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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 March 31, 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.)**

40 Speen Street, Suite 102
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 LLC
Purchase Warrants	XBIOW	The Nasdaq Stock Market LLC

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 May 6, 2022, the number of outstanding shares of the registrant's common stock was 14,316,596.

XENETIC BIOSCIENCES, INC.
FORM 10-Q
QUARTERLY PERIOD ENDED MARCH 31, 2022

PART I – FINANCIAL INFORMATION

ITEM 1 - FINANCIAL STATEMENTS

XENETIC BIOSCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2022 (Unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash	$ 16,156,339	$ 18,244,030
Prepaid expenses and other	732,368	479,399
Total current assets	16,888,707	18,723,429
Other assets	1,094,802	1,091,931
Total assets	$ 17,983,509	$ 19,815,360
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 280,680	$ 362,470
Accrued expenses and other current liabilities	782,588	1,058,633
Total current liabilities	1,063,268	1,421,103
Total liabilities	1,063,268	1,421,103
Commitments and contingencies (Note 9)	–	–
Stockholders' equity:		
Preferred stock, 10,000,000 shares authorized		
Series B, $0.001 par value: 1,804,394 shares issued and outstanding as of March 31, 2022 and December 31, 2021	1,804	1,804
Series A, $0.001 par value: 970,000 shares issued and outstanding as of March 31, 2022 and December 31, 2021	970	970
Common stock, $0.001 par value; 50,000,000 shares authorized as of March 31, 2022 and December 31, 2021; 13,468,287 and 13,466,603 shares issued as of March 31, 2022 and December 31, 2021, respectively; 13,441,296 and 13,439,612 shares outstanding as of March 31, 2022 and December 31, 2021, respectively	13,467	13,465
Additional paid in capital	206,072,322	205,952,729
Accumulated deficit	(184,140,876)	(182,547,265)
Accumulated other comprehensive income	253,734	253,734
Treasury stock	(5,281,180)	(5,281,180)
Total stockholders' equity	16,920,241	18,394,257
Total liabilities and stockholders' equity	$ 17,983,509	$ 19,815,360

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 March 31,	
	2022	**2021**
Revenue:		
Royalty revenue	$ 388,993	$ 191,216
Total revenue	388,993	191,216
Operating costs and expenses:		
Research and development	(1,101,399)	(629,729)
General and administrative	(907,309)	(930,578)
Total operating costs and expenses	(2,008,708)	(1,560,307)
Loss from operations	(1,619,715)	(1,369,091)
Other income:		
Other income	199	884
Interest income	25,905	22,262
Total other income	26,104	23,146
Net loss	$ (1,593,611)	$ (1,345,945)
Basic and diluted loss per share	$ (0.12)	$ (0.15)
Weighted-average shares of common stock outstanding, basic and diluted	13,440,057	8,746,263

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 MARCH 31, 2022

	Preferred Stock		Common Stock						
	Number of Shares	Par Value ($0.001)	Number of Shares	Par Value ($0.001)	Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Treasury Stock	Total Stockholders' Equity
Balance as of January 1, 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
Share-based expense	–	–	–	–	119,595	–	–	–	119,595
Exercise of purchase warrants	–	–	1,684	2	(2)	–	–	–	–
Net loss	–	–	–	–	–	(1,593,611)	–	–	(1,593,611)
Balance as of March 31, 2022	2,774,394	$ 2,774	13,468,287	$ 13,467	$ 206,072,322	$ (184,140,876)	$ 253,734	$ (5,281,180)	$ 16,920,241

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 MARCH 31, 2021

	Preferred Stock		Common Stock						
	Number of Shares	Par Value ($0.001)	Number of Shares	Par Value ($0.001)	Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Treasury Stock	Total Stockholders' Equity
Balance as of January 1, 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
Share-based expense	–	–	–	–	76,284	–	–	–	76,284
Exercise of purchase warrants	–	–	1,485	1	(1)	–	–	–	–
Net loss	–	–	–	–	–	(1,345,945)	–	–	(1,345,945)
Balance as of March 31, 2021	2,774,394	$ 2,774	8,773,683	$ 8,772	$ 194,209,794	$ (178,248,031)	$ 253,734	$ (5,281,180)	$ 10,945,863

