

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, 2022

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 Accelerated filer
Non-accelerated filer Smaller reporting company
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

As of November 4, 2022, the number of outstanding shares of the registrant's common stock was 15,166,596.

XENETIC BIOSCIENCES, INC.
FORM 10-Q
QUARTERLY PERIOD ENDED SEPTEMBER 30, 2022

PART I **FINANCIAL INFORMATION**

Item 1	<u>Condensed Consolidated Financial Statements:</u>	3
	<u>Condensed Consolidated Balance Sheets as of September 30, 2022 (Unaudited) and December 31, 2021</u>	3
	<u>Condensed Consolidated Statements of Operations (Unaudited) for the three and nine months ended September 30, 2022 and 2021</u>	4
	<u>Condensed Consolidated Statements of Stockholders' Equity (Unaudited) for the three and nine months ended September 30, 2022 and 2021</u>	5
	<u>Condensed Consolidated Statements of Cash Flows (Unaudited) for the nine months ended September 30, 2022 and 2021</u>	7
	<u>Notes to Condensed Consolidated Financial Statements (Unaudited)</u>	8
Item 2	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	16
Item 3	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	23
Item 4	<u>Controls and Procedures</u>	23

PART II **OTHER INFORMATION**

Item 1	<u>Legal Proceedings</u>	24
Item 1A	<u>Risk Factors</u>	24
Item 2	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	26
Item 3	<u>Defaults Upon Senior Securities</u>	26
Item 4	<u>Mine Safety Disclosures</u>	26
Item 5	<u>Other Information</u>	26
Item 6	<u>Exhibits</u>	27
	<u>Signatures</u>	28

PART I – FINANCIAL INFORMATION

ITEM 1 – FINANCIAL STATEMENTS

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

	<u>September 30, 2022</u>	<u>December 31, 2021</u>
	<u>(Unaudited)</u>	
ASSETS		
Current assets:		
Cash	\$ 13,848,172	\$ 18,244,030
Prepaid expenses and other	319,103	479,399
Total current assets	<u>14,167,275</u>	<u>18,723,429</u>
Other assets	1,405,851	1,091,931
Total assets	<u>\$ 15,573,126</u>	<u>\$ 19,815,360</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 202,778	\$ 362,470
Accrued expenses and other current liabilities	848,080	1,058,633
Total current liabilities	<u>1,050,858</u>	<u>1,421,103</u>
Total liabilities	<u>1,050,858</u>	<u>1,421,103</u>
Commitments and contingencies (Note 10)		
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, 2022 and December 31, 2021	1,804	1,804
Series A, \$0.001 par value: 970,000 shares issued and outstanding as of September 30, 2022 and December 31, 2021	970	970
Common stock, \$0.001 par value; 50,000,000 shares authorized as of September 30, 2022 and December 31, 2021; 14,343,587 and 13,466,603 shares issued as of September 30, 2022 and December 31, 2021, respectively; 14,316,596 and 13,439,612 shares outstanding as of September 30, 2022 and December 31, 2021, respectively	14,342	13,465
Additional paid in capital	207,149,681	205,952,729
Accumulated deficit	(187,617,083)	(182,547,265)
Accumulated other comprehensive income	253,734	253,734
Treasury stock	(5,281,180)	(5,281,180)
Total stockholders' equity	<u>14,522,268</u>	<u>18,394,257</u>
Total liabilities and stockholders' equity	<u>\$ 15,573,126</u>	<u>\$ 19,815,360</u>

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		NINE MONTHS ENDED	
	SEPTEMBER 30,		SEPTEMBER 30,	
	2022	2021	2022	2021
Revenue:				
Royalty revenue	\$ 414,250	\$ 349,269	\$ 1,219,953	\$ 828,088
Total revenue	<u>414,250</u>	<u>349,269</u>	<u>1,219,953</u>	<u>828,088</u>
Operating costs and expenses:				
Research and development	(398,803)	(780,153)	(3,577,701)	(1,934,432)
General and administrative	(863,233)	(945,115)	(2,796,832)	(2,766,397)
Total operating costs and expenses	<u>(1,262,036)</u>	<u>(1,725,268)</u>	<u>(6,374,533)</u>	<u>(4,700,829)</u>
Loss from operations	<u>(847,786)</u>	<u>(1,375,999)</u>	<u>(5,154,580)</u>	<u>(3,872,741)</u>
Other income (expense):				
Other expense	(1,706)	(2,906)	(2,583)	(1,784)
Interest income, net	45,475	28,029	87,345	71,026
Total other income	<u>43,769</u>	<u>25,123</u>	<u>84,762</u>	<u>69,242</u>
Net loss	<u>\$ (804,017)</u>	<u>\$ (1,350,876)</u>	<u>\$ (5,069,818)</u>	<u>\$ (3,803,499)</u>
Basic and diluted net loss per share	<u>\$ (0.06)</u>	<u>\$ (0.13)</u>	<u>\$ (0.36)</u>	<u>\$ (0.41)</u>
Weighted-average shares of common stock outstanding, basic and diluted	<u>14,316,596</u>	<u>10,162,167</u>	<u>13,944,286</u>	<u>9,223,560</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

