

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 June 30, 2021

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-37937

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

**Nevada**  
(State or other jurisdiction of incorporation or organization)

**45-2952962**  
(I.R.S. Employer Identification No.)

**40 Speen Street, Suite 102**  
**Framingham, Massachusetts**  
(Address of principal executive offices)

**01701**  
(Zip Code)

**781-778-7720**  
(Registrant's telephone number, including area code)

**N/A**  
(Former name, former address and former fiscal year, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, \$0.001 par value per share	XBIO	The Nasdaq Stock Market LLC
Purchase Warrants	XBIOW	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act:

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

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

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

The number of shares outstanding of the registrant's common stock, par value \$0.001 per share, as of August 6, 2021 was 9,703,845.

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**XENETIC BIOSCIENCES, INC.**  
**FORM 10-Q**  
**QUARTERLY PERIOD ENDED JUNE 30, 2021**

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PART I – FINANCIAL INFORMATION

ITEM 1 - FINANCIAL STATEMENTS

XENETIC BIOSCIENCES, INC.  
CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2021 (Unaudited)	December 31, 2020
<b>ASSETS</b>		
Current assets:		
Cash	\$ 9,281,554	\$ 11,527,552
Prepaid expenses and other	917,826	841,958
Total current assets	<u>10,199,380</u>	<u>12,369,510</u>
Other assets	715,898	809,985
Total assets	<u>\$ 10,915,278</u>	<u>\$ 13,179,495</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 305,088	\$ 327,396
Accrued expenses and other current liabilities	653,126	609,532
Total current liabilities	<u>958,214</u>	<u>936,928</u>
Other long-term liabilities	7,957	27,043
Total liabilities	<u>966,171</u>	<u>963,971</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 June 30, 2021 and December 31, 2020	1,804	1,804
Series A, \$0.001 par value: 970,000 shares issued and outstanding as of June 30, 2021 and December 31, 2020	970	970
Common stock, \$0.001 par value; 50,000,000 shares authorized as of June 30, 2021 and December 31, 2020; 8,773,683 and 8,772,198 shares issued as of June 30, 2021 and December 31, 2020, respectively; 8,746,692 and 8,745,207 shares outstanding as of June 30, 2021 and December 31, 2020, respectively		
	8,772	8,771
Additional paid in capital	194,319,716	194,133,511
Accumulated deficit	(179,354,709)	(176,902,086)
Accumulated other comprehensive income	253,734	253,734
Treasury stock	(5,281,180)	(5,281,180)
Total stockholders' equity	<u>9,949,107</u>	<u>12,215,524</u>
Total liabilities and stockholders' equity	<u>\$ 10,915,278</u>	<u>\$ 13,179,495</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 JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	2021	2020	2021	2020
Revenue:				
Royalty revenue	\$ 287,603	\$ 112,927	\$ 478,819	\$ 169,676
Total revenue	<u>287,603</u>	<u>112,927</u>	<u>478,819</u>	<u>169,676</u>
Operating costs and expenses:				
Research and development	(524,550)	(307,900)	(1,154,279)	(667,551)
General and administrative	(890,704)	(787,486)	(1,821,282)	(1,715,366)
Total operating costs and expenses	<u>(1,415,254)</u>	<u>(1,095,386)</u>	<u>(2,975,561)</u>	<u>(2,382,917)</u>
Loss from operations	<u>(1,127,651)</u>	<u>(982,459)</u>	<u>(2,496,742)</u>	<u>(2,213,241)</u>
Other income:				
Other income	238	192	1,122	58
Interest income, net	20,735	28,625	42,997	80,112
Total other income	<u>20,973</u>	<u>28,817</u>	<u>44,119</u>	<u>80,170</u>
Net loss	<u>\$ (1,106,678)</u>	<u>\$ (953,642)</u>	<u>\$ (2,452,623)</u>	<u>\$ (2,133,071)</u>
Basic and diluted net loss per share	<u>\$ (0.13)</u>	<u>\$ (0.15)</u>	<u>\$ (0.28)</u>	<u>\$ (0.34)</u>
Weighted-average shares of common stock outstanding, basic and diluted	<u>8,746,692</u>	<u>6,288,351</u>	<u>8,746,479</u>	<u>6,260,841</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 JUNE 30, 2021**

	<u>Preferred Stock</u>		<u>Common Stock</u>		<u>Additional Paid in Capital</u>	<u>Accumulated Deficit</u>	<u>Accumulated Other Comprehensive Income</u>	<u>Treasury Stock</u>	<u>Total Stockholders' Equity</u>
	<u>Number of Shares</u>	<u>Par Value (\$0.001)</u>	<u>Number of Shares</u>	<u>Par Value (\$0.001)</u>					
<b>Balance as of April 1, 2021</b>	2,774,394	\$ 2,774	8,773,683	\$ 8,772	\$ 194,209,794	\$ (178,248,031)	\$ 253,734	\$ (5,281,180)	\$ 10,945,863
Share-based expense	-	-	-	-	109,922	-	-	-	109,922
Net loss	-	-	-	-	-	(1,106,678)	-	-	(1,106,678)
<b>Balance as of June 30, 2021</b>	<u>2,774,394</u>	<u>\$ 2,774</u>	<u>8,773,683</u>	<u>\$ 8,772</u>	<u>\$ 194,319,716</u>	<u>\$ (179,354,709)</u>	<u>\$ 253,734</u>	<u>\$ (5,281,180)</u>	<u>\$ 9,949,107</u>

