance as of September 30, 2023</b>	<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**

	<b>Preferred Stock</b>		<b>Common Stock</b>		<b>Additional</b>		<b>Accumulated</b>	<b>Other</b>		<b>Total</b>
	<b>Number of</b>	<b>Par Value</b>	<b>Number of</b>	<b>Par Value</b>	<b>Paid in</b>	<b>Accumulated</b>	<b>Comprehensive</b>	<b>Treasury</b>		<b>Stockholders'</b>
	<b>Shares</b>	<b>(\$0.001)</b>	<b>Shares</b>	<b>(\$0.001)</b>	<b>Capital</b>	<b>Deficit</b>	<b>Income</b>	<b>Stock</b>		<b>Equity</b>
<b>Balance as of January 1, 2023</b>	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)
<b>Balance as of September 30, 2023</b>	<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 STOCKHOLDERS' EQUITY**  
(Unaudited)

**THREE MONTHS ENDED SEPTEMBER 30, 2022**

	<b>Preferred Stock</b>		<b>Common Stock</b>		<b>Additional</b>		<b>Accumulated</b>	<b>Other</b>		<b>Total</b>
	<b>Number of</b>	<b>Par Value</b>	<b>Number of</b>	<b>Par Value</b>	<b>Paid in</b>	<b>Accumulated</b>	<b>Comprehensive</b>	<b>Treasury</b>		<b>Stockholders'</b>
	<b>Shares</b>	<b>(\$0.001)</b>	<b>Shares</b>	<b>(\$0.001)</b>	<b>Capital</b>	<b>Deficit</b>	<b>Income</b>	<b>Stock</b>		<b>Equity</b>
<b>Balance as of July 1, 2022</b>	2,774,394	\$ 2,774	1,434,360	\$ 1,435	\$ 207,025,224	\$ (186,813,066)	\$ 253,734	\$ (5,281,180)		\$ 15,188,921
Share-based expense	—	—	—	—	137,364	—	—	—		137,364
Net loss	—	—	—	—	—	(804,017)	—	—		(804,017)
<b>Balance as of September 30, 2022</b>	<u>2,774,394</u>	<u>\$ 2,774</u>	<u>1,434,360</u>	<u>\$ 1,435</u>	<u>\$ 207,162,588</u>	<u>\$ (187,617,083)</u>	<u>\$ 253,734</u>	<u>\$ (5,281,180)</u>		<u>\$ 14,522,268</u>

**NINE MONTHS ENDED SEPTEMBER 30, 2022**

	<b>Preferred Stock</b>		<b>Common Stock</b>		<b>Additional</b>		<b>Accumulated</b>	<b>Other</b>		<b>Total</b>
	<b>Number of</b>	<b>Par Value</b>	<b>Number of</b>	<b>Par Value</b>	<b>Paid in</b>	<b>Accumulated</b>	<b>Comprehensive</b>	<b>Treasury</b>		<b>Stockholders'</b>
	<b>Shares</b>	<b>(\$0.001)</b>	<b>Shares</b>	<b>(\$0.001)</b>	<b>Capital</b>	<b>Deficit</b>	<b>Income</b>	<b>Stock</b>		<b>Equity</b>
<b>Balance as of January 1, 2022</b>	2,774,394	\$ 2,774	1,346,661	\$ 1,347	\$ 205,964,847	\$ (182,547,265)	\$ 253,734	\$ (5,281,180)		\$ 18,394,257
Issuance of common stock in connection with purchase of in-process research and development	—	—	87,500	88	804,912	—	—	—		805,000
Share-based expense	—	—	—	—	392,829	—	—	—		392,829
Exercise of purchase warrants	—	—	199	—	—	—	—	—		—
Net loss	—	—	—	—	—	(5,069,818)	—	—		(5,069,818)
<b>Balance as of September 30, 2022</b>	<u>2,774,394</u>	<u>\$ 2,774</u>	<u>1,434,360</u>	<u>\$ 1,435</u>	<u>\$ 207,162,588</u>	<u>\$ (187,617,083)</u>	<u>\$ 253,734</u>	<u>\$ (5,281,180)</u>		<u>\$ 14,522,268</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)

