

**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, 2020

or

TRANSITION REPORTS PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the transition period from _____ to _____

Commission File Number: 001-37937

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

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

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

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

As of November 9, 2020, the number of outstanding shares of the registrant's common stock was 6,296,227.

XENETIC BIOSCIENCES, INC.
FORM 10-Q
QUARTERLY PERIOD ENDED SEPTEMBER 30, 2020

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PART I – FINANCIAL INFORMATION

ITEM 1 - FINANCIAL STATEMENTS

XENETIC BIOSCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2020 (Unaudited)	December 31, 2019
ASSETS		
Current assets:		
Cash	\$ 7,054,387	\$ 10,367,920
Prepaid expenses and other	937,596	722,079
Total current assets	<u>7,991,983</u>	<u>11,089,999</u>
Property and equipment, net	–	757
Indefinite-lived intangible assets	–	9,243,128
Other assets	704,431	1,213,042
Total assets	<u>\$ 8,696,414</u>	<u>\$ 21,546,926</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 251,033	\$ 931,128
Accrued expenses and other current liabilities	537,440	484,029
Total current liabilities	<u>788,473</u>	<u>1,415,157</u>
Deferred tax liability	–	2,918,518
Total liabilities	<u>788,473</u>	<u>4,333,675</u>
Commitments (Note 11)		
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, 2020 and December 31, 2019	1,804	1,804
Series A, \$0.001 par value: 970,000 shares issued and outstanding as of September 30, 2020 and December 31, 2019	970	970
Common stock, \$0.001 par value; 12,500,000 shares authorized as of September 30, 2020 and December 31, 2019; 6,323,218 and 6,092,432 shares issued as of September 30, 2020 and December 31, 2019, respectively; 6,296,227 and 6,065,441 shares outstanding as of September 30, 2020 and December 31, 2019, respectively	6,322	6,092
Additional paid in capital	188,628,352	188,240,451
Accumulated deficit	(175,702,061)	(166,008,620)
Accumulated other comprehensive income	253,734	253,734
Treasury stock	(5,281,180)	(5,281,180)
Total stockholders' equity	<u>7,907,941</u>	<u>17,213,251</u>
Total liabilities and stockholders' equity	<u>\$ 8,696,414</u>	<u>\$ 21,546,926</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 SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2020	2019	2020	2019
Revenue:				
Royalty revenue	\$ 115,934	\$ –	\$ 285,610	\$ –
Total revenue	<u>115,934</u>	<u>–</u>	<u>285,610</u>	<u>–</u>
Operating costs and expenses:				
Research and development	(573,061)	(3,520,638)	(1,240,612)	(4,471,939)
General and administrative	(804,149)	(2,142,505)	(2,519,515)	(3,896,657)
Asset impairment charges	(9,243,128)	(3,283,379)	(9,243,128)	(3,283,379)
Total operating costs and expenses	<u>(10,620,338)</u>	<u>(8,946,522)</u>	<u>(13,003,255)</u>	<u>(11,651,975)</u>
Loss from operations	<u>(10,504,404)</u>	<u>(8,946,522)</u>	<u>(12,717,645)</u>	<u>(11,651,975)</u>
Other income (expense):				
Other income (expense)	585	(223)	643	267
Interest income, net	24,931	46,617	105,043	46,930
Total other income	<u>25,516</u>	<u>46,394</u>	<u>105,686</u>	<u>47,197</u>
Loss before income taxes	(10,478,888)	(8,900,128)	(12,611,959)	(11,604,778)
Income tax benefit	2,918,518	–	2,918,518	–
Net loss	\$ (7,560,370)	\$ (8,900,128)	\$ (9,693,441)	\$ (11,604,778)
Deemed dividend	–	(1,404,932)	–	(5,284,379)
Net loss applicable to common stockholders	<u>\$ (7,560,370)</u>	<u>\$ (10,305,060)</u>	<u>\$ (9,693,441)</u>	<u>\$ (16,889,157)</u>
Basic and diluted net loss per share	<u>\$ (1.20)</u>	<u>\$ (2.67)</u>	<u>\$ (1.55)</u>	<u>\$ (9.07)</u>
Weighted-average shares of common stock outstanding, basic and diluted	<u>6,296,227</u>	<u>3,862,936</u>	<u>6,272,722</u>	<u>1,861,867</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, 2020

	<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, 2020	2,774,394	\$ 2,774	6,323,218	\$ 6,322	\$ 188,517,553	\$ (168,141,691)	\$ 253,734	\$ (5,281,180)	\$ 15,357,512
Share-based expense	-	-	-	-	110,799	-	-	-	110,799
Net loss	-	-	-	-	-	(7,560,370)	-	-	(7,560,370)
Balance as of September 30, 2020	<u>2,774,394</u>	<u>\$ 2,774</u>	<u>6,323,218</u>	<u>\$ 6,322</u>	<u>\$ 188,628,352</u>	<u>\$ (175,702,061)</u>	<u>\$ 253,734</u>	<u>\$ (5,281,180)</u>	<u>\$ 7,907,941</u>

NINE MONTHS ENDED SEPTEMBER 30, 2020

	<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, 2020	2,774,394	\$ 2,774	6,092,432	\$ 6,092	\$ 188,240,451	\$ (166,008,620)	\$ 253,734	\$ (5,281,180)	\$ 17,213,251
Issuance of common stock to vendor	-	-	1,188	1	(1)	-	-	-	-
Share-based expense	-	-	-	-	388,131	-	-	-	388,131
Exercise of purchase warrants	-	-	229,598	229	(229)	-	-	-	-
Net loss	-	-	-	-	-	(9,693,441)	-	-	(9,693,441)
Balance as of September 30, 2020	<u>2,774,394</u>	<u>\$ 2,774</u>	<u>6,323,218</u>	<u>\$ 6,322</u>	<u>\$ 188,628,352</u>	<u>\$ (175,702,061)</u>	<u>\$ 253,734</u>	<u>\$ (5,281,180)</u>	<u>\$ 7,907,941</u>

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

XENETIC BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(Unaudited)
THREE MONTHS ENDED SEPTEMBER 30, 2019