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

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

	Three Months Ended March 31,	
	2022	**2021**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (1,593,611)	$ (1,345,945)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of right of use asset	9,475	8,413
Share-based expense	119,595	76,284
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(265,315)	(109,728)
Accounts payable, accrued expenses and other liabilities	(357,835)	(148,212)
Net cash used in operating activities	(2,087,691)	(1,519,188)
Net change in cash	(2,087,691)	(1,519,188)
Cash at beginning of period	18,244,030	11,527,552
Cash at end of period	$ 16,156,339	$ 10,008,364
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash paid for interest	$ –	$ –
SUPPLEMENTAL SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Issuance of common stock from cashless exercise of purchase warrants	$ 2	$ 1

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

1. The Company

Background

Xenetic Biosciences, Inc. ("Xenetic" or the "Company"), incorporated in the state of Nevada and based in Framingham, Massachusetts, is a biopharmaceutical company focused on advancing innovative immune-oncology technologies addressing hard to treat oncology indications. The Company's Deoxyribonuclease ("DNase") oncology platform, in development for the treatment of solid tumors, is aimed at improving outcomes of existing treatments, including immunotherapies, by targeting Neutrophil Extracellular Traps ("NETs"). The Company is also developing its personalized 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. On April 26, 2022, the Company entered into exclusive license and sublicense agreements with CLS Therapeutics Ltd. ("CLS") to develop its interventional DNase based oncology platform as more fully described in Note 11.

Additionally, Xenetic is leveraging its proprietary drug delivery platform, PolyXen®, by partnering with biotechnology and pharmaceutical companies. PolyXen is an enabling platform technology which can be applied to protein or peptide therapeutics. PolyXen has demonstrated its ability to improve the half-life and other pharmacological properties of next-generation biologic drugs. The Company receives royalty payments under an exclusive license arrangement in the field of blood coagulation disorders.

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

The Company, directly or indirectly, through its wholly-owned subsidiaries, Hesperix S.A. ("Hesperix") and Xenetic Biosciences (U.K.) Limited ("Xenetic UK"), and the wholly-owned subsidiaries of Xenetic UK, Lipoxen Technologies Limited ("Lipoxen"), Xenetic Bioscience, Incorporated and SymbioTec, GmbH ("SymbioTec"), own various United States ("U.S.") federal trademark registrations and applications along with unregistered trademarks and service marks, including but not limited to XCART, OncoHist™, PolyXen, ErepoXen™, and ImuXen™, which 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 second quarter of 2023. 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, and factors related to financial, economic, geo-political, industry and market conditions, many of which are beyond its control. The capital markets for the biotech industry can be highly volatile, which make the terms, timing and extent of any future financing uncertain.

2. Impact of 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 2020 and 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.

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 months ended March 31, 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. We are currently evaluating the impact of adoption, but we do not anticipate that it will have a material effect on our 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 and its collaborative partners continue to engage in research and development activities with no resultant commercial products through March 31, 2022. No amounts were recognized as revenue related to the Serum Institute, Pharmsynthez or SynBio agreements during the three months ended March 31, 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 $0.2 million were recorded as revenue by the Company during the three months ended March 31, 2022 and 2021, respectively, and are based on single digit royalties on net sales of certain covered products. The Company's policy is to recognize royalty payments as revenue when they are reliably measurable, which is upon receipt of reports from Takeda. The Company receives these reports in the quarter subsequent to the actual sublicensee sales. At the time the revenue was received, there were no remaining performance obligations and all other revenue recognition criteria were met.

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 has 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 is payable by the Company to Scripps Research on a quarterly basis in accordance with a negotiated budget, which provides 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. The Company has paid $2.4 million to Scripps Research under this agreement through March 31, 2022. As of March 31, 2022 and 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.