	<b>Nine Months Ended September 30,</b>	
	<b>2023</b>	<b>2022</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (2,963,072)	\$ (5,069,818)
Adjustments to reconcile net loss to net cash used in operating activities:		
Acquired in-process research and development	–	1,305,000
Amortization of right of use asset	–	27,043
Share-based expense	208,507	392,829
Changes in operating assets and liabilities:		
Prepaid expenses and other	(924,468)	133,253
Other assets	362,500	(313,920)
Accounts payable, accrued expenses and other liabilities	(4,659)	(370,245)
Net cash used in operating activities	<u>(3,321,192)</u>	<u>(3,895,858)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Net cash paid to acquire in-process research and development	–	(500,000)
Net cash used in investing activities	<u>–</u>	<u>(500,000)</u>
Net change in cash	(3,321,192)	(4,395,858)
Cash at beginning of period	<u>13,097,265</u>	<u>18,244,030</u>
Cash at end of period	<u>\$ 9,776,073</u>	<u>\$ 13,848,172</u>
<b>SUPPLEMENTAL CASH FLOW INFORMATION:</b>		
Cash paid for interest	<u>\$ –</u>	<u>\$ –</u>
<b>SUPPLEMENTAL SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:</b>		
Issuance of common stock from cashless exercise of purchase warrants	<u>\$ –</u>	<u>\$ 2</u>
Issuance of common stock to acquire in-process research and development	<u>\$ –</u>	<u>\$ 805,000</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. XCART<sup>™</sup> is the Company’s personalized Chimeric Antigen Receptor (“CAR”) T platform technology engineered to target patient specific tumor neoantigens with a demonstrated proof of mechanism in B-cell lymphomas. Additionally, Xenetic has partnered with biotechnology and pharmaceutical companies to develop its proprietary drug delivery platform, PolyXen<sup>®</sup>, 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<sup>™</sup>, PolyXen, ErepoXen<sup>™</sup>, and ImuXen<sup>™</sup>, 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. These factors raise substantial doubt about its ability to continue as a going concern. 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 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 may need additional capital in the long-term to pursue its business initiatives. 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. On June 3, 2022, the Company received a written notification (the “Notice”) from the Listing Qualifications Department of Nasdaq notifying the Company that the closing bid price for its common stock had been below \$1.00 for 30 consecutive business days and that the Company therefore was not in compliance with the minimum bid price requirement for continued inclusion on Nasdaq under Nasdaq Listing Rule 5550(a)(2) (the “Bid Price Requirement”). The Notice had no immediate effect on the listing of the Company’s common stock on the Nasdaq Capital Market. 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 May 30, 2023, the Company received a letter from Nasdaq notifying the Company that it has regained compliance with the Bid Price Requirement as a result of the closing bid price of the Company’s 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 is now closed.



## **2. Risks and Uncertainties**

### ***Effects of the COVID-19 Pandemic***

During March 2020, a global pandemic was declared by the World Health Organization related to the outbreak of a novel strain of coronavirus, or COVID-19. The pandemic significantly affected economic conditions in the U.S., accelerating during the first half of March 2020 and continuing throughout 2021 and 2022 and into 2023, as federal, state and local governments reacted to the public health crisis with mitigation measures, creating significant uncertainties in the U.S. economy. The Company continues to evaluate the effects of the COVID-19 pandemic on its business and while there has been no significant impact to the Company's operations to date, the Company at this time remains uncertain of the impact this event may have on the Company's future operations. The extent to which the COVID-19 pandemic affects our business, operations and financial results will depend on numerous evolving factors that we may not be able to accurately predict, and such uncertainty is expected to continue for some time.

### ***Impact of the conflict in Ukraine on Operations***

The short and long-term implications of Russia's invasion of Ukraine are difficult to predict at this time. The imposition of 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, 2022 filed with the SEC on March 22, 2023, and amended on April 28, 2023.

On May 15, 2023, the Company effected 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, or option to purchase common stock were proportionately reduced on the same basis as the common stock; (iii) the exercise price of each outstanding warrant or option to purchase common stock were proportionately increased on a 1-to-10 basis; and (iv) the number of shares of common stock into which each share of preferred stock were 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. All intercompany balances and transactions have been eliminated in consolidation.