	Preferred Stock		Common Stock		Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Treasury Stock	Total Stockholders' Equity
	Number of Shares	Par Value (\$0.001)	Number of Shares	Par Value (\$0.001)					
Balance as of June 30, 2019	2,774,394	\$ 2,774	949,218	\$ 948	\$ 171,352,760	\$ (155,938,245)	\$ 253,734	\$ (5,281,180)	\$ 10,390,791
Issuance of common stock and warrants in July 2019 public offering, net of issuance costs	–	–	1,746,666	1,747	13,420,203	–	–	–	13,421,950
Issuance of common stock in connection with purchase of in-process research and development	–	–	624,995	625	3,030,601	–	–	–	3,031,226
Exercise of pre-funded warrants	–	–	450,000	450	4,050	–	–	–	4,500
Exercise of purchase warrants	–	–	1,889,602	1,890	(1,890)	–	–	–	–
Issuance of warrants in connection with reverse stock split	–	–	–	–	63,536	–	–	–	63,536
Deemed dividend related to Series B Preferred Stock down round provision	–	–	–	–	1,404,932	–	–	–	1,404,932
Accretion of deemed dividend related to Series B Preferred Stock down round provision	–	–	–	–	(1,404,932)	–	–	–	(1,404,932)
Share-based expense	–	–	–	–	232,437	–	–	–	232,437
Common stock awards to vendors	–	–	–	–	15,000	–	–	–	15,000
Net loss	–	–	–	–	–	(8,900,128)	–	–	(8,900,128)
Balance as of September 30, 2019	<u>2,774,394</u>	<u>\$ 2,774</u>	<u>5,660,481</u>	<u>\$ 5,660</u>	<u>\$ 188,116,697</u>	<u>\$ (164,838,373)</u>	<u>\$ 253,734</u>	<u>\$ (5,281,180)</u>	<u>\$ 18,259,312</u>

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

XENETIC BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(Unaudited)
NINE MONTHS ENDED SEPTEMBER 30, 2019

	Preferred Stock		Common Stock		Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Treasury Stock	Total Stockholders' Equity
	Number of Shares	Par Value (\$0.001)	Number of Shares	Par Value (\$0.001)					
Balance as of January 1, 2019	2,774,394	\$ 2,774	810,856	\$ 811	\$ 168,170,244	\$ (153,233,595)	\$ 253,734	\$ (5,281,180)	\$ 9,912,788
Issuance of common stock and warrants in March 2019 registered direct offering, net of issuance costs	–	–	86,667	87	2,698,963	–	–	–	2,699,050
Issuance of common stock and warrants in July 2019 public offering, net of issuance costs	–	–	1,746,666	1,747	13,420,203	–	–	–	13,421,950
Issuance of common stock in connection with purchase of in-process research and development	–	–	624,995	625	3,030,601	–	–	–	3,031,226
Exercise of pre-funded warrants	–	–	492,417	492	4,517	–	–	–	5,009
Exercise of purchase warrants	–	–	1,889,602	1,890	(1,890)	–	–	–	–
Issuance of common stock to vendor	–	–	7,836	7	(7)	–	–	–	–
Issuance of warrants in connection with reverse stock split	–	–	–	–	63,536	–	–	–	63,536
Issuance of common stock to adjust for reverse split rounding	–	–	1,442	1	(1)	–	–	–	–
Deemed dividend related to Series B Preferred Stock down round provision	–	–	–	–	5,284,379	–	–	–	5,284,379
Accretion of deemed dividend related to Series B Preferred Stock down round provision	–	–	–	–	(5,284,379)	–	–	–	(5,284,379)
Share-based expense	–	–	–	–	683,104	–	–	–	683,104
Common stock awards to vendors	–	–	–	–	47,427	–	–	–	47,427
Net loss	–	–	–	–	–	(11,604,778)	–	–	(11,604,778)
Balance as of September 30, 2019	<u>2,774,394</u>	<u>\$ 2,774</u>	<u>5,660,481</u>	<u>\$ 5,660</u>	<u>\$ 188,116,697</u>	<u>\$ (164,838,373)</u>	<u>\$ 253,734</u>	<u>\$ (5,281,180)</u>	<u>\$ 18,259,312</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,	
	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (9,693,441)	\$ (11,604,778)
Adjustments to reconcile net loss to net cash used in operating activities:		
Acquired in-process research and development	–	3,031,226
Asset impairment charges	9,243,128	3,283,379
Deferred income taxes	(2,918,518)	–
Depreciation	757	3,366
Amortization of right of use asset	20,042	16,629
Gain on sale of property and equipment	–	(2,000)
Gain on settlement with vendor	(143,639)	–
Share-based expense	388,131	683,104
Issuance of warrants in connection with reverse stock split	–	63,536
Vendor share-based expense	–	47,427
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	273,052	(297,712)
Accounts payable, accrued expenses and other liabilities	(483,045)	54,171
Net cash used in operating activities	(3,313,533)	(4,721,652)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sale of property and equipment	–	2,000
Net cash provided by investing activities	–	2,000
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from issuance of common stock and warrants in July 2019 public offering	–	13,421,950
Net proceeds from issuance of common stock and warrants in March 2019 registered direct offering	–	2,699,050
Proceeds from exercise of warrants	–	5,009
Net cash provided by financing activities	–	16,126,009
Net change in cash	(3,313,533)	11,406,357
Cash at beginning of period	10,367,920	638,115
Cash at end of period	\$ 7,054,387	\$ 12,044,472
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash paid for interest	\$ –	\$ 8
SUPPLEMENTAL SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Right of use asset acquired in exchange for lease liability	\$ –	\$ 43,330
Issuance of common stock to vendor	\$ 1	\$ 7
Issuance of common stock to acquire in-process research and development	\$ –	\$ 3,031,226
Issuance of common stock to adjust for Reverse Stock Split	\$ –	\$ 1
Issuance of common stock from cashless exercise of purchase warrants	\$ 229	\$ 1,890

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 progressing XCART™, a personalized Chimeric Antigen Receptor (“CAR”) T platform technology engineered to target patient- and tumor-specific neoantigens. The Company is initially advancing 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. The XCART technology, developed by the Scripps Research Institute in collaboration with the Shemyakin-Ovchinnikov Institute of Bioorganic Chemistry, is believed to have the potential to significantly enhance the safety and efficacy of cell therapy for B-cell lymphomas by generating patient- and tumor-specific CAR T cells.

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. It employs the natural polymer polysialic acid to prolong a drug’s circulating half-life and potentially improve other pharmacological properties. Xenetic incorporates its patented and proprietary technologies into a number of drug candidates currently under development with biotechnology and pharmaceutical industry collaborators to create what the Company believes will be the next-generation biologic drugs with improved pharmacological properties over existing therapeutics.