**SIX MONTHS ENDED JUNE 30, 2021**

	<u>Preferred Stock</u>		<u>Common Stock</u>		<u>Additional Paid in Capital</u>	<u>Accumulated Deficit</u>	<u>Accumulated Other Comprehensive Income</u>	<u>Treasury Stock</u>	<u>Total Stockholders' Equity</u>
	<u>Number of Shares</u>	<u>Par Value (\$0.001)</u>	<u>Number of Shares</u>	<u>Par Value (\$0.001)</u>					
<b>Balance as of January 1, 2021</b>	2,774,394	\$ 2,774	8,772,198	\$ 8,771	\$ 194,133,511	\$ (176,902,086)	\$ 253,734	\$ (5,281,180)	\$ 12,215,524
Share-based expense	-	-	-	-	186,206	-	-	-	186,206
Exercise of purchase warrants	-	-	1,485	1	(1)	-	-	-	-
Net loss	-	-	-	-	-	(2,452,623)	-	-	(2,452,623)
<b>Balance as of June 30, 2021</b>	<u>2,774,394</u>	<u>\$ 2,774</u>	<u>8,773,683</u>	<u>\$ 8,772</u>	<u>\$ 194,319,716</u>	<u>\$ (179,354,709)</u>	<u>\$ 253,734</u>	<u>\$ (5,281,180)</u>	<u>\$ 9,949,107</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 JUNE 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>					
<b>Balance as of April 1, 2020</b>	2,774,394	\$ 2,774	6,311,906	\$ 6,311	\$ 188,405,830	\$ (167,188,049)	\$ 253,734	\$ (5,281,180)	\$ 16,199,420
Issuance of common stock to vendor	-	-	1,188	1	(1)	-	-	-	-
Share-based expense	-	-	-	-	111,734	-	-	-	111,734
Exercise of purchase warrants	-	-	10,124	10	(10)	-	-	-	-
Net loss	-	-	-	-	-	(953,642)	-	-	(953,642)
<b>Balance as of June 30, 2020</b>	<u>2,774,394</u>	<u>\$ 2,774</u>	<u>6,323,218</u>	<u>\$ 6,322</u>	<u>\$ 188,517,553</u>	<u>\$ (168,141,691)</u>	<u>\$ 253,734</u>	<u>\$ (5,281,180)</u>	<u>\$ 15,357,512</u>

**SIX MONTHS ENDED JUNE 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>					
<b>Balance as of January 1, 2020</b>	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	-	-	-	-	277,332	-	-	-	277,332
Exercise of purchase warrants	-	-	229,598	229	(229)	-	-	-	-
Net loss	-	-	-	-	-	(2,133,071)	-	-	(2,133,071)
<b>Balance as of June 30, 2020</b>	<u>2,774,394</u>	<u>\$ 2,774</u>	<u>6,323,218</u>	<u>\$ 6,322</u>	<u>\$ 188,517,553</u>	<u>\$ (168,141,691)</u>	<u>\$ 253,734</u>	<u>\$ (5,281,180)</u>	<u>\$ 15,357,512</u>

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

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

	<b>Six Months Ended June 30,</b>	
	<b>2021</b>	<b>2020</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (2,452,623)	\$ (2,133,071)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	–	757
Amortization of right of use asset	17,160	13,765
Gain on settlement with vendor	–	(143,639)
Share-based expense	186,206	277,332
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	1,059	167,586
Accounts payable, accrued expenses and other liabilities	2,200	(484,190)
Net cash used in operating activities	(2,245,998)	(2,301,460)
Net change in cash	(2,245,998)	(2,301,460)
Cash at beginning of period	11,527,552	10,367,920
Cash at end of period	\$ 9,281,554	\$ 8,066,460
<b>SUPPLEMENTAL CASH FLOW INFORMATION:</b>		
Cash paid for interest	\$ –	\$ –
<b>SUPPLEMENTAL SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:</b>		
Issuance of common stock from cashless exercise of purchase warrants	\$ 1	\$ 229

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 (“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.

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 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 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. On December 4, 2020, the Company closed on a \$6.0 million registered direct offering of the Company’s common stock, par value \$0.001, resulting in \$5.4 million of net proceeds to the Company. On July 28, 2021, the Company completed a \$12.5 million private placement of the Company’s common stock, par value \$0.001, resulting in approximately \$11.4 million of net proceeds to the Company. The Company believes that these financings, coupled with the Company’s existing resources, will be adequate for the Company to continue as a going concern. However, the Company anticipates it may need additional capital in the long-term to pursue its business initiatives. The terms, timing and extent of any future financing will depend upon several factors, including the achievement of progress in its clinical development programs, its ability to identify and enter into licensing or other strategic arrangements, and factors related to financial, economic and market conditions, many of which are beyond its control.