### ***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. Cash deposits are insured by the Federal Deposit Insurance Corporations up to \$250,000. The Company maintains its primary banking relationship with one large financial institution and all cash on deposit is covered under federally insured limits.

### ***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, 2023 and 2022, basic and diluted net loss per share are the same for each respective 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 Standards***

In June 2016, the Financial Accounting Standards Board issued Accounting Standards Update ("ASU") 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. The guidance modified the measurement and recognition of credit losses for most financial assets and certain other instruments. The amendment updated the guidance for measuring and recording credit losses on financial assets measured at amortized cost by replacing the "incurred loss" model with an "expected loss" model. This may result in earlier recognition of allowance for losses. The Company adopted ASU 2016-13 as of January 1, 2023 and the adoption did not have a material effect on our 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 the three and nine months ended September 30, 2023, respectively, and approximately \$0.4 million and \$1.2 million were recorded as revenue by the Company during the three and nine months ended September 30, 2022, 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.

### ***CLS Therapeutics Ltd. (“CLS”)***

On April 26, 2022, the Company entered into an Exclusive Sublicense Agreement (the “Sublicense Agreement”) with CLS pursuant to which the Company received an exclusive license, under certain patent rights and know-how owned or controlled by CLS, to develop and commercialize pharmaceutical products and methods incorporating DNase enzyme for use in treatment of cancer (the “Sublicensed Products”). Under the terms of the Sublicense Agreement, the Company will have sole responsibility for, and shall use commercially reasonable efforts to, among other things, research, develop and obtain marketing approval for the Sublicensed Products in the U.S. and certain European markets, and to commercialize such Sublicensed Products in the relevant market once marketing approval is obtained.

Concurrent with the Sublicense Agreement, the Company entered into an Exclusive License Agreement (the “License Agreement”) with CLS, pursuant to which the Company received an exclusive license under certain patent rights and know-how owned or controlled by CLS to develop and commercialize pharmaceutical products and methods incorporating DNase in conjunction with CAR T therapies (the “Licensed Products”). Under the terms of the License Agreement, the Company will have sole responsibility for, and shall use commercially reasonable efforts to, among other things, research, develop and obtain marketing approval for the Licensed Products in the U.S. and certain European markets, and to commercialize such Licensed Products in the relevant market once marketing approval is obtained.

### ***Volition Collaboration***

On August 2, 2022, the Company announced a research and development collaboration with Belgian Volition SARL Limited (“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<sup>®</sup> 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. On July 10, 2023 the Company entered into the first Collaborator Statement of Work as part of this collaboration with Volition.

### ***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 (“MSA”) 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. In addition, in the event of any conflict between the project-specific terms and conditions set forth in the SOW and the MSA, the MSA terms and conditions shall govern. The estimated total cost of the project contemplated by the SOW is expected to be up to approximately \$5 million (exclusive of certain fees and potential alternatives) for the manufacturing services over the course of the term of the project with each phase of the project invoiced separately in connection with the commencement of such phase. The SOW is terminable by the Company at any time with 30 days’ prior written notice to Catalent. The SOW also contains customary provisions related to, among other things, confidentiality, warranties, intellectual property and indemnification. The Company has paid Catalent approximately \$2.4 million through September 30, 2023, of which \$0.9 million and \$0.3 million has been recognized as an advance payment and is included in prepaid expenses and other as of September 30, 2023 and December 31, 2022, respectively.

### ***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 \$938,000 to fund 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 \$78,000 on the date of the Agreement and subsequent monthly payments of approximately \$78,000 over a 12-month period. 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.

Unless earlier terminated, the term of the Agreement continues from the date of the Agreement for fifteen (15) months. The Agreement may be terminated by the Company with 30 days advance written notice to Scripps Research beginning six (6) months after the Effective Date (as defined in the Agreement) or by Scripps Research if the Company fails to make timely payments due under the Agreement, subject to 30 days' written notice to cure such nonpayment. The Agreement may further be terminated by either party in the event of the other party's uncured failure to perform any obligations under the Agreement or the bankruptcy of the other party.