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 had an accumulated deficit of approximately \$175.7 million at September 30, 2020 as compared to an accumulated deficit of approximately \$166.0 million at December 31, 2019. Working capital was approximately \$7.2 million and \$9.7 million at September 30, 2020 and December 31, 2019, respectively. During the nine months ended September 30, 2020, our working capital decreased by \$2.5 million primarily due to our net loss for the nine months ended September 30, 2020. The Company expects to continue incurring losses for the foreseeable future and may need to raise additional capital or pursue other strategic alternatives in the near term in order to continue the pursuit of its business plan and 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. During 2019, the Company completed two stock offerings that resulted in \$16.1 million of net proceeds to the Company. The Company believes that its existing resources will be adequate to fund the Company's operations through mid-2021. However, the Company anticipates it may need additional capital in the near 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 and market conditions, many of which are beyond its control.

While these condensed consolidated financial statements have been prepared on a going concern basis, if the Company does not successfully raise additional working capital, there can be no assurance that the Company will be able to continue its operations and these conditions raise substantial doubt about its ability to continue as a going concern. Under such circumstances, the Company would have to further reduce the planned scale of, or possibly suspend, some or all of its pre-clinical development initiatives and clinical trials. In addition, the Company would have to continue to reduce its general and administrative and other operating expenses and delay or cease the purchase of clinical research services if and until the Company is able to obtain additional financing. The accompanying condensed consolidated financial statements do not include any adjustments related to the recoverability or classification of asset carrying amounts or the amounts and classification of liabilities that may result should the Company be unable to continue as a going concern.

2. Impact of COVID-19

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 and continuing into November, as federal, state and local governments react 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 is 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, 2019 filed with the SEC on March 26, 2020 and amended on April 29, 2020.

On June 25, 2019, the Company effected a reduction, on a 1 for 12 basis, in its authorized common stock, par value \$0.001, along with a corresponding and proportional decrease in the number of shares issued and outstanding (the "Reverse Stock Split"). On the effective date of the Reverse Stock Split, (i) every 12 shares of common stock were reduced to one share of common stock, with any fractional amounts rounded up to one share; (ii) the number of shares of common stock into which each outstanding warrant, restricted stock unit, or option to purchase common stock were proportionately reduced on the same basis as the common stock; (iii) the exercise price of each outstanding warrant or option to purchase common stock were proportionately increased on a 1 for 12 basis; and (iv) the number of shares of common stock into which each share of preferred stock could be converted were proportionately reduced on the same basis as the common stock. Unless otherwise indicated, all of the share numbers, share prices, and exercise prices have been adjusted, on a retroactive basis, to reflect this Reverse Stock Split.

Certain prior period amounts have been reclassified to conform to the presentation for the current period.

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, 2020 and 2019, 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 November 2018, the Financial Accounting Standards Board ("FASB") issued ASU 2018-18, *Clarifying the Interaction between Topic 808 and Topic 606*. The guidance clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606 when the collaborative arrangement participant is a customer for a promised good or service that is distinct within the collaborative arrangement. The guidance also precludes entities from presenting amounts related to transactions with a collaborative arrangement participant that is not a customer as revenue, unless those transactions are directly related to third-party sales. ASU 2018-18 is effective in the first quarter of 2020 and should be applied retrospectively to January 1, 2018, when the Company adopted ASC 606. Early adoption is permitted. The new guidance was adopted on January 1, 2020 and it did not have a material effect on the Company's condensed consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, *Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*. The guidance eliminates, adds and modifies certain disclosure requirements for fair value measurements as part of its disclosure framework project. ASU 2018-13 is effective for annual reporting periods beginning after December 15, 2019 and interim periods within those annual periods and early adoption is permitted. The new guidance was adopted on January 1, 2020 and it did not have a material effect on the Company's condensed consolidated financial statements.

4. Significant Strategic Collaborations

The Company has entered into various research, development, license and supply agreements with Takeda Pharmaceuticals Co. Ltd. ("Takeda"), Serum Institute of India ("Serum Institute"), Pharmsynthez and SynBio LLC ("SynBio"), a wholly owned subsidiary of Pharmsynthez. The Company and its collaborative partners continue to engage in research and development activities with no resultant commercial products through September 30, 2020. In October 2017, the Company granted to Takeda the right to grant a non-exclusive sublicense to certain patents related to the Company's PolyXen technology that were previously exclusively licensed to Takeda in connection with products related to the treatment of blood and bleeding disorders. Royalty payments of approximately \$116,000 and \$286,000 were recorded as revenue by the Company during the three and nine months ended September 30, 2020, respectively. 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. There were no remaining performance obligations and all other revenue recognition criteria were met. There were no amounts recognized under this sublicense agreement during the three and nine months ended September 30, 2019. No amounts were recognized as revenue related to the Serum Institute, Pharmsynthez or SynBio agreements during the three and nine months ended September 30, 2020 and 2019, respectively.

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.

5. Property and Equipment, net

Property and equipment, net consists of the following:

	September 30, 2020	December 31, 2019
Office and computer equipment	\$ 42,289	\$ 42,289
Furniture and fixtures	14,738	14,738
Property and equipment – at cost	57,027	57,027
Less accumulated depreciation	(57,027)	(56,270)
Property and equipment – net	\$ –	\$ 757

There was no depreciation expense for the three months ended September 30, 2020. Depreciation expense was approximately \$1,000 for the three months ended September 30, 2019 and approximately \$800 and \$3,000 for the nine months ended September 30, 2020 and 2019, respectively.