## **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 2020 and continuing into 2021, 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, 2020 filed with the SEC on March 16, 2021 and amended on April 28, 2021.

### ***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 six months ended June 30, 2021 and 2020, basic and diluted net loss per share are the same for each respective period due to the Company's net loss position. Potentially dilutive, non-participating securities have not been included in the calculations of diluted net loss per share, as their inclusion would be anti-dilutive.

#### ***Recent Accounting Standards***

In June 2016, the Financial Accounting Standards Board issued Accounting Standards Update (“ASU”) 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. The guidance modifies the measurement and recognition of credit losses for most financial assets and certain other instruments. The amendment updates the guidance for measuring and recording credit losses on financial assets measured at amortized cost by replacing the “incurred loss” model with an “expected loss” model. This may result in earlier recognition of allowance for losses. ASU 2016-13 is effective for smaller reporting public entities for fiscal years beginning after December 15, 2022 but early adoption is permitted. The Company is currently evaluating the impact of adoption, but it does not anticipate that it will have a material effect on the Company’s consolidated financial statements.

#### **4. Significant Strategic Collaborations**

The Company has entered into various research, development, license and supply agreements with 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 June 30, 2021.

In October 2017, the Company granted to Takeda the right to grant a non-exclusive sublicense to certain patents related to the Company’s PolyXen technology that were previously exclusively licensed to Takeda in connection with products related to the treatment of blood and bleeding disorders. Royalty payments of approximately \$0.3 million and \$0.5 million were recorded as revenue by the Company during the three and six months ended June 30, 2021, respectively, and approximately \$0.1 million and \$0.2 million were recorded as revenue by the Company during the three and six months ended June 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. At the time the revenue was received, there were no remaining performance obligations and all other revenue recognition criteria were met. There are no active projects under the Exclusive Research, Development and License Agreement, dated August 15, 2005, by and between Lipoxen and Baxter Healthcare SA, as amended, (the “Takeda Agreement”), and the parties are discussing a potential termination of the agreement. Any such termination of the Takeda Agreement would have no impact on the Company and its non-exclusive sublicense agreement and the royalties being generated. No amounts were recognized as revenue related to the Serum Institute, Pharmsynthez or SynBio agreements during the three months ended June 30, 2021 and 2020, respectively.

On May 15, 2020, the Company and Scripps Research entered into a Research Funding and Option Agreement (the “Scripps Agreement”), pursuant to which the Company has agreed to provide Scripps Research an aggregate of up to \$3.0 million to fund research relating to advancing the pre-clinical development of XCART. The research funding is payable by the Company to Scripps Research on a quarterly basis in accordance with a negotiated budget, which provides for an initial payment of approximately \$300,000 on the date of the Scripps Agreement and subsequent quarterly payments of approximately \$300,000 over a 27-month period. Under the Scripps Agreement, Scripps Research has granted the Company a license within the Field (as defined in the Scripps Agreement) to any Patent Rights or Technology (as defined in the Scripps Agreement) under the terms of that certain license agreement with Scripps Research, dated February 25, 2019, assigned to the Company on March 1, 2019. Additionally, the Company has the option to acquire a worldwide exclusive license to Scripps Research’s rights in the Technology or Patent Rights not already licensed to the Company, as well as a non-exclusive, royalty-free, non-transferrable license to make and use Scripps Research Technology (as defined in the Scripps Agreement) solely for the Company’s internal research purposes during the performance of the research program contemplated by the Scripps Agreement. The Company has paid \$1.5 million to Scripps Research under this agreement through June 30, 2021. As of June 30, 2021 and December 31, 2020, approximately \$0.2 million has been recognized as an advance payment under this agreement and is included in Prepaid expenses and other current assets.

## 5. Property and Equipment, net

Property and equipment, net consists of the following:

	June 30, 2021	December 31, 2020
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)	(57,027)
Property and equipment – net	\$ –	\$ –

Depreciation expense was approximately \$200 and \$800 for the three and six months ended June 30, 2020. There was no depreciation expense for the three and six months ended June 30, 2021.

## 6. 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 during 2020 and concluded that the following factors indicated 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. The Company recorded an asset impairment charge of \$9.2 million during the third quarter of 2020 representing the excess of the IPR&D asset's carrying value over its estimated fair value. A reconciliation of the change in the carrying value of Indefinite-Lived Intangible Assets is as follows:

Balance as of January 1, 2020	\$ 9,243,128
Impairment	(9,243,128)
Balance as of December 31, 2020	\$ –

## 7. Fair Value Measurements

Accounting Standards Codification Topic 820, *Fair