5. Fair Value Measurements

Accounting Standards Codification Topic 820, *Fair Value Measurement,* defines fair value as the price that would be received to sell an asset or be paid to transfer a liability in an orderly transaction between market participants at the measurement date. The Company applies the following fair value hierarchy, which prioritizes the inputs used to measure fair value into three levels and bases the categorization within the hierarchy upon the lowest level of input that is available and significant to the fair value measurement. Level 1 inputs are quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date. Level 2 utilizes quoted market prices in markets that are not active, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency. Level 3 inputs are unobservable inputs for the asset or liability in which there is little, if any, market activity for the asset or liability at the measurement date. As of March 31, 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 months ended March 31, 2022 and 2021.

6. 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 months ended March 31, 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 March 31, 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 March 31, 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 "XBIOW." 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. Warrants to purchase approximately 1,684 shares and 1,485 shares of common stock were exercised on a cashless, one-for-one basis during the three months ended March 31, 2022 and 2021, respectively. None of these warrants were forfeited during the three months ended March 31, 2022 and 2021.

Warrants to purchase approximately 8,000 shares of the Company's common stock were outstanding as of March 31, 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 months ended March 31, 2022 and 2021.

7. Share-Based Expense

Total share-based expense related to stock options and restricted stock units ("RSUs") was approximately $0.1 million during each of the three months ended March 31, 2022 and 2021.

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

	Three Months Ended March 31,	
	2022	2021
Research and development expenses	$ 19,178	$ 10,710
General and administrative expenses	100,417	65,574
	$ 119,595	$ 76,284

Employee Stock Options

During the three months ended March 31, 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 three months ending March 31, 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 three months ended March 31, 2021, the Company granted 200,000 stock option awards to purchase shares of common stock. The Company recognized a total of approximately $0.1 million of compensation expense related to employee stock options during each of the three months ended March 31, 2022 and 2021, respectively. No employee stock options or RSUs were exercised and none expired during the three months ended March 31, 2022 and 2021.

Non-Employee Stock Options

There were no non-employee stock options granted or exercised and none expired during the three months ended March 31, 2022 and 2021, respectively. The Company did not recognize any expense related to non-employee stock options during the three months ended March 31, 2022 and 2021, respectively.

8. Income Taxes

During the three months ended March 31, 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 $31.8 million and $31.4 million as of March 31, 2022 and December 31, 2021, respectively.

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

9. Commitments

Supplemental cash flow information and non-cash activity related to our operating leases are as follows:

	Three Months Ended March 31, 2022	Three Months Ended March 31, 2021
Operating cash flow information:		
Cash paid for amounts included in the measurement of lease liabilities	$ 9,475	$ 8,413

Supplemental balance sheet information related to our operating leases is as follows:

	Balance Sheet Classification	March 31, 2022	March 31, 2021
Right-of-use assets - ST	Prepaid expenses and other	$ 17,568	$ 36,545
Right-of-use assets - LT	Other assets	$ –	$ 17,568
Current lease liabilities	Accrued expenses and other current liabilities	$ 17,568	$ 36,545
Non-current lease liabilities	Other long-term liabilities	$ –	$ 17,568

10. Related Party Transactions

The Company has entered into various research, development, license and supply agreements with Serum Institute and Pharmsynthez, each a related party whose relationship has not materially changed from that disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 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, and is secured by all of the common and preferred stock of the Company owned by Pharmsynthez and SynBio. The Company recognized approximately $9,000 and $12,000 of interest income related to this loan during the three months ended March 31, 2022 and 2021, respectively.

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, remain 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 until September 2022. The Company agreed to extend the maturity date, although final terms of such extension are under negotiation. All other terms of the Pharmsynthez Loan, as amended, are expected to remain in effect. As a result of this request and the current 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 March 31, 2022 and December 31, 2021. The Company assessed the collectability of the loan and determined that the 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 outstanding principal balance. As of March 31, 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 agreed to license certain technology from CLS as described in Note 11. 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 Health, Inc. ("OPKO").