The Company has paid Scripps Research approximately \$0.5 million under the Agreement through September 30, 2023, of which approximately \$0.3 million has been recognized as an advance payment and is included in prepaid expenses and other as of September 30, 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, 2023. No amounts were recognized as revenue related to the Serum Institute, Pharmsynthez or SynBio agreements during the three and nine months ended September 30, 2023 and 2022, respectively.

### **5. 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 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, 2023 and December 31, 2022, 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, 2023 and 2022.

### **6. Stockholders' Equity**

#### ***Common Stock***

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***

In connection with its July 2021 private placement, the Company issued warrants to purchase an aggregate of 462,963 shares of the Company's common stock (the "Series A Warrants"). 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 three and nine months ended September 30, 2023 and 2022.

In addition, the Company has publicly traded warrants to purchase approximately 2,100 shares of common stock outstanding as of both September 30, 2023 and December 31, 2022. These warrants have an exercise price of \$130.00 per share and expire on July 17, 2024. The warrants trade on Nasdaq under the symbol “XBLOW.” The warrants also provide 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. None of these warrants were exercised during the three and nine months ended September 30, 2023. Warrants to purchase approximately 199 shares of common stock were exercised on a cashless, one-for-one basis during the nine months ended September 30, 2022. No warrants were exercised during the three months ended September 30, 2022. None of these warrants were forfeited during the three and nine months ended September 30, 2023 and 2022.

The Company also has outstanding warrants to purchase approximately 800 shares of the Company’s common stock as of September 30, 2023 and December 31, 2022. These warrants have an exercise price of \$29.09 per share and expire on July 3, 2026. None of these warrants were exercised or forfeited during the three and nine months ended September 30, 2023 and 2022.

## 7. Share-Based Expense

Total share-based expense related to stock options, restricted stock units and common stock awards was approximately \$0.1 million for each of the three months ended September 30, 2023 and 2022 and approximately \$0.2 million and \$0.4 million for the nine months ended September 30, 2023 and 2022, respectively.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Research and development expenses	\$ 13,961	\$ 23,382	\$ 41,427	\$ 65,688
General and administrative expenses	56,305	113,982	167,080	327,141
	<u>\$ 70,266</u>	<u>\$ 137,364</u>	<u>\$ 208,507</u>	<u>\$ 392,829</u>

### *Employee Stock Options*

No stock option awards to purchase shares of common stock were granted during the three and nine months ended September 30, 2023. During the nine months ended September 30, 2022, the Company granted 20,000 stock option awards to purchase shares of common stock. The Company recognized a total of \$0.1 million of share-based expense related to employee stock options during each of the three months ended September 30, 2023 and 2022 and \$0.2 million and \$0.4 million during the nine months ended September 30, 2023 and 2022, respectively. No employee stock options or RSUs were exercised and none expired during the three and nine months ended September 30, 2023 and 2022.

### *Non-Employee Stock Options*

There were no non-employee stock options granted or exercised during the three and nine months ended September 30, 2023 and 2022, respectively. During the nine months ended September 30, 2023, non-employee stock option grants to purchase approximately 100 shares of common stock expired. No non-employee stock option grants expired during the nine months ended September 30, 2022. The Company did not recognize any share-based expense related to non-employee stock options during the three and nine months ended September 30, 2023 and 2022, respectively.

## 8. Income Taxes

During the three and nine months ended September 30, 2023 and 2022, 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 \$39.2 million and \$38.6 million as of September 30, 2023 and December 31, 2022, respectively.

As of September 30, 2023 and December 31, 2022, the Company did not record any unrecognized tax positions.

## 9. Commitments and Contingencies

Supplemental cash flow information and non-cash activity related to the Company's operating leases are as follows:

	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022
<b>Operating cash flow information:</b>		
Cash paid for amounts included in the measurement of lease liabilities	\$ —	\$ 27,043

Effective October 1, 2022, the Company did not apply the provisions of ASU 2016-02 as its leases had terms of 12-month or less at inception. As of September 30, 2023, total minimum lease payments were approximately \$25,000.