	<u>Preferred Stock</u>		<u>Common Stock</u>		<u>Additional Paid in Capital</u>	<u>Accumulated Deficit</u>	<u>Accumulated Other Comprehensive Income</u>	<u>Treasury Stock</u>	<u>Total Stockholders' Equity</u>
	<u>Number of Shares</u>	<u>Par Value (\$0.001)</u>	<u>Number of Shares</u>	<u>Par Value (\$0.001)</u>					
Balance as of July 1, 2022	2,774,394	\$ 2,774	14,343,587	\$ 14,342	\$ 207,012,317	\$ (186,813,066)	\$ 253,734	\$ (5,281,180)	\$ 15,188,921
Share-based expense	-	-	-	-	137,364	-	-	-	137,364
Net loss	-	-	-	-	-	(804,017)	-	-	(804,017)
Balance as of September 30, 2022	<u>2,774,394</u>	<u>\$ 2,774</u>	<u>14,343,587</u>	<u>\$ 14,342</u>	<u>\$ 207,149,681</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

	<u>Preferred Stock</u>		<u>Common Stock</u>		<u>Additional Paid in Capital</u>	<u>Accumulated Deficit</u>	<u>Accumulated Other Comprehensive Income</u>	<u>Treasury Stock</u>	<u>Total Stockholders' Equity</u>
	<u>Number of Shares</u>	<u>Par Value (\$0.001)</u>	<u>Number of Shares</u>	<u>Par Value (\$0.001)</u>					
Balance as of January 1, 2022	2,774,394	\$ 2,774	13,466,603	\$ 13,465	\$ 205,952,729	\$ (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	-	-	875,000	875	804,125	-	-	-	805,000
Share-based expense	-	-	-	-	392,829	-	-	-	392,829
Exercise of purchase warrants	-	-	1,984	2	(2)	-	-	-	-
Net loss	-	-	-	-	-	(5,069,818)	-	-	(5,069,818)
Balance as of September 30, 2022	<u>2,774,394</u>	<u>\$ 2,774</u>	<u>14,343,587</u>	<u>\$ 14,342</u>	<u>\$ 207,149,681</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 STOCKHOLDERS' EQUITY
(Unaudited)

THREE MONTHS ENDED SEPTEMBER 30, 2021

	<u>Preferred Stock</u>		<u>Common Stock</u>		<u>Additional Paid in Capital</u>	<u>Accumulated Deficit</u>	<u>Accumulated Other Comprehensive Income</u>	<u>Treasury Stock</u>	<u>Total Stockholders' Equity</u>
	<u>Number of Shares</u>	<u>Par Value (\$0.001)</u>	<u>Number of Shares</u>	<u>Par Value (\$0.001)</u>					
Balance as of July 1, 2021	2,774,394	\$ 2,774	8,773,683	\$ 8,772	\$ 194,319,716	\$ (179,354,709)	\$ 253,734	\$ (5,281,180)	\$ 9,949,107
Issuance of common stock and warrants, net of issuance costs	-	-	950,000	950	11,449,916	-	-	-	11,450,866
Exercise of pre-funded warrants	-	-	3,679,630	3,679	-	-	-	-	3,679
Exercise of purchase warrants	-	-	2,547	3	(3)	-	-	-	-
Issuance of common stock to vendor	-	-	7,153	7	(7)	-	-	-	-
Share-based expense	-	-	-	-	111,131	-	-	-	111,131
Net loss	-	-	-	-	-	(1,350,876)	-	-	(1,350,876)
Balance as of September 30, 2021	<u>2,774,394</u>	<u>\$ 2,774</u>	<u>13,413,013</u>	<u>\$ 13,411</u>	<u>\$ 205,880,753</u>	<u>\$ (180,705,585)</u>	<u>\$ 253,734</u>	<u>\$ (5,281,180)</u>	<u>\$ 20,163,907</u>

NINE MONTHS ENDED SEPTEMBER 30, 2021

	<u>Preferred Stock</u>		<u>Common Stock</u>		<u>Additional Paid in Capital</u>	<u>Accumulated Deficit</u>	<u>Accumulated Other Comprehensive Income</u>	<u>Treasury Stock</u>	<u>Total Stockholders' Equity</u>
	<u>Number of Shares</u>	<u>Par Value (\$0.001)</u>	<u>Number of Shares</u>	<u>Par Value (\$0.001)</u>					
Balance as of January 1, 2021	2,774,394	\$ 2,774	8,772,198	\$ 8,771	\$ 194,133,511	\$ (176,902,086)	\$ 253,734	\$ (5,281,180)	\$ 12,215,524
Issuance of common stock and warrants, net of issuance costs	-	-	950,000	950	11,449,916	-	-	-	11,450,866
Exercise of pre-funded warrants	-	-	3,679,630	3,679	-	-	-	-	3,679
Exercise of purchase warrants	-	-	4,032	4	(4)	-	-	-	-
Issuance of common stock to vendor	-	-	7,153	7	(7)	-	-	-	-
Share-based expense	-	-	-	-	297,337	-	-	-	297,337
Net loss	-	-	-	-	-	(3,803,499)	-	-	(3,803,499)
Balance as of September 30, 2021	<u>2,774,394</u>	<u>\$ 2,774</u>	<u>13,413,013</u>	<u>\$ 13,411</u>	<u>\$ 205,880,753</u>	<u>\$ (180,705,585)</u>	<u>\$ 253,734</u>	<u>\$ (5,281,180)</u>	<u>\$ 20,163,907</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,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (5,069,818)	\$ (3,803,499)
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	26,199
Share-based expense	392,829	297,337
Changes in operating assets and liabilities:		
Prepaid expenses and other	133,253	(62,484)
Other long-term assets	(313,920)	105,555
Accounts payable, accrued expenses and other liabilities	(370,245)	157,524
Net cash used in operating activities	<u>(3,895,858)</u>	<u>(3,279,368)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Net cash paid to acquire in-process research and development	(500,000)	–
Net cash used in investing activities	<u>(500,000)</u>	<u>–</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from issuance of common stock and warrants	–	11,450,866
Proceeds from exercise of warrants	–	3,679
Net cash provided by financing activities	<u>–</u>	<u>11,454,545</u>
Net change in cash	(4,395,858)	8,175,177
Cash at beginning of period	18,244,030	11,527,552
Cash at end of period	<u>\$ 13,848,172</u>	<u>\$ 19,702,729</u>
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash paid for interest	<u>\$ –</u>	<u>\$ –</u>
SUPPLEMENTAL SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Issuance of common stock to acquire in-process research and development	<u>\$ 805,000</u>	<u>\$ –</u>
Issuance of common stock to vendor	<u>\$ –</u>	<u>\$ 7</u>
Issuance of common stock from cashless exercise of purchase warrants	<u>\$ 2</u>	<u>\$ 4</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 Deoxyribonuclease (“DNase”) platform is designed to improve outcomes of existing treatments, including immunotherapies, by targeting neutrophil extracellular traps (“NETs”). Xenetic is currently focused on advancing its systemic DNase program into the clinic as an adjunctive therapy for pancreatic carcinoma and locally advanced or metastatic solid tumors. The Company is also developing its personalized Chimeric Antigen Receptor (“CAR”) T platform technology, XCART™, to develop cell-based therapeutics targeting the unique B-cell receptor on the surface of an individual patient’s malignant tumor cells, for the treatment of B-cell lymphomas. Additionally, Xenetic 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, and unregistered trademarks and service marks, including but not limited to XCART, OncoHist™, PolyXen, ErepoXen™, and ImuXen™, which are 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 into the first quarter of 2024. 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 clinical 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 is not in compliance with the minimum bid price requirement for continued inclusion on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(2) (the “Bid Price Requirement”). The Notice has no immediate effect on the listing of the Company’s common stock on the Nasdaq Capital Market. Under the Nasdaq Listing Rules, the Company has a period of 180 calendar days from the date of the Notice to regain compliance with the Bid Price Requirement. Accordingly, the Company has until November 30, 2022 to regain compliance with the Bid Price Requirement and may be eligible for an additional 180 calendar day compliance period if certain other criteria are met.