11. Subsequent Events

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

Exclusive Sublicense Agreement

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

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 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.

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 need to raise additional working capital in the future for the purpose of further developing our DNase and XCART technologies 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 and XCART technologies;
- 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 oncology indications. The Company's DNase oncology platform, in development for the treatment of solid tumors, is aimed at improving outcomes of existing treatments, including immunotherapies, by targeting NETs. The Company is also developing its personalized CAR T platform technology, XCART™, to develop cell-based therapeutics targeting the unique B-cell receptor on the surface of an individual patient's malignant tumor cells for the treatment of B-cell lymphomas. We acquired 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 are leveraging our proprietary drug delivery platform, PolyXen, by partnering with biotechnology and pharmaceutical companies. PolyXen is an enabling platform technology which can be applied to protein or peptide therapeutics. It employs the natural polymer polysialic acid ("PSA") to prolong a drug's circulating half-life and potentially improve other pharmacological properties.

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 development efforts during the three months ended March 31, 2022, was on advancing 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 react 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 our operations were not materially affected during the year ended December 31, 2021 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, 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.

RESULTS OF OPERATIONS

Comparison of Quarter Ended March 31, 2022 and 2021

The comparison of our historical results of operations for the fiscal quarter ended March 31, 2022 to the fiscal quarter ended March 31, 2021 is as follows:

Description	Quarter Ended March 31, 2022	Quarter Ended March 31, 2021	Increase (Decrease)	Percentage Change
Revenue:				
Royalty revenue	$ 388,993	$ 191,216	$ 197,777	103.4
Operating costs and expenses:				
Research and development	(1,101,399)	(629,729)	471,670	74.9
General and administrative	(907,309)	(930,578)	(23,269)	(2.5)
Total operating costs and expenses	(2,008,708)	(1,560,307)	448,401	28.7
Loss from operations	(1,619,715)	(1,369,091)	250,624	18.3
Other income:				
Other income	199	884	(685)	(77.5)
Interest income	25,905	22,262	3,643	16.4
Net loss	$ (1,593,611)	$ (1,345,945)	$ 247,666	18.4

Revenue

Revenue for the three months ended March 31, 2022 increased by $0.2 million, or 103.4%, to $0.4 million from approximately $0.2 million for the three months ended March 31, 2021. This increase represents an increase in royalty revenue related to our sublicense agreement with Takeda Pharmaceuticals Co. Ltd. (“Takeda”) as compared to the same period in 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 March 31, 2022 increased by $0.5 million, or 74.9%, to approximately $1.1 million from approximately $0.6 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 March 31, 2022 and 2021:

	Quarter Ended	
Category of Expense	March 31, 2022	March 31, 2021
Outside services and contract research organizations	$ 833,670	$ 452,625
Personnel costs	111,984	130,047
Share-based expense	19,178	10,710
Other	136,567	36,347
Total research and development expense	$ 1,101,399	$ 629,729

The increase in outside services and contract research organizations expense was primarily due to increased spending related to our XCART platform technology during the three months ended March 31, 2022 as compared to the same period in the prior year. Costs related to our XCART program were significantly higher in 2022 as compared to the same period in 2021 as we continued to invest in our U.S. pre-clinical developments efforts to advance the technology. The increase in other expense was due to consulting costs incurred during the first quarter of 2022 in connection with the licensing of the DNase oncology platform from CLS.

General and Administrative Expenses

General and administrative expenses for the three months ended March 31, 2022 decreased by approximately $23,000, or 2.5%, to approximately $0.9 million from approximately $0.9 million in the comparable quarter in 2021. The decrease was primarily due to lower consulting costs offset by an increase in legal costs related to the licensing of the DNase oncology platform from CLS during the three months ended March 31, 2022 compared to the same period in 2021.

Other Income

Other income was approximately $200 for the three months ended March 31, 2022 compared to approximately $900 of other income for the same period in 2021. This decrease in other income was primarily related to changes in foreign currency exchange rates during the three months ended March 31, 2022 as compared to the same period in 2021.