6. Goodwill and Indefinite-Lived Intangible Assets

Goodwill

Goodwill is comprised of the purchase price of business combinations in excess of the fair value assigned at acquisition to the net tangible and identifiable intangible assets acquired and is not amortized. The Company assessed goodwill for impairment at least annually, or when events or changes in the business environment indicated that the carrying value may not be fully recoverable. The Company performed its annual impairment review during the fourth quarter at the reporting unit level. Goodwill may be considered impaired if the carrying value of the reporting unit, including goodwill, exceeds the reporting unit’s fair value. The Company is comprised of one reporting unit. The Company experienced a significant decline in its stock price during the three months ended September 30, 2019 resulting in a drop in its market capitalization indicating potential impairment. As a result, the Company performed an interim impairment test during the three months ended September 30, 2019 to determine the fair value of the reporting unit using its market capitalization, concluding that the fair value of the reporting unit is less than the carrying amount in excess of Goodwill, therefore fully impairing Goodwill. For the three and nine months ended September 30, 2019, the Company recorded an asset impairment charge of \$3.3 million in our condensed consolidated statement of operations related to Goodwill. A reconciliation of the change in the carrying value of Goodwill is as follows:

Balance as of January 1, 2019	\$ 3,283,379
Impairment	(3,283,379)
Balance as of September 30, 2019	\$ –

Indefinite-Lived Intangible Assets

The Company's indefinite-lived intangible asset, OncoHist, is in-process research and development ("IPR&D") relating to the Company's business combination with SymbioTec in 2012. IPR&D is tested for impairment whenever events or changes in circumstances indicate that the carrying value may not be recoverable, although it is to be tested at least annually until the project is completed or abandoned. The Company completed an impairment analysis of the IPR&D as of September 30, 2020 and concluded that the following factors indicate that the IPR&D was impaired: a decision by management to delay indefinitely any further development of the IPR&D and to not support the underlying intellectual property; the failure to sell or license the IPR&D to a third party; and the reduction in market capitalization. For the three and nine months ended September 30, 2020, the Company recorded an asset impairment charge of \$9.2 million in our condensed consolidated statement of operations, which represents the excess of the IPR&D asset's carrying value over its estimated fair value. No indefinite-lived intangible asset impairment was recorded during the year ended December 31, 2019. A reconciliation of the change in the carrying value of Indefinite-Lived Intangible Assets is as follows:

Balance as of January 1, 2019	\$	9,243,128
No changes		—
Balance as of December 31, 2019		9,243,128
Impairment		(9,243,128)
Balance as of September 30, 2020	\$	—

7. Fair Value Measurements

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

8. Stockholders' Equity

Warrants

In connection with certain of the Company's collaboration agreements and consulting arrangements, the Company has issued warrants to purchase shares of common stock as payment for services. As of September 30, 2020 and December 31, 2019, collaboration warrants to purchase 30,307 and 32,412 shares of common stock were outstanding, respectively. During the nine months ended September 30, 2020, collaboration warrants to purchase 2,105 shares expired. No collaboration warrants expired during the three months ended September 30, 2020. The outstanding warrants as of September 30, 2020 have an average weighted exercise price of \$124.74 and expiration dates ranging from April 2021 through May 2021. No collaboration warrants were granted or exercised in connection with collaboration or consulting services during the three and nine months ended September 30, 2020 and 2019, respectively.

In addition, the Company has outstanding warrants to purchase an aggregate of 378,453 and 658,557 shares of common stock in connection with debt and equity financing arrangements as of September 30, 2020 and December 31, 2019, respectively. These warrants have an average weighted exercise price of \$38.41 as of September 30, 2020 and expiration dates ranging from March 2021 through September 2026. There were prefunded warrants to purchase approximately 0.5 million and 0.6 million shares of Common Stock issued during the three and nine months ended September 30, 2019, respectively, of which approximately 0.5 million were exercised during the three and nine months ended September 30, 2019 with the remaining 0.1 million of prefunded warrants having been exercised during the fourth quarter of 2019. As of December 31, 2019, there were no pre-funded warrants outstanding. During the three and nine months ended September 30, 2019 debt and equity warrants to purchase approximately 2.5 million and 2.6 million shares of common stock were granted and 1.9 million debt and equity warrants were exercised during the three and nine months ended September 30, 2019. During the nine months ended September 30, 2020, debt and equity financing warrants to purchase approximately 0.2 million shares of common stock were exercised on a cashless one-for-one basis. In addition, approximately 0.1 million of debt and equity warrants expired during the nine months ended September 30, 2020. No debt and equity warrants expired during the nine months ended September 30, 2019.

9. Share-Based Expense

Total share-based expense related to stock options, restricted stock units (“RSUs”) and common stock awards were approximately \$0.1 million and \$0.2 million during the three months ended September 30, 2020 and 2019, respectively, and approximately \$0.4 million and \$0.7 million for the nine months ended September 30, 2020 and 2019, 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,	
	2020	2019	2020	2019
Research and development expenses	\$ 13,078	\$ 38,843	\$ 39,372	\$ 81,921
General and administrative expenses	97,721	208,594	348,759	648,610
	<u>\$ 110,799</u>	<u>\$ 247,437</u>	<u>\$ 388,131</u>	<u>\$ 730,531</u>

Employee Stock Options

There were no employee stock options or RSUs granted or exercised during the nine months ended September 30, 2020. During the three and nine months ended September 30, 2019, the Company granted 50,000 stock option awards. The weighted average grant date fair value per option share was \$1.18. Key assumptions used in the Black-Scholes option pricing model for options granted during the three and nine months ending September 30, 2019 were the Company’s stock price, a risk free rate of 1.60%, an expected life of 5.5 years and an expected volatility of 119.11%. There were no employee stock options exercised during the nine months ended September 30, 2019. The Company recognized a total of \$0.1 million and \$0.2 million of compensation expense related to employee stock options during the three months ended September 30, 2020 and 2019, respectively, and \$0.4 million and \$0.7 million during the nine months ended September 30, 2020 and 2019, respectively.

Non-Employee Stock Options

The Company did not grant any non-employee stock options during the nine months ended September 30, 2020 and 2019. There were no non-employee stock options exercised during the nine months ended September 30, 2020 and 2019. The Company recognized approximately \$4,000 and \$11,000 of expense during the three and nine months ended September 30, 2020, respectively. The Company did not recognize any expense related to non-employee stock options during the three and nine months ended September 30, 2019, respectively.

Common Stock Awards

During the three and nine months ended September 30, 2019, the Company granted 7,153 and 9,026 common stock awards, respectively, based on the value of the professional services provided and the average stock price during the respective periods. As all services were rendered during the three and nine months ended September 30, 2019, approximately \$15,000 and \$47,000 of expense related to common stock awards was recognized, respectively. There were no common stock awards granted during the three and nine months ended September 30, 2020. During the nine months ended September 30, 2020, the Company issued 1,188 shares related to these awards. As of September 30, 2020, there were 7,406 common stock awards authorized but not issued.

10. Income Taxes

Deferred tax assets and liabilities reflect the net tax effect of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. 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 \$26.5 million and \$25.9 million as of September 30, 2020 and December 31, 2019, respectively.