## 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, 2022 filed with the SEC on March 22, 2023, as amended on April 28, 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, 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. The Company recognized approximately \$9,000 of interest income related to the Pharmsynthez Loan during the nine months ended September 30, 2022. As of December 31, 2022, approximately \$0.4 million was included in other assets on the condensed consolidated balance sheet. No amounts were outstanding as of 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 discussed below. On October 24, 2023, all of the Company's Series A Preferred Stock was converted into approximately 8,000 shares of common stock.

## 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: the lingering effects of the coronavirus, or COVID-19, global pandemic and the responses thereto, including the pandemic’s impact on general economic and market conditions, as well as on our business, results of operations and financial condition; anticipated effects of geopolitical events, including the conflict between Russia and Ukraine and associated sanctions imposed by the United States (“U.S.”) and other countries in response; our plans to develop our proposed drug candidates; our expectations regarding the nature, timing and extent of clinical trials and proposed clinical trials; our expectations regarding the timing for proposed submissions of regulatory filings, including but not limited to, any Investigational New Drug filing or any New Drug Application; the nature, timing and extent of collaboration arrangements; the expected results pursuant to collaboration arrangements, including the receipts of 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 address certain markets, engage third party manufacturers, and evaluate additional drug candidates for subsequent commercial development along with the likelihood and extent of competition to 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”) and our expectations to prioritize our efforts and resources on this newly licensed technology; the development of the XCART™ Chimeric Antigen Receptor (“CAR”) T cell (“XCART”) technology; and our expectations regarding our PolyXen® platform.

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:

- unexpected costs, charges or expenses resulting from the transaction with CLS Therapeutics LTD (“CLS”) and the licensing of the DNase platform;
- uncertainty of the expected financial performance of the Company following completion of the transaction with CLS and the licensing of the DNase platform;
- failure to realize the anticipated potential of the DNase, XCART or PolyXen technologies;

- our ability to implement our business strategy;
- our failure to meet the continued listing requirements of the Nasdaq Capital 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;
- 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 Russian invasion of Ukraine, 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. We are focused on advancing our DNase platform, which 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 licensed the DNase oncology platform in April 2022 and are focusing the majority of our resources on advancing our systemic DNase program into the clinic as an adjunctive therapy for pancreatic carcinoma and locally advanced or metastatic solid tumors. We also have a personalized CAR T platform technology, XCART™, to develop cell-based therapeutics targeting the unique B-cell receptor on the surface of an individual patient's malignant tumor cells, for the treatment of B-cell lymphomas. Additionally, 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 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 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, 2023, was on the advancement of our DNase platform.

### Impact of the Conflict in Ukraine on Our Operations

The short and long-term implications of Russia's invasion of Ukraine are difficult to predict at this time. The imposition of 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, 2023 and 2022

The comparison of our historical results of operations for the fiscal quarter ended September 30, 2023 to the fiscal quarter ended September 30, 2022 is as follows:

Description	Quarter Ended September 30, 2023	Quarter Ended September 30, 2022	Increase (Decrease)	Percentage Change
Revenues:				
Royalty revenue	\$ 611,174	\$ 414,250	\$ 196,924	47.5%
Operating costs and expenses:				
Research and development	(1,020,618)	(398,803)	621,815	155.9
General and administrative	(737,241)	(863,233)	(125,992)	(14.6)
Total operating costs and expenses	(1,757,859)	(1,262,036)	495,823	39.3
Loss from operations	(1,146,685)	(847,786)	298,899	35.3
Other income (expense):				
Other expense	(666)	(1,706)	(1,040)	(61.0)
Interest income, net	91,796	45,475	46,321	101.9
Net loss	\$ (1,055,555)	\$ (804,017)	\$ 251,538	31.3

## Revenue

Revenue for the three months ended September 30, 2023 increased by approximately \$0.2 million, or 47.5%, to approximately \$0.6 million from approximately \$0.4 million for the three months ended September 30, 2022. This increase represents an increase in royalty revenue related to our sublicense agreement with Takeda Pharmaceuticals Co. Ltd. (“Takeda”) as compared to the same period in 2022.