2. Risks and Uncertainties

Effects of the COVID-19

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 has significantly affected economic conditions in the U.S., accelerating during the first half of March 2020 and continuing throughout 2021 and into 2022, 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, 2021 filed with the SEC on March 22, 2022, and amended on April 28, 2022.

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.

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, 2022 and 2021, 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 modifies the measurement and recognition of credit losses for most financial assets and certain other instruments. The amendment updates 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. ASU 2016-13 is effective for smaller reporting public entities for fiscal years beginning after December 15, 2022 but early adoption is permitted. The Company is currently evaluating the impact of adoption, but it does not anticipate that adoption will have a material effect on the Company's consolidated financial statements.

4. Significant Strategic Collaborations

The Company has 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’s collaborative partners continue to engage in research and development activities with no resultant commercial products through September 30, 2022. No amounts were recognized as revenue related to the Serum Institute, Pharmsynthez or SynBio agreements during the three and nine months ended September 30, 2022 and 2021, respectively.

In October 2017, the Company granted to Takeda Pharmaceuticals Co. Ltd. (“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 \$0.4 million and \$1.2 million were recorded as revenue by the Company during the three and nine months ended September 30, 2022, respectively, and approximately \$0.3 million and \$0.8 million were recorded as revenue by the Company during the three and nine months ended September 30, 2021, 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.

On May 15, 2020, the Company and The Scripps Research Institute (“Scripps Research”) entered into a Research Funding and Option Agreement (the “Scripps Agreement”), pursuant to which the Company had agreed to provide Scripps Research an aggregate of up to \$3.0 million to fund research relating to advancing the pre-clinical development of XCART. The research funding was payable by the Company to Scripps Research on a quarterly basis in accordance with a negotiated budget, which provided for an initial payment of approximately \$300,000 on the date of the Scripps Agreement and subsequent quarterly payments of approximately \$300,000 over a 27-month period. Under the Scripps Agreement, Scripps Research has granted the Company a license within the Field (as defined in the Scripps Agreement) to any Patent Rights or Technology (as defined in the Scripps Agreement) under the terms of that certain license agreement with Scripps Research, dated February 25, 2019, assigned to the Company on March 1, 2019. Additionally, the Company has the option to acquire a worldwide exclusive license to Scripps Research’s rights in the Technology or Patent Rights not already licensed to the Company, as well as a non-exclusive, royalty-free, non-transferrable license to make and use Scripps Research Technology (as defined in the Scripps Agreement) solely for the Company’s internal research purposes during the performance of the research program contemplated by the Scripps Agreement. During the second quarter of 2022, the parties mutually agreed to terminate additional funding under the Scripps Agreement. As a result, Scripps Research agreed to continue to perform work under the agreement until funding previously advanced was expended. The Company paid \$2.4 million to Scripps Research under this agreement through September 30, 2022. There were no amounts recognized as an advance payment under this agreement or accrued as of September 30, 2022. As of December 31, 2021, approximately \$0.2 million has been recognized as an advance payment under this agreement and is included in prepaid expenses and other current assets.

On June 30, 2022, the Company entered into a Statement of Work (the “SOW”) with Catalent Pharma Solutions, LLC (“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. Unless earlier terminated, the manufacturing services contemplated by the SOW are currently expected to take approximately 17 months from the start date. 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. During the three and nine months ended September 30, 2022, the Company paid Catalent \$0.3 million, which has been recorded as a long-term prepayment as of September 30, 2022.