As of December 31, 2019, the net deferred tax liability of \$2.9 million on the condensed consolidated balance sheets is related to book and tax basis differences for intangible assets with indefinite lives. In accordance with ASC 740-10-30-18, the deferred tax liability related to the intangible assets cannot be used to offset deferred tax assets when determining the amount of the valuation allowance for deferred tax assets which are not more-likely-than-not to be realized. This results in a net deferred tax liability, even though the Company has a full valuation allowance on its other net deferred tax assets. During the three and nine months ended September 30, 2020, the related intangible assets were impaired and the net deferred tax liability was eliminated. As a result, the Company recorded an income tax benefit of \$2.9 million during the three and nine months ended September 30, 2020. There was no provision for income taxes for the three and nine months ended September 30, 2019 as the Company incurred losses during both periods.

As of September 30, 2020 and December 31, 2019, the Company did not record any unrecognized tax positions.

11. Commitments

The Company determines whether an arrangement is a lease at inception. On October 1, 2020, the Company entered into a two-year lease for its corporate headquarters in Framingham, Massachusetts. This lease calls for total future minimum rent payments of approximately \$78,000 and has a termination date of September 30, 2022. The Company does not have options to extend, termination options or material residual value guarantees. As the lease agreement was not executed until October 1, 2020, the Company will record a right-of-use ("ROU") asset and corresponding lease liability of approximately \$71,000 in the fourth quarter of 2020. As the lease does not provide an implicit rate, we used our incremental borrowing rate (10.2%) based on the information available at the lease's commencement date in determining the present value of lease payments.

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

	Nine Months Ended September 30, 2020
Operating cash flow information:	
Cash paid for amounts included in the measurement of lease liabilities	\$ 20,042

As the Company's existing operating lease expired on September 30, 2020, there was no ROU or lease liability reflected on the September 30, 2020 balance sheet.

12. Related Party Transactions

The Company has entered into various research, development, license and supply agreements with Serum Institute and Pharmsynthez (as well as SynBio, a wholly owned subsidiary of 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, 2019 filed with the SEC on March 26, 2020, as amended on April 29, 2020.

On July 19, 2019, the Company acquired the XCART technology platform from Hesperix and Opko Pharmaceuticals LLC ("OPKO"). Dr. Dmitry Genkin, one of our directors and Chairman of Pharmsynthez, was a director and significant shareholder of Hesperix. In addition, the Company agreed to repay an approximate \$225,000 loan that Dr. Genkin entered into with Hesperix. Mr. Adam Logal, one of our directors, is Senior Vice President, Chief Financial Officer, Chief Accounting Officer and Treasurer of OPKO Health, Inc., the parent company of OPKO.

During the third quarter of 2019, the Company entered into a Sponsored Research Agreement with Pharmsynthez (the "SRA") related to experiments identified by the Company to support its efforts for initial tech transfer of the XCART methods to a future academic collaborator. Under the agreement, the Company made a \$350,000 payment to Pharmsynthez during the third quarter of 2019, which is refundable on pro rata basis if the project is terminated prematurely as a result of Pharmsynthez failing to perform the work. The Company expensed approximately \$0.2 million related to this agreement during the nine months ended September 30, 2020. The Company did not record any expense during the three months ended September 30, 2020 as the Company and Pharmsynthez entered into a Master Services Agreement ("MSA") on June 12, 2020 that terminated and superseded the SRA. As of September 30, 2020 and December 31, 2019, approximately \$0.1 million and \$0.2 million, respectively, was recorded as an advanced payment and included in Prepaid expenses and other on the condensed consolidated balance sheets.

In October 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 August 2011 Stock Subscription and Collaborative Development of Pharmaceutical Products Agreement between the Company and SynBio. The Pharmsynthez Loan has a term of 15-months and accrues 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 equity interests of the Company owned by Pharmsynthez and SynBio. The Company recognized approximately \$13,000 and \$38,000 of interest income related to this loan during the three and nine months ended September 30, 2020, respectively. As of September 30, 2020, the Pharmsynthez Loan was included in Prepaid expenses and other on the condensed consolidated balance sheets. As of December 31, 2019, the Pharmsynthez Loan was included in Other assets on the condensed consolidated balance sheets.

On June 12, 2020, the Company and Pharmsynthez entered into the MSA to advance the development of the Company's XCART technology for B-cell malignancies. Under the MSA, Pharmsynthez agreed to provide services pursuant to work orders agreed upon by the parties from time to time, which services include, but are not limited to, acting as the Company's primary contract research organization to assist in managing collaborations with multiple academic institutions in Russia and Belarus. The Company is required to pay reasonable fees, expenses and pass-through costs incurred by Pharmsynthez in providing the services in accordance with a budget and payment terms set forth in each work order. Additionally, in the event that a work order provides for milestone payments, the Company is required to make such payments to Pharmsynthez, or third party service providers designated by Pharmsynthez, in accordance with the terms set forth in the work order, which milestone payments may be made, at the sole discretion of the Company, in cash or shares of the Company's common stock. The MSA terminated and superseded the SRA between the Company and Pharmsynthez.

The Company and Pharmsynthez executed a work order on June 12, 2020 (the “Work Order”) under the MSA pursuant to which Pharmsynthez agreed to conduct a Stage 1 study of the Company’s XCART technology under the research program as set forth in the Work Order. The activities to be performed under the Work Order are currently expected to take approximately 20 months unless earlier terminated in accordance with the MSA. Under the terms of the Work Order, the Company paid Pharmsynthez \$51,000 as an initial payment for trial startup costs, which amount was credited against the amounts paid under the SRA. The Work Order provides for additional pass-through costs to be invoiced by Pharmsynthez upon execution of contracts with third party sites, which will be further credited against the SRA. The total cost under the Work Order is currently estimated to be approximately \$1.8 million. Additionally, the Work Order provides for milestone payments of up to an aggregate of \$1,050,000, or, in the Company’s sole discretion, up to an aggregate of 1,000,000 shares of the Company’s common stock, to be paid or issued, as applicable, by the Company upon achievement of milestones associated with completion of early stages of the research program as set forth in the Work Order. For the three and nine months ended September 30, 2020, the Company expensed \$34,000 under the Work Order.