## Research and Development Expenses

Research & development (“R&D”) expenses for the three months ended September 30, 2023 increased by approximately \$0.6 million, or 155.9%, to approximately \$1.0 million from approximately \$0.4 million in the comparable quarter in 2022. The table below sets forth the R&D costs incurred by us by category of expense for the quarters ended September 30, 2023 and 2022:

Category of Expense	Quarter Ended,	
	September 30, 2023	September 30, 2022
Outside services and contract research organizations	\$ 877,647	\$ 214,453
Personnel costs	88,557	112,875
Share-based expense	13,961	23,382
Other	40,453	48,093
Total research and development expense	<u>\$ 1,020,618</u>	<u>\$ 398,803</u>

The increase in outside services and contract research organizations expense was primarily due to increased spending in connection with our pre-clinical development efforts associated with our DNase platform. We licensed the DNase platform in April 2022 and expect to continue to direct our efforts and resources on the development of this newly acquired technology. As a result, we suspended development of our XCART technology platform.

## General and Administrative Expenses

General and administrative expenses for the three months ended September 30, 2023 decreased by approximately \$0.1 million, or 14.6%, to approximately \$0.7 million from approximately \$0.9 million in the comparable quarter in 2022. The decrease was primarily due to decreases in personnel costs and share-based expense during the three months ended September 30, 2023 compared to the same period in 2022.

## Other Income (Expense)

Other expense was approximately \$700 for the three months ended September 30, 2023 compared to approximately \$1,700 of other expense for the same period in 2022. This decrease in other expense was primarily related to favorable changes in foreign currency exchange rates during the three months ended September 30, 2023 as compared to the same period in 2022.

## Interest Income

Interest income increased to approximately \$92,000 during the three months ended September 30, 2023 as compared to approximately \$45,000 for the same period in the prior year. This increase is due to higher interest rates on invested funds during the three months ended September 30, 2023 compared to the same period in 2022.

### Comparison of Nine Months Ended September 30, 2023 and 2022

The comparison of our historical results of operations for the nine months ended September 30, 2023 to the nine months ended September 30, 2022 is as follows:

Description	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022	Increase (Decrease)	Percentage Change
Revenues:				
Royalty revenue	\$ 1,868,023	\$ 1,219,953	\$ 648,070	53.1%
Operating costs and expenses:				
Research and development	(2,519,137)	(3,577,701)	(1,058,564)	(29.6)
General and administrative	(2,608,934)	(2,796,832)	(187,898)	(6.7)
Total operating costs and expenses	(5,128,071)	(6,374,533)	(1,246,462)	(19.6)
Loss from operations	(3,260,048)	(5,154,580)	(1,894,532)	(36.8)
Other income (expense):				
Other income (expense)	24,976	(2,583)	27,559	1,066.9
Interest income, net	272,000	87,345	184,655	211.4
Net loss	<u>\$ (2,963,072)</u>	<u>\$ (5,069,818)</u>	<u>\$ (2,106,746)</u>	(41.6)

### Revenue

Revenue for the nine months ended September 30, 2023 increased by \$0.6 million, or 53.1%, to \$1.9 million from approximately \$1.2 million for the nine months ended September 30, 2022. This increase represents an increase in royalty revenue related to our sublicense agreement with Takeda as compared to the same period in 2022.

### Research and Development Expenses

Overall, R&D expenses for the nine months ended September 30, 2023 decreased by \$1.1 million, or 29.6% to \$2.5 million from \$3.6 million in the comparable period in 2022 primarily due to in-process research and development (“IPR&D”) expense of \$1.3 million. During the nine months ended September 30, 2022, the Company expensed \$1.3 million of IPR&D associated with the Company’s licensing of the DNase oncology platform. There was no similar expense in 2023. Excluding the \$1.3 million of IPR&D expense from total R&D expense of approximately \$3.6 million for the nine months ended September 30, 2022, R&D expenses for the nine months ended September 30, 2023 increased approximately \$0.2 million, or 10.8% to \$2.5 million, from approximately \$2.3 million for the nine months ended September 30, 2022. The table below sets forth the R&D costs incurred by us, by category of expense, for the nine months ended September 30, 2023 and 2022:

Category of Expense	Nine Months Ended,	
	September 30, 2023	September 30, 2022
IPR&D expense	\$ –	\$ 1,305,000
Outside services and contract research organizations	2,034,601	1,751,134
Salaries and wages	340,307	345,232
Share-based expense	41,427	65,688
Other	102,802	110,647
Total research and development expense	<u>\$ 2,519,137</u>	<u>\$ 3,577,701</u>

The increase in outside services and contract research organizations expense was primarily due to increased spending in connection with our pre-clinical development efforts associated with our DNase platform. We licensed the DNase platform in April 2022 and expect to continue to direct our efforts and resources on the development of this newly acquired technology. As a result, we suspended development of our XCART technology platform.