5. Licensing Arrangements

Exclusive Sublicense Agreement

On April 26, 2022, the Company entered into an Exclusive Sublicense Agreement (the “Sublicense Agreement”) with CLS Therapeutics Ltd. (“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.

In consideration for the license and other rights granted to the Company under the Sublicense Agreement, the Company issued to CLS 375,000 shares of the Company’s common stock (the “Sublicense Agreement Shares”), of which 250,000 Sublicense Agreement Shares were issued directly to OPKO Health, Inc. (“OPKO”) in lieu of transfer indirectly from CLS to EirGen Pharma Ltd. (“EirGen”), a wholly owned subsidiary of OPKO, in satisfaction of certain third-party contractual obligations between CLS and EirGen. Additionally, the Company is obligated to pay to CLS up to \$13,000,000 in cash in potential milestone payments for the achievement of certain clinical and regulatory milestones, as well as issue an additional 950,000 shares of the Company’s common stock to CLS based on the achievement of certain regulatory milestones. In addition, the Company is obligated to pay tiered royalties ranging from the mid-single to low-double digits on net sales of licensed products falling within the scope of the license during the Royalty Term (as defined in the Sublicense Agreement), as well as pay a percentage share in the low-to-mid teens of certain consideration received by the Company from any sublicensees.

Exclusive License Agreement

On April 26, 2022, 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.

In consideration for the license and other rights granted to the Company under the License Agreement, the Company paid CLS a one-time fee of \$500,000 in cash, issued to CLS 500,000 shares of the Company’s common stock, and is obligated to pay up to \$13,000,000 in cash in potential milestone payments for the achievement of certain clinical and regulatory milestones for each Licensed Product. In addition, the Company is obligated to pay tiered royalties ranging from the mid-single to low-double digits on net sales of licensed products falling within the scope of the license during the Royalty Term (as defined in the License Agreement), as well as pay a percentage share in the mid-teens to low double digits of certain consideration received by the Company from any sublicensees.

The total consideration for the Sublicense and License Agreements was approximately \$1.3 million, which consists of a \$0.5 million cash payment and the fair value of the 875,000 common shares issued of \$0.8 million utilizing the closing market price of the Company’s stock price at the closing date. As there was no future alternative use for the sublicense and license, the Company recorded an expense of \$1.3 million to research and development expense for the nine months ended September 30, 2022. In addition, the Company incurred approximately \$0.2 million and \$0.4 million related to consulting, transaction and development costs in connection with the Sublicense and License Agreements in the three and nine months ended September 30, 2022, respectively.

Patent Assignment and Volition Collaboration

On October 4, 2022, the Company completed a patent assignment related to its collaboration with Belgian Volition SARL Limited (“Volition”) and CLS. In connection with the patent assignment, the Company entered into a Subscription Agreement with CLS Therapeutics, LLC, a Delaware limited liability company (“CLS LLC”) on October 12, 2022, pursuant to which the Company agreed to issue to CLS LLC, and CLS LLC agreed to subscribe for, 850,000 shares of the Company’s common stock (the “Shares”) as consideration for the assignment by CLS and its affiliates to the Company of certain patent rights owned by CLS and its affiliates. The Shares were issued on October 12, 2022.

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.

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 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, 2022 and December 31, 2021, 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, 2022 and 2021.

7. Stockholders' Equity

Warrants

In connection with its July 2021 private placement, the Company issued warrants to purchase an aggregate of 4,629,630 shares of the Company's common stock (the "Series A Warrants"). The Series A Warrants are immediately exercisable at a price of \$3.30 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, 2022.

In addition to the Series A Warrants, warrants to purchase approximately 29,000 and 31,000 shares of the Company's common stock were outstanding as of September 30, 2022 and December 31, 2021, respectively, as described below.

Publicly traded warrants to purchase approximately 21,000 and 23,000 shares of common stock were outstanding as of September 30, 2022 and December 31, 2021, respectively. These warrants have an exercise price of \$13.00 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. No warrants to purchase shares of common stock were exercised during the three months ended September 30, 2022. Warrants to purchase approximately 2,547 shares of common stock were exercised on a cashless, one-for-one basis during the three months ended September 30, 2021. Warrants to purchase approximately 1,984 shares and 4,032 shares of common stock were exercised on a cashless, one-for-one basis during the nine months ended September 30, 2022 and 2021, respectively. None of these warrants were forfeited during the three and nine months ended September 30, 2022 and 2021.

Warrants to purchase approximately 8,000 shares of the Company's common stock were outstanding as of September 30, 2022 and December 31, 2021. These warrants have an exercise price of \$2.91 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, 2022 and 2021.

8. 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, 2022 and 2021 and approximately \$0.4 million and \$0.3 million for the nine months ended September 30, 2022 and 2021, respectively.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development expenses	\$ 23,382	\$ 19,236	\$ 65,688	\$ 48,972
General and administrative expenses	113,982	91,895	327,141	248,365
	<u>\$ 137,364</u>	<u>\$ 111,131</u>	<u>\$ 392,829</u>	<u>\$ 297,337</u>

Employee Stock Options

During the nine months ended September 30, 2022, the Company granted 200,000 stock option awards to purchase shares of common stock. The weighted average grant date fair value per option share was \$0.99. Key assumptions used in the Black-Scholes option pricing model for options granted during the nine months ending September 30, 2022 were the Company's stock price, a risk free rate of 2.38%, an expected life of 5.88 years and an expected volatility rate of 126.32%. During the nine months ended September 30, 2021, the Company granted 200,000 stock option awards to purchase shares of common stock. The Company recognized a total of \$0.1 million of compensation expense related to employee stock options during each of the three months ended September 30, 2022 and 2021 and \$0.4 million and \$0.3 million during the nine months ended September 30, 2022 and 2021, respectively.