13. 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 Note 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; our plans to develop our proposed drug candidates; our expectations regarding the nature, timing and extent of clinical trials and proposed clinical trials including the timing of generating clinical data from these trials; our expectations regarding the timing for proposed submissions of regulatory filings, including but not limited to any Investigational New Drug (“IND”) 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, and the likelihood and extent of competition to our drug candidates; the development of the XCART™ Chimeric Antigen Receptor (“CAR”) T technology; our plans to apply the XCART technology to advance 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; our beliefs regarding the expected results of the XCART technology, including its potential to significantly enhance the safety and efficacy of cell therapy for B-cell lymphomas by generating patient- and tumor-specific CAR T cells; and our anticipation that our primary focus will now be on advancing the XCART technology through regulatory approval and commercialization technology.

In some cases, these statements may be identified by terminology such as “may”, “will”, “should”, “expect”, “plan”, “anticipate”, “believe”, “estimate”, “predict”, “potential”, 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:

- the impact of natural disasters or public health emergencies, such as the COVID-19 global pandemic, on our financial condition and results of operations;
- 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 XCART 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, including integration of the acquisition of the XCART technology;
- product development and commercialization risks, including our ability to successfully develop the XCART technology;
- the impact of adverse safety outcomes and clinical trial results for CAR-T cell therapies;
- our ability to secure and maintain a manufacturer for the XCART technology;
- 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; and
- other factors set forth in the Risk Factors section of our Annual Report on Form 10-K and in subsequent filings with the 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 progressing XCART™, a personalized CAR T platform technology engineered to target patient- and tumor-specific neoantigens. We are initially advancing 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. XCART has the potential to fuel a robust pipeline of the therapeutic assets targeting high-value oncology indications. The XCART technology, developed by the Scripps Research Institute ("Scripps Research") in collaboration with the Shemyakin-Ovchinnikov Institute of Bioorganic Chemistry, is believed to have the potential to significantly enhance the safety and efficacy of cell therapy for B-cell lymphomas by generating patient- and tumor-specific CAR T cells. We are currently advancing XCART preclinical efforts through strategic collaborations with Scripps Research and Pharmsynthez.

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 to prolong a drug's circulating half-life and potentially improve other pharmacological properties.

We incorporate our patented and proprietary technologies into a number of 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 United States ("U.S.") by the U.S. 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.

We also have oncology therapeutic investigational drug candidate XBIO-101™ (sodium cridanimod) for the treatment of progesterin resistant endometrial cancer. We have exclusive rights to develop and commercialize XBIO-101 worldwide, except for specified countries in the Commonwealth of Independent States. XBIO-101 has been granted orphan drug designation by the FDA for the potential treatment of progesterone receptor negative endometrial cancer in conjunction with progesterone therapy. We commenced a Phase 2 trial under an IND in 2017, with first patient dosed in October 2017. We closed patient enrollment in the trial in March 2019 as a result of slower than expected progress on the trial resulting from patient enrollment and retention challenges and have suspended further development of XBIO-101. We currently have no plans to continue development of XBIO-101.

Although we hold a broad patent portfolio, the focus of our internal development efforts during the three and nine months ended September 30, 2020 and during 2019 was limited to winding down the XBIO-101 Phase 2 trial and preliminary development efforts associated with the XCART technology.

Critical Accounting Estimates

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

There has been no material change to our critical accounting estimates since those critical accounting estimates described in our Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on March 26, 2020, as amended on April 29, 2020.

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 and continuing into November, 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 first nine months of 2020 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, 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 September 30, 2020 and 2019

The comparison of our historical results of operations for the fiscal quarter ended September 30, 2020 to the fiscal quarter ended September 30, 2019 is as follows:

Description	Quarter Ended September 30, 2020	Quarter Ended September 30, 2019	Increase (Decrease)	Percentage Change
Revenues:				
Royalty revenue	\$ 115,934	\$ –	\$ 115,934	100.0
Operating costs and expenses:				
Research and development	(573,061)	(3,520,638)	(2,947,577)	(83.7)
General and administrative	(804,149)	(2,142,505)	(1,338,356)	(62.5)
Asset impairment charges	(9,243,128)	(3,283,379)	5,959,749	181.5
Total operating costs and expenses	(10,620,338)	(8,946,522)	1,673,816	18.7
Loss from operations	(10,504,404)	(8,946,522)	1,557,882	17.4
Other income (expense):				
Other income (expense)	585	(223)	808	362.3
Interest income, net	24,931	46,617	(21,686)	(46.5)
Loss before income taxes	\$ (10,478,888)	\$ (8,900,128)	\$ 1,578,760	17.7
Income tax benefit	2,918,518	–	2,918,518	100.0
Net loss	\$ (7,560,370)	\$ (8,900,128)	\$ (1,339,758)	(15.1)

Revenue

For the three months ended September 30, 2020, revenue represented royalty revenue related to our right to sublicense agreement with Takeda Pharmaceuticals Co. Ltd. (“Takeda”). Royalty payments earned on sales by the sublicensee during the second quarter of 2020 were recorded as revenue by us during the three months ended September 30, 2020. We anticipate recognizing these royalty payments as revenue when they are reliably measurable, which is upon receipt of reports from Takeda. As the reported sales are not reliably measurable until we receive notification from Takeda, we expect to recognize revenue from these royalty payments in the quarter subsequent to the actual sales by the sublicensee. We did not recognize any revenue for the three months ended September 30, 2019.

Research and Development Expenses

Overall, research & development (“R&D”) expenses for the three months ended September 30, 2020 decreased by \$2.9 million, or 83.7% to \$0.6 million from \$3.5 million in the comparable quarter in 2019 primarily due to in-process research and development (“IPR&D”) expense of \$3.0 million. During the three months ended September 30, 2019, the Company expensed \$3.0 million of IPR&D associated with the Company’s acquisition of the XCART technology. There was no similar expense in 2020. Excluding the \$3.0 million of IPR&D expense from total R&D expense of \$3.5 million, R&D expense for the three months ended September 30, 2019 was approximately \$0.5 million compared to \$0.6 million for the same period in 2020.