#### **General and Administrative Expenses**

General and administrative expenses for the nine months ended September 30, 2023 was \$2.6 million, decreasing approximately \$0.2 million, or 6.7%, compared to the same period in the prior year. The decrease was primarily due to decreases in share-based expense, legal costs and personnel costs partially offset by increases in accounting and consulting costs during the nine months ended September 30, 2023 as compared to the same period in 2022.

#### **Other Income (Expense)**

Other income was approximately \$25,000 for the nine months ended September 30, 2023 compared to approximately \$2,600 of other expense for the same period in 2022. This increase in other income was primarily related to fees associated with the Pharmsynthez Loan recognized during the nine months ended September 30, 2023. There were no similar fees received in the same period in 2022.

#### **Interest Income**

Interest income increased to approximately \$0.3 million during the nine months ended September 30, 2023 as compared to approximately \$0.1 million for the same period in the prior year. This increase is due to higher interest rates on invested funds during the nine months ended September 30, 2023 compared to the same period in 2022 as well as an increase in interest income on the Pharmsynthez Loan.

#### **Non-GAAP Measures**

In our narrative discussion of operations above, we exclude the impact of non-cash expenses from certain operating measures, 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 \$3.0 million for the nine months ended September 30, 2023. We had an accumulated deficit of approximately \$192.1 million at September 30, 2023, as compared to an accumulated deficit of approximately \$189.1 million at December 31, 2022. Working capital was approximately \$10.2 million at September 30, 2023, and \$12.6 million at December 31, 2022. During the nine months ended September 30, 2023, our working capital decreased by \$2.4 million primarily due to our net loss for the nine months ended September 30, 2023, partially offset by proceeds from the repayment of the Pharmsynthez Loan.

Our principal source of liquidity consists of cash. At September 30, 2023, we had approximately \$9.8 million in cash and \$1.1 million in current liabilities. At December 31, 2022, we had approximately \$13.1 million in cash and \$1.1 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. These factors raise substantial doubt about our ability to continue as a going concern. 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. 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 these financial statements. However, we anticipate we may need additional capital in the long-term to pursue our business initiatives. 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. On June 3, 2022, we received a written notification (the “Notice”) 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 minimum bid price requirement for continued inclusion on Nasdaq under Nasdaq Listing Rule 5550(a)(2) (the “Bid Price Requirement”). The Notice had no immediate effect on the listing of our common stock on Nasdaq. 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. On May 30, 2023, the Company received a letter from Nasdaq notifying us that we had regained compliance with the 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 is now closed.

On March 10, 2023, Silicon Valley Bank (“SVB”) was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (“FDIC”) as receiver. We maintained our cash primarily with SVB. On March 12, 2023, the U.S. Treasury, Federal Reserve and FDIC rolled out emergency measures to fully protect all depositors of SVB and, on March 13, 2023, we had full access to our cash on deposit with SVB. As of June 30, 2023, we have transferred our primary banking relationship to a large financial institution and all cash on deposit is covered under federally insured limits.

#### **Cash Flows from Operating Activities**

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 Pharmsynthes Loan. Cash flows used in operating activities for the nine months ended September 30, 2022 totaled approximately \$3.9 million, which was primarily due to our net loss for the period, partially offset by non-cash charges associated with acquired IPR&D and share-based expense. In addition, current liabilities decreased during the nine months ended September 30, 2022.

#### **Cash Flows from Investing Activities**

Cash flows used in investing activities for the nine months ended September 30, 2022 totaled \$500,000, which represented cash paid to license the DNase oncology platform. There were no cash flows from investing activities for the nine months ended September 30, 2023.

#### **Cash Flow from Financing Activities**

There were no cash flows from financing activities for the nine months ended September 30, 2023 and 2022.