Non-Employee Stock Options

The Company did not grant any non-employee stock options during the nine months ended September 30, 2022 and 2021. The Company did not recognize any expense related to non-employee stock options during the three and nine months ended September 30, 2022 and 2021, respectively.

9. Income Taxes

During the three and nine months ended September 30, 2022 and 2021, 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 \$32.8 million and \$31.4 million as of September 30, 2022 and December 31, 2021, respectively.

As of September 30, 2022 and December 31, 2021, the Company did not record any unrecognized tax positions.

10. Commitments

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

	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Operating cash flow information:		
Cash paid for amounts included in the measurement of lease liabilities	\$ 27,043	\$ 26,199

Supplemental balance sheet information related to the Company’s operating leases is as follows:

		September 30,	
		2022	September 30, 2021
Balance Sheet Classification			
Right-of-use assets - ST	Prepaid expenses and other	\$	– \$ 36,326
Right-of-use assets - LT	Other assets	\$	– \$ –
Current lease liabilities	Accrued expenses and other current liabilities	\$	– \$ 36,326
Non-current lease liabilities	Other long-term liabilities	\$	– \$ –

11. 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, 2021, filed with the SEC on March 22, 2022, as amended on April 28, 2022.

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 a term of 15-months and accrued interest at a rate of 10% per annum. The Pharmsynthez Loan is guaranteed by all of the operating subsidiaries of Pharmsynthez, including SynBio and AS Kevelt (“Kevelt”), and is secured by all of the common and preferred stock of the Company owned by Pharmsynthez and SynBio. The Company recognized approximately \$12,000 of interest income related to this loan during the three months ended September 30, 2021 and approximately \$9,000 and \$35,000 of interest income related to this loan during the nine months ended September 30, 2022 and 2021, respectively. The Company did not recognize any interest income during the three months ended September 30, 2022 as Pharmsynthez informed the Company that it could not make interest payments commencing in the second quarter as a result of Russian sanctions imposed in response to sanctions from the U.S. and other countries, as discussed below.

Effective January 23, 2021, the Company entered into a First Amendment to Loan Agreement and Other Loan Documents with Pharmsynthez, Kevelt and SynBio (the “Pharmsynthez Loan Extension”) to modify the repayment terms and maturity of the Pharmsynthez Loan to January 2022. The terms of the Pharmsynthez Loan Extension called for two (2) equal monthly principal payments of \$25,000 in each of January 23, 2021 and February 28, 2021 and the payment of all outstanding accrued interest in six (6) equal monthly installments from January 31, 2021 through June 30, 2021. In addition, the Pharmsynthez Loan Extension required monthly interest payments and the repayment of the remaining principal amount in six (6) equal monthly installments from August 2021 through January 2022.

Effective August 31, 2021, the Company entered into a Second Amendment to Loan Agreement and Other Loan Documents with Pharmsynthez, Kevelt and SynBio (the “Second Pharmsynthez Loan Extension”) to modify the repayment terms and maturity of the Pharmsynthez Loan to July 2022. The terms of the Second Pharmsynthez Loan Extension called for an upfront fee of \$12,500 and two (2) equal monthly principal payments of \$25,000 on September 30, 2021 and October 31, 2021. In addition, the Second Pharmsynthez Loan Extension required monthly interest payments and the repayment of the remaining principal amount in six (6) equal monthly installments from February 2022 through July 2022. All other terms of the Pharmsynthez Loan, as amended, remained in effect. All required payments under the Second Pharmsynthez Loan Extension had been made through January 31, 2022. In February 2022, the Company received a request from Pharmsynthez to further extend the principal repayments and the maturity of the loan.

Subsequent to quarter end, the Company entered into a Third Amendment to Loan Agreement and Other Loan Documents with Pharmsynthez, Kevelt and SynBio dated October 31, 2022 (the “Third Pharmsynthez Loan Extension”) primarily to modify the repayment terms and maturity of the Pharmsynthez Loan to May 31, 2023. The terms of the Third Pharmsynthez Loan Extension require certain payments of principal, interest and fees at the signing of the Third Pharmsynthez Loan Extension. In addition, the Third Pharmsynthez Loan Extension requires the repayment of the remaining principal amount, plus interest, in seven (7) monthly installments from November 30, 2022 through May 31, 2023 as well as certain other terms and conditions. All other terms of the Pharmsynthez Loan, as amended, remained in effect. As the payments required under the Third Pharmsynthez Loan Extension have not been received to date and as a result of the ongoing economic uncertainty due to the conflict between Russia and Ukraine and associated sanctions imposed by the U.S. and other countries in response, the Company has classified the loan receivable as long-term as of September 30, 2022 and December 31, 2021. The Company assessed the collectability of the loan and determined that the U.S.-based collateral held by the Company, consisting of all of the common and preferred stock of the Company owned by Pharmsynthez and SynBio, was adequate to support the repayment of the outstanding principal balance. As of September 30, 2022 and December 31, 2021, approximately \$0.4 million was included in other assets on the condensed consolidated balance sheet.

In April 2022, the Company entered into Exclusive License and Sublicense Agreements with CLS as described in Note 5. One of the Company’s directors, Roger Kornberg, is a member of the scientific advisory board of CLS, however, Mr. Kornberg does not own any equity of CLS and is not receiving any economic benefit as a result of the transactions contemplated by the License Agreement and Sublicense Agreement. Mr. Adam Logal, one of our directors, is Senior Vice President, Chief Financial Officer, Chief Accounting Officer and Treasurer of OPKO.