The table below sets forth the R&D costs incurred by the Company by category of expense for the quarters ended September 30, 2020 and 2019:

Category of Expense	Quarter Ended,	
	September 30, 2020	September 30, 2019
IPR&D expense	\$ –	\$ 3,031,226
Outside services and contract research organizations	422,748	313,957
Salaries and wages	73,127	72,809
Share-based expense	13,078	38,843
Other	64,108	63,803
Total research and development expense	<u>\$ 573,061</u>	<u>\$ 3,520,638</u>

The increase in outside services and contract research organizations expense was primarily due to increased spending on our XCART pre-clinical development efforts, which were substantially offset by decreased spending on our XBIO-101 Phase 2 clinical trial during the three months ended September 30, 2020 compared to the same period in the prior year. Costs related to the phase 2 clinical trial were generally lower as we closed patient enrollment during the first quarter of 2019 and suspended further development of XBIO-101.

General and Administrative Expenses

General and administrative expenses for the three months ended September 30, 2020 was \$0.8 million, decreasing by approximately \$1.3 million, or 62.5%, compared to the same period in the prior year, primarily due to \$1.1 million of transaction costs associated with the XCART acquisition incurred during the three months ended September 30, 2019. There was no similar expense for the comparable period in 2020. Excluding the \$1.1 million of transaction costs associated with the XCART acquisition from the total G&A expense of \$2.1 million, G&A expenses for the three months ended September 30, 2019 was \$1.0 million compared to \$0.8 million for the same period in 2020. The \$0.2 million, or 22.7%, decrease was primarily due to a decrease in share-based expense during the three months ended September 30, 2020 compared to the same period in 2019.

Asset Impairment Charges

Asset impairment charges were \$9.2 million for the three months ended September 30, 2020 compared to \$3.3 million for the three months ended September 30, 2019. During the third quarter of 2020, we recorded an asset impairment charge of \$9.2 million related to our IPR&D. During the third quarter of 2019, we recorded an asset impairment charge of \$3.3 million related to our Goodwill.

Other Income (Expense)

Other income was approximately \$600 for the three months ended September 30, 2020 compared to approximately \$200 of other expense for the same period in 2019. This increase in other income was primarily related to changes in foreign currency exchange rates during the third quarter of 2020 as compared to the same period in 2019.

Interest Income, net

Interest income, net decreased to approximately \$25,000 during the three months ended September 30, 2020 as compared to approximately \$47,000 for the same period in the prior year. This decrease is primarily due to a decrease in cash and lower interest rates in the third quarter of 2020 as compared to the third quarter of 2019.

Income Tax Benefit

Income tax benefit of \$2.9 million for the three months ended September 30, 2020 was due to the impairment of IPR&D during the third quarter of 2020. There was no similar benefit during the same period in the prior year.

Comparison of Nine Months Ended September 30, 2020 and 2019

The comparison of our historical results of operations for the nine months ended September 30, 2020 to the nine months ended September 30, 2019 is as follows:

Description	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019	Increase (Decrease)	Percentage Change
Revenues:				
Royalty revenue	\$ 285,610	\$ –	\$ 285,610	100.0
Operating costs and expenses:				
Research and development	(1,240,612)	(4,471,939)	(3,231,327)	(72.3)
General and administrative	(2,519,515)	(3,896,657)	(1,377,142)	(35.3)
Asset impairment charges	(9,243,128)	(3,283,379)	5,959,749	181.5
Total operating costs and expenses	(13,003,255)	(11,651,975)	1,351,280	11.6
Loss from operations	(12,717,645)	(11,651,975)	1,065,670	9.1
Other income:				
Other income	643	267	376	140.8
Interest income, net	105,043	46,930	58,113	123.8
Loss before income taxes	(12,611,959)	(11,604,778)	1,007,181	8.7
Income tax benefit	2,918,518	–	2,918,518	100.0
Net loss	\$ (9,693,441)	\$ (11,604,778)	\$ (1,911,337)	(16.5)

Revenue

For the nine months ended September 30, 2020, revenue represented royalty revenue related to our right to sublicense agreement with Takeda. Royalty payments earned on sales by the sublicensee during the fourth quarter of 2019 and the first and second quarters of 2020 were recorded as revenue by us during the nine months ended September 30, 2020. We anticipate recognizing these royalty payments as revenue when they are reliably measurable, which is upon receipt of reports from Takeda. As the reported sales are not reliably measurable until we receive notification from Takeda, we expect to recognize revenue from these royalty payments in the quarter subsequent to the actual sales by the sublicensee. We did not recognize any revenue for the nine months ended September 30, 2019.

Research and Development Expenses

Overall, R&D expenses for the nine months ended September 30, 2020 decreased by \$3.2 million, or 72.3% to \$1.2 million from \$4.5 million in the comparable period in 2019, primarily due to IPR&D expense of \$3.0 million. During the nine months ended September 30, 2019, the Company expensed \$3.0 million of IPR&D associated with the Company's acquisition of the XCART technology. There was no similar expense in 2020. Excluding the \$3.0 million of IPR&D expense from total R&D expense of \$4.5 million, R&D expense for the nine months ended September 30, 2019 was \$1.4 million compared to \$1.2 million for the nine months ended September 30, 2020, a decrease of \$0.2 million, or 13.9%.

The table below sets forth the R&D costs incurred by us, by category of expense, for the nine months ended September 30, 2020 and 2019:

Category of Expense	Nine Months Ended,	
	September 30, 2020	September 30, 2019
IPR&D expense	\$ —	\$ 3,031,226
Outside services and contract research organizations	797,038	986,369
Salaries and wages	275,024	227,257
Share-based expense	39,372	115,253
Other	129,178	111,834
Total research and development expense	<u>\$ 1,240,612</u>	<u>\$ 4,471,939</u>

The decrease in outside services and contract research organizations expense was primarily due to decreased spending on our XBIO-101 phase 2 clinical trial during the nine months ended September 30, 2020 as compared to same period in the prior year. Costs related to the phase 2 clinical trial were generally lower as we closed patient enrollment during the first quarter of 2019 and suspended further development of XBIO-101. The decrease in XBIO-101 costs were substantially offset by increased costs associated with our XCART pre-clinical development efforts. Salaries and wages increased during the nine months ended September 30, 2020 due to slightly higher employee related costs, which was partially offset by lower share-based expense.

General and Administrative Expenses

General and administrative expenses decreased by approximately \$1.4 million, or 35.3% for the nine months ended September 30, 2020, to \$2.5 million from \$3.9 million in the comparable period in 2019, primarily due to \$1.1 million of transaction costs associated with the XCART acquisition incurred during the nine months ended September 30, 2019. There was no similar expense for the comparable period in 2020. Excluding the \$1.1 million of transaction costs associated with the XCART acquisition from total G&A expenses of \$3.9 million, G&A expenses for the nine months ended September 30, 2019 was \$2.8 million, compared to \$2.5 million for the nine months ended September 30, 2020, a decrease of \$0.3 million, or 9.8%. This decrease was primarily due to lower share-based expense and a gain on settlement of certain vendor amounts related to the close-out of our XBIO-101 trial. These decreases were partially offset by increased employee costs during the nine months ended September 30, 2020 compared to the same period in the prior year.