Interest Income

Interest income increased to approximately $26,000 during the three months ended March 31, 2022 as compared to approximately $22,000 for the same period in the prior year. This increase is primarily due to a higher cash balance during the first quarter of 2022 compared to the same period in 2021.

Liquidity and Capital Resources

We incurred a net loss of approximately $1.6 million for the three months ended March 31, 2022. We had an accumulated deficit of approximately $184.1 million at March 31, 2022, as compared to an accumulated deficit of approximately $182.5 million at December 31, 2021. Working capital was approximately $15.8 million at March 31, 2022, and $17.3 million at December 31, 2021, respectively. During the three months ended March 31, 2022, our working capital decreased by $1.5 million due to our net loss for the three months ended March 31, 2022. We expect to continue incurring losses for the foreseeable future and may need to raise additional capital or pursue other strategic alternatives in the long-term in order to continue the pursuit of our business plan.

Our principal source of liquidity consists of cash. At March 31, 2022, we had approximately $16.2 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 have historically relied upon sales of our equity securities to fund our operations. We expect the majority of our funding through equity or equity-linked instruments, debt financings, corporate collaborations, related party funding and/or licensing agreements to continue as a trend for the foreseeable future.

Management evaluates 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 second quarter of 2023. 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, and factors related to financial, economic, geo-political, industry and market conditions, many of which are beyond our control. The capital markets for the biotech industry can be highly volatile, which make the terms, timing and extent of any future financing uncertain.

Cash Flows from Operating Activities

Cash flows used in operating activities for the three months ended March 31, 2022 totaled approximately $2.1 million, which was primarily due to our net loss for the period, partially offset by non-cash charges associated with share-based expense. In addition, prepaid expenses increased and current liabilities decreased during the three months ended March 31, 2022. Cash flows used in operating activities for the three months ended March 31, 2021 totaled approximately $1.5 million, which was primarily due to our net loss for the period, offset by non-cash charges associated with share-based expense.

Cash Flows from Investing Activities

There were no cash flows from investing activities for the three months ended March 31, 2022 and 2021.

Cash Flow from Financing Activities

There were no cash flows from financing activities for the three months ended March 31, 2022 and 2021.

Contractual Obligations and Commitments

As of March 31, 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, change in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures, or capital resources.

Recent Accounting Standards

See Note 3 in our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on March 22, 2022, as amended on April 28, 2022, for a discussion of recent accounting standards.

Critical Accounting Estimates

Our condensed consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles. The preparation of our condensed consolidated financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenue, costs and expenses. We base our estimates and assumptions on historical experience and other factors that we believe to be reasonable under the circumstances. We evaluate our estimates and assumptions on an ongoing basis. The result of these evaluations forms the basis for making judgments about the carrying values of assets and liabilities and the reported amount of expenses that are not readily apparent from other sources. Because future events and their effects cannot be determined with certainty, actual results and outcomes may differ materially from our estimates, judgments and assumptions. There have been no material changes in our critical accounting estimates from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 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 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 March 31, 2022, we had an accumulated deficit of approximately $184.1 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.

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*	Certification of Jeffrey F. Eisenberg, Principal Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of James Parslow, Principal Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	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.
101*	The following financial statements from the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 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 XBRL and included in Exhibit 101).

* Filed herewith.

** Exhibit 32.1 is being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall such exhibits be deemed to be incorporated by reference in any registration statement or other document filed under the Securities Act of 1933, as amended or the Securities Exchange Act of 1934, as amended, except as otherwise stated in such filing.

SIGNATURES

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

XENETIC BIOSCIENCES, INC.

May 12, 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)

EXHIBIT 31.1

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: May 12, 2022

By: /s/ Jeffrey F. Eisenberg
Jeffrey F. Eisenberg
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

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: May 12, 2022

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

EXHIBIT 32.1

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 March 31, 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: May 12, 2022

In Witness Whereof, the undersigned have set their hands hereto as of the 12th day of May 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."