12. 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 other than described in Notes 5 and 11, there were no such events requiring recognition or disclosure in the financial statements.

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 anticipated effects and duration of the novel 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; the uncertainty due to 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”) oncology 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 acquired technology; the development of the XCART™ Chimeric Antigen Receptor (“CAR”) T cell technology and plans to develop cell-based therapeutics by targeting the unique B cell receptor on the surface of an individual patient’s malignant tumor cells for the treatment of B-cell lymphomas; and our expectations regarding our PolyXen® platform, including concerning our plans to leverage the platform by partnering with biotechnology and pharmaceutical companies and its application to protein or peptide therapeutics and its application to improve the half-life and other pharmaceutical properties of next-generation biologic drugs.

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;
- our need to raise additional working capital in the future for the purpose of further developing our DNase technology 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;
- 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;
- 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. The Company's DNase platform is designed to improve outcomes of existing treatments, including immunotherapies, by targeting NETs. We licensed the DNase oncology platform in April 2022 and expect to prioritize our efforts and resources on the development of this newly acquired technology. 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 in the U.S. by the Food and Drug Administration ("FDA") nor in any other 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, 2022, was on the acquisition and advancing of our DNase oncology platform and on the development of our XCART platform technology.

Effects of the COVID-19 Pandemic

During March 2020, a global pandemic was declared by the World Health Organization related to the rapidly growing outbreak of a novel strain of coronavirus, or COVID-19. The pandemic has significantly affected economic conditions in the U.S., accelerating during the first half of March 2020 and continuing throughout 2021 and into 2022, as federal, state and local governments reacted to the public health crisis with mitigation measures, creating significant uncertainties in the U.S. economy. We continue to evaluate the effects of the COVID-19 pandemic on our business, and while there has been no significant impact to our operations to date despite social distancing and other measures taken in response to the pandemic, the ultimate impact of the COVID-19 pandemic on our results of operations and financial condition is dependent on future developments, including the duration of the pandemic and the related extent of its severity, the pace and rate at which vaccines are administered, and the continued emergence of new strains of COVID-19, such as the Delta and Omicron variants and any subvariants, as well as its impact on macroeconomic conditions, which are uncertain and cannot be predicted at this time. If the global response to contain the COVID-19 pandemic escalates further or is unsuccessful, or if governmental decisions to ease pandemic related restrictions are ineffective, premature or counterproductive, we could experience a material adverse effect on our business, financial condition, results of operations and cash flows.

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, 2022 and 2021

The comparison of our historical results of operations for the fiscal quarter ended September 30, 2022 to the fiscal quarter ended September 30, 2021 is as follows:

Description	Quarter Ended September 30, 2022	Quarter Ended September 30, 2021	Increase (Decrease)	Percentage Change
Revenues:				
Royalty revenue	\$ 414,250	\$ 349,269	\$ 64,981	18.6%
Operating costs and expenses:				
Research and development	(398,803)	(780,153)	(381,350)	(48.9)
General and administrative	(863,233)	(945,115)	(81,882)	(8.7)
Total operating costs and expenses	<u>(1,262,036)</u>	<u>(1,725,268)</u>	<u>(463,232)</u>	<u>(26.9)</u>
Loss from operations	(847,786)	(1,375,999)	(528,213)	(38.4)
Other income (expense):				
Other expense	(1,706)	(2,906)	(1,200)	(41.3)
Interest income, net	45,475	28,029	17,446	62.2
Net loss	<u>\$ (804,017)</u>	<u>\$ (1,350,876)</u>	<u>\$ (546,859)</u>	<u>(40.5)</u>

Revenue

Revenue for the three months ended September 30, 2022 increased by \$0.1 million, or 18.6%, to \$0.4 million from approximately \$0.3 million for the three months ended September 30, 2021. This increase represents an increase in royalty revenue related to our sublicense agreement with Takeda Pharmaceuticals Co. Ltd. ("Takeda") for the three months ended September 30, 2022 as compared to the same period in 2021 as Takeda's sublicensee continued its worldwide launch of the product.

Research and Development Expenses

Research & development ("R&D") expenses for the three months ended September 30, 2022 decreased by \$0.4 million, or 48.9% to \$0.4 million from \$0.8 million in the comparable quarter in 2021. The table below sets forth the R&D costs incurred by the Company by category of expense for the quarters ended September 30, 2022 and 2021:

Category of Expense	Quarter Ended,	
	September 30, 2022	September 30, 2021
Outside services and contract research organizations	\$ 214,453	\$ 607,967
Salaries and wages	112,875	102,404
Share-based expense	23,382	19,236
Other	48,093	50,546
Total research and development expense	<u>\$ 398,803</u>	<u>\$ 780,153</u>

The decrease in outside services and contract research organizations expense was primarily due to decreased spending related to our XCART platform technology partially offset by spending related to our DNase oncology platform during the three months ended September 30, 2022 as compared to the same period in the prior year. Costs related to our XCART program were significantly lower for the three months ended September 30, 2022 as compared to the same period in 2021 as we prioritized our R&D efforts and resources on our newly acquired DNase oncology platform.

General and Administrative Expenses

General and administrative expenses for the three months ended September 30, 2022 decreased by approximately \$82,000, or 8.7%, to approximately \$863,000 from approximately \$945,000 in the comparable quarter in 2021. The decrease was primarily due to a decrease in costs related to our intellectual property during the three months ended September 30, 2022 compared to the same period in 2021.

Other Expense

Other expense was approximately \$1,700 for the three months ended September 30, 2022 compared to approximately \$2,900 of other expense for the same period in 2021. This decrease in other expense was primarily related to changes in foreign currency exchange rates during the three months ended September 30, 2022 as compared to the same period in 2021.