Asset Impairment Charges

Asset impairment charges were \$9.2 million for the nine months ended September 30, 2020 compared to \$3.3 million for the nine months ended September 30, 2019. During the nine months ended September 30, 2020, we recorded an asset impairment charge of \$9.2 million related to our IPR&D. During the nine months ended September 30, 2019, we recorded an asset impairment charge of \$3.3 million related to our Goodwill.

Other Income

Other income was approximately \$600 for the nine months ended September 30, 2020 compared to approximately \$300 for the same period in 2019. This increase was primarily related to changes in foreign currency exchange rates during the nine months ended September 30, 2020 as compared to the same period in 2019.

Interest Income, net

Interest income, net increased to approximately \$105,000 during the nine months ended September 30, 2020 as compared to approximately \$47,000 for the same period in the prior year. This increase is primarily due to interest earned on the net proceeds from our July 2019 public offering for nine months in 2020 compared to two-and-half months in the comparable period in 2019.

Income Tax Benefit

Income tax benefit of \$2.9 million for the nine months ended September 30, 2020 due to impairment of IPR&D during the third quarter of 2020. There was no similar benefit during the same period in the prior year.

Non-GAAP Measures

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

Liquidity and Capital Resources

We incurred a net loss of approximately \$9.7 million for the nine months ended September 30, 2020. We had an accumulated deficit of approximately \$175.7 million at September 30, 2020 as compared to an accumulated deficit of approximately \$166.0 million at December 31, 2019. Working capital was approximately \$7.2 million at September 30, 2020 and \$9.7 million at December 31, 2019, respectively. During the nine months ended September 30, 2020, our working capital decreased by \$2.5 million primarily due to our net loss for the nine months ended September 30, 2020. We expect to continue incurring losses for the foreseeable future and may need to raise additional capital or pursue other strategic alternatives in the near term in order to continue the pursuit of our business plan.

Our principal source of liquidity consists of cash. At September 30, 2020, we had approximately \$7.1 million in cash and \$0.8 million in current liabilities. At December 31, 2019, we had approximately \$10.4 million in cash and \$1.4 million in current liabilities.

We have historically relied upon sales of our equity securities to fund our operations. From 2005 until September 30, 2020 we have raised approximately \$76.0 million in proceeds from offerings of our common and preferred stock and received approximately \$20.0 million from revenue producing activities. More than 90% of the milestone and sublicense revenue received to date has been from a single collaborator, Takeda. 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. During 2019, we completed two stock offerings that resulted in \$16.1 million of net proceeds to us. We believe that our existing resources will be adequate to fund our operations through mid-2021. However, we anticipate we may need additional capital in the near 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 and market conditions, many of which are beyond our control.

Cash Flows from Operating Activities

Cash flows used in operating activities for the nine months ended September 30, 2020 of approximately \$3.3 million was primarily due to our net loss for the period, offset by non-cash charges associated with asset impairment charges, deferred income taxes, share-based expense, and settlement of certain amounts payable to a vendor related to the close-out of our XBIO-101 trial. Cash flows used in operating activities for the nine months ended September 30, 2019 totaled approximately \$4.7 million, which was primarily due to our net loss for the period, offset by non-cash charges associated with asset impairment charges, acquired IPR&D and share-based expense.

Cash Flows from Investing Activities

There were no cash flows from investing activities for the nine months ended September 30, 2020. Cash flows provided by investing activities for the nine months ended September 30, 2019 totaled \$2,000, which represented proceeds from the sale of property and equipment.

Cash Flow from Financing Activities

There were no cash flows from financing activities for the nine months ended September 30, 2020. Cash flows provided by financing activities for the nine months ended September 30, 2019 totaled approximately \$16.1 million representing net proceeds from our registered direct offering in March 2019 and our public offering in July 2019.

Contractual Obligations and Commitments

As of September 30, 2020, 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, 2019, filed with the SEC on March 26, 2020, as amended on April 29, 2020.

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 2 in our Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 26, 2020, as amended on April 29, 2020, 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 from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on March 26, 2020, as amended on April 29, 2020.

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 Securities Exchange Act of 1934, as amended (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 Securities Exchange Act of 1934, as amended (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

Except as provided below, 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, 2019 filed with the SEC on March 26, 2020, as amended on April 29, 2020, and as updated by our Quarterly Reports on Form 10-Q for the quarter ended March 31, 2020 and for the quarter ended June 30, 2020.

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 October 29, 2020, 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 April 27, 2021 (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.

Our financial condition, results of operations, business and cash flow may be negatively affected by a public health crisis such as the recent coronavirus (COVID-19) outbreak.

We may face risks related to health epidemics and pandemics or other outbreaks of communicable diseases. 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 (COVID-19). The global spread of COVID-19 has created, and continues to create, significant volatility, uncertainty and economic disruption, including significant volatility in the capital markets. The extent to which the COVID-19 pandemic affects our business, operations, financial results and the trading price of our common stock will depend on numerous evolving factors that we may not be able to accurately predict, including: the duration and scope of the pandemic; governmental and business actions that have been and continue to be taken in response to the pandemic (including mitigation efforts such as stay at home and other social distancing orders) and the impact of the pandemic on economic activity and actions taken in response (including stimulus efforts such as the Families First Coronavirus Act and the Coronavirus Aid, Relief, and Economic Security Act).

Although the Company's operations were not materially affected in the nine months ended September 30, 2020 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, 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.

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.INS*	Inline XBRL Instance Document - The instance document does not appear in the interactive data file because its XBRL tags are embedded within the inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	The cover page of this Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, formatted in Inline XBRL (included within the Exhibit 101 attachments).
*	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 Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

XENETIC BIOSCIENCES, INC.

November 12, 2020

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 12, 2020

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 12, 2020

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, 2020, to which this Certification is attached as Exhibit 32.1 (the “Periodic Report”), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

Date: November 12, 2020

In Witness Whereof, the undersigned have set their hands hereto as of the 12th day of November 2020.

/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.”