#### **Contractual Obligations and Commitments**

As of September 30, 2023, 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, 2022, filed with the SEC on March 22, 2023, as amended on April 28, 2023.

### **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, 2022, filed with the SEC on March 22, 2023, as amended on April 28, 2023, for a discussion of recent accounting standards.

### **Critical Accounting Policies and 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, 2022, filed with the SEC on March 22, 2023, as amended on April 28, 2023.

### **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 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 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 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, 2022 filed with the SEC on March 22, 2023, as amended on April 28, 2023, other than the risks set forth below.

#### Risks Related to the Reverse Stock Split

*The Reverse Stock Split may decrease the liquidity of our common shares.*

The liquidity of our common stock may be adversely affected by the reduced number of shares outstanding after the Reverse Stock Split. In addition, the Reverse Stock Split may have increased the number of shareholders who own odd lots (less than 100 shares) of our common shares, creating the potential for such shareholders to experience an increase in the cost of selling their shares and greater difficulty effecting such sales.

*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 Nasdaq. While we are currently in compliance, we have in the past been, and may in the future be, unable to comply with certain of the listing standards that we are required to meet to maintain the listing of our common shares on Nasdaq. For instance, on June 3, 2022, we received the Notice 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 Bid Price Requirement. Our Board of Directors and the Financing Committee of the Board approved the Reverse Stock Split on May 11, 2023, and on May 15, 2023, we effected the Reverse Stock Split. On May 30, 2023, we received a letter from Nasdaq notifying us that we had regained compliance with the 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 now closed.

The primary intent for the Reverse Stock Split was that the anticipated increase in the price of our common shares immediately following and resulting from a reverse stock split due to the reduction in the number of issued and outstanding common shares would help us meet the minimum bid price requirement. It cannot be assured that the Reverse Stock Split will result in any sustained proportionate increase in the market price of our common shares, which is dependent upon many factors, including the business and financial performance of the company, general market conditions, and prospects for future success, which are unrelated to the number of shares of our common shares outstanding. It is not uncommon for the market price of a company's common shares to decline in the period following a reverse stock split. Thus, while we have regained compliance with the continued listing requirements for Nasdaq, it cannot be assured that we will continue to do so. If Nasdaq delists our common shares from trading on its exchange for failure to meet the listing standards, an investor would likely find it significantly more difficult to dispose of or obtain our shares, and our ability raise future capital through the sale of our shares could be severely limited. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities.

**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**

None.

**ITEM 6 – EXHIBITS**

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

EXHIBIT NUMBER	DESCRIPTION
31.1*	<a href="#"><u>Certification of Jeffrey F. Eisenberg, Principal Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u></a>
31.2*	<a href="#"><u>Certification of James Parslow, Principal Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u></a>
32.1**	<a href="#"><u>Certifications of Jeffrey F. Eisenberg, Principal Executive Officer, and James Parslow, Principal Financial Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u></a>
101*	The following financial statements from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, formatted in inline XBRL, include: (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statements of 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 9, 2023

By: /S/ JEFFREY F. EISENBERG

\_\_\_\_\_  
Jeffrey F. Eisenberg  
Chief Executive Officer  
(Principal Executive Officer)

By: /S/ JAMES PARSLow

\_\_\_\_\_  
James Parslow  
Chief Financial Officer  
(Principal Financial Officer and Principal Accounting Officer)

I, Jeffrey F. Eisenberg, 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. The registrant's other certifying officer(s) and I are 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. The registrant's other certifying officer(s) and 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 9, 2023

By: /s/ JEFFREY F. EISENBERG

Jeffrey F. Eisenberg  
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. The registrant's other certifying officer(s) and I are 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. The registrant's other certifying officer(s) and 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 9, 2023

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), Jeffrey F. Eisenberg, Chief Executive Officer of Xenetic Biosciences, Inc. (the “Company”), and James Parslow, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

The Company’s Quarterly Report on Form 10-Q for the period ended September 30, 2023, 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 9, 2023

**IN WITNESS WHEREOF**, the undersigned have set their hands hereto as of the 9th day of November 2023.

/s/ Jeffrey F. Eisenberg  
Jeffrey F. Eisenberg  
Chief Executive Officer

/s/ James Parslow  
James Parslow  
Chief 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.”