Interest Income

Interest income increased to approximately \$45,000 during the three months ended September 30, 2022 as compared to approximately \$28,000 for the same period in the prior year. This increase is primarily due to higher interest rates on invested funds during the third quarter of 2022 as compared to the same period in the prior year.

Comparison of Nine Months Ended September 30, 2022 and 2021

The comparison of our historical results of operations for the nine months ended September 30, 2022 to the nine months ended September 30, 2021 is as follows:

Description	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021	Increase (Decrease)	Percentage Change
Revenues:				
Royalty revenue	\$ 1,219,953	\$ 828,088	\$ 391,865	47.3%
Operating costs and expenses:				
Research and development	(3,577,701)	(1,934,432)	1,643,269	84.9
General and administrative	(2,796,832)	(2,766,397)	30,435	1.1
Total operating costs and expenses	(6,374,533)	(4,700,829)	1,673,704	35.6
Loss from operations	(5,154,580)	(3,872,741)	1,281,839	33.1
Other income (expense):				
Other expense	(2,583)	(1,784)	799	44.8
Interest income, net	87,345	71,026	16,319	23.0
Net loss	\$ (5,069,818)	\$ (3,803,499)	\$ 1,266,319	33.3

Revenue

Revenue for the nine months ended September 30, 2022 increased by \$0.4 million, or 47.3%, to \$1.2 million from approximately \$0.8 million for the nine months ended September 30, 2021. This increase represents an increase in royalty revenue related to our sublicense agreement with Takeda as compared to the same period in 2021, as the sublicensee continued its worldwide launch of the product.

Research and Development Expenses

Overall, R&D expenses for the nine months ended September 30, 2022 increased by \$1.6 million, or 84.9% to \$3.6 million from \$1.9 million in the comparable period in 2021 primarily due to 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 2021. Excluding the \$1.3 million of IPR&D expense from total R&D expense of \$3.6 million, R&D expenses increased approximately \$0.3 million, or 17.5% to \$2.3 million for the nine months ended September 30, 2022, from \$1.9 million for the nine months ended September 30, 2021. The table below sets forth the R&D costs incurred by us, by category of expense, for the nine months ended September 30, 2022 and 2021:

Category of Expense	Nine Months Ended,	
	September 30, 2022	September 30, 2021
IPR&D expense	\$ 1,305,000	\$ –
Outside services and contract research organizations	1,751,134	1,418,980
Salaries and wages	345,232	341,199
Share-based expense	65,688	48,972
Other	110,647	125,281
Total research and development expense	<u>\$ 3,577,701</u>	<u>\$ 1,934,432</u>

The increase in outside services and contract research organizations expense was primarily due to increased spending in connection with the acquisition and our initial development efforts related to our DNase oncology platform during the nine months ended September 30, 2022 as compared to the same period in the prior year.

General and Administrative Expenses

General and administrative expenses for the nine months ended September 30, 2022 was \$2.8 million, increasing slightly by approximately \$30,000, or 1.1%, compared to the same period in the prior year. The increase was primarily due to an increase in legal costs related to the licensing of the DNase oncology platform from CLS during the nine months ended September 30, 2022 compared to the same period in 2021, substantially offset by decreased spend on intellectual property and decreased consulting costs.

Other Expense

Other expense was approximately \$2,600 for the nine months ended September 30, 2022 compared to other expense of approximately \$1,800 for the same period in 2021. This increase in other expense was primarily related to changes in foreign currency exchange rates during the nine months ended September 30, 2022 as compared to the same period in 2021.

Interest Income

Interest income increased to approximately \$87,000 during the nine months ended September 30, 2022 as compared to approximately \$71,000 for the same period in the prior year. This increase is primarily due to an increase in interest income on invested funds due to higher interest rates on invested funds during the first nine months of 2022 compared to the same period in 2021. This increase was partially offset by a decrease in interest income on the Pharmsynthez Loan.

Liquidity and Capital Resources

We incurred a net loss of approximately \$5.1 million for the nine months ended September 30, 2022. We had an accumulated deficit of approximately \$187.6 million at September 30, 2022, as compared to an accumulated deficit of approximately \$182.5 million at December 31, 2021. Working capital was approximately \$13.1 million at September 30, 2022, and \$17.3 million at December 31, 2021, respectively. During the nine months ended September 30, 2022, our working capital decreased by \$4.2 million primarily due to our net loss for the nine months ended September 30, 2022 and cash used of \$0.5 million to obtain a license to the DNase oncology platform. Our principal source of liquidity consists of cash. At September 30, 2022, we had approximately \$13.8 million in cash and \$1.1 million in current liabilities. At December 31, 2021, we had approximately \$18.2 million in cash and \$1.4 million in current liabilities.

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 into the first quarter of 2024. 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 the Nasdaq Stock Market (“Nasdaq”), and factors related to financial, economic, geo-political, industry and market conditions, many of which are beyond our control. The capital markets for the biotech industry can be highly volatile, which make the terms, timing and extent of any future financing uncertain. 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 are not in compliance with the minimum bid price requirement for continued inclusion on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(2) (the “Bid Price Requirement”). The Notice has no immediate effect on the listing of our common stock on the Nasdaq Capital Market. Under the Nasdaq Listing Rules, we have 180 calendar days from the date of the Notice to regain compliance with the Bid Price Requirement. Accordingly, we have until November 30, 2022 to regain compliance with the Bid Price Requirement and may be eligible for an additional 180 calendar day compliance period if certain other criteria are met.

Cash Flows from Operating Activities

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 used in operating activities for the nine months ended September 30, 2021 totaled approximately \$3.3 million, which was primarily due to our net loss for the period, partially offset by non-cash charges associated with share-based expense.

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, 2021.

Cash Flow from Financing Activities

There were no cash flows from financing activities for the nine months ended September 30, 2022. Cash flows from financing activities for the nine months ended September 30, 2021 totaled approximately \$11.5 million representing net proceeds from our private placement in July 2021.

Contractual Obligations and Commitments

As of September 30, 2022, 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, 2021, filed with the SEC on March 22, 2022, as amended on April 28, 2022.

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, changes 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, 2021, filed with the SEC on March 22, 2022, as amended on April 28, 2022, for a discussion of recent accounting standards.

Critical Accounting Policies and Estimates

Our condensed consolidated financial statements are prepared in accordance with U.S. GAAP. 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. Our actual results may differ from these estimates. There have been no material changes in our critical accounting policies and estimates from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on March 22, 2022, as amended on April 28, 2022.

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, 2021 filed with the SEC on March 22, 2022, as amended on April 28, 2022 other than as set forth below.

Risks Related to Our Financial Condition and Capital Requirements

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

We are a clinical-stage biopharmaceutical company with a limited operating history. Pharmaceutical product and technology development is a highly speculative undertaking and involves a substantial degree of risk. To date, we have focused primarily on developing XCART and researching additional drug candidates. We have no products approved for commercial sale and have generated only limited revenue to date. Due to capital constraints in 2021, we focused solely on pre-clinical development efforts associated with our XCART technology. With the licensing of the DNase oncology platform from CLS in April 2022, our primary focus will be on advancing that technology via partnering opportunities or through regulatory approval and commercialization, and we will continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we have never been profitable and we may not achieve profitability in the foreseeable future, if at all. Our ability to generate profits in the future will depend on a number of factors, including:

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

As of September 30, 2022, we had an accumulated deficit of approximately \$187.6 million. We expect to incur additional significant operating losses as we expand our research and development activities and our commercialization, marketing and sales efforts. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. In addition, because of the numerous risks and uncertainties associated with pharmaceutical product development, including that our current drug candidates may not achieve the clinical endpoints of applicable trials, we are unable to predict the timing or amount of increased expenses and if or when we will achieve or maintain profitability. If we are unable to generate sufficient revenue from our operations to pay expenses or we are unable to obtain additional financing on commercially reasonable terms, our business, financial condition and results of operations may be materially and adversely affected.

Risks Related to the Discovery and Development of our Pharmaceutical Products

Our business is substantially dependent on the success of the DNase oncology platform.

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

Risks Related to Our Reliance on Third-Parties

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

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

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

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

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

Risks Related to Our Common Stock

Our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a de-listing of our common stock. Failure to regain compliance with Nasdaq listing rules could affect the market price of our Common Stock and liquidity and reduce our ability to raise capital.

Currently, our Common Stock trades on the Nasdaq Capital Market. On June 3, 2022, the Company received a written notification (the "Notice") from the Listing Qualifications Department of the NASDAQ Stock Market LLC ("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 is not in compliance with the minimum bid price requirement for continued inclusion on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(2) (the "Bid Price Requirement"). The Notice has no immediate effect on the listing of the Company's common stock on the Nasdaq Capital Market.

Under the Nasdaq Listing Rules, the Company has a period of 180 calendar days from the date of the Notice to regain compliance with the Bid Price Requirement. Accordingly, the Company has until November 30, 2022 (the "Compliance Date"), to regain compliance with the Bid Price Requirement. To regain compliance, the closing bid price of the Company's common stock must be at least \$1.00 for a minimum of ten consecutive business days prior to the Compliance Date. In the event the Company does not regain compliance by the Compliance Date, the Company may be eligible for an additional 180 calendar day compliance period. To qualify for this second compliance period, the Company will be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the Bid Price Requirement, and will need to provide written notice of its intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary.

The Company intends to monitor the closing bid price of its common stock and may, if appropriate, consider available options to regain compliance with the Bid Price Requirement. However, there can be no assurance that the Company will be able to regain compliance with the Bid Price Requirement, or will otherwise be in compliance with other Nasdaq Listing Rules. If we fail to regain compliance with the Nasdaq Listing Rules, including the Bid Price Requirement, we could be delisted and our stock would be considered a penny stock under regulations of the SEC, and would therefore be subject to rules that impose additional sales practice requirements on broker-dealers who sell our securities. The additional burdens imposed upon broker-dealers by these requirements could discourage broker-dealers from effecting transactions in our common stock, which could severely limit the market liquidity of our common stock and stockholder's ability to sell our securities in the secondary market. If our common stock were to be delisted from the NASDAQ Capital Market, the liquidity of our common stock would be materially affected, which would decrease the attractiveness of our common stock to investors and result in a decline in the market price of our common stock. Also, it may be difficult for us to raise additional capital if we are not listed on a major exchange.

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*	<u>Certification of Jeffrey F. Eisenberg, Principal Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>
31.2*	<u>Certification of James Parslow, Principal Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>
32.1**	<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>
101*	The following financial statements from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, 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.
#	Portions of this exhibit, marked by brackets and asterisks, have been omitted pursuant to Item 601(b)(10) of Regulation S-K under the Securities Act of 1933, as amended, because they are both (i) not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed. The registrant undertakes to promptly provide an unredacted copy of the exhibit on a supplemental basis, if requested by the Commission or its staff.

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, 2022

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, 2022

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, 2022

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, 2022, 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, 2022

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 9th day of November 2022.

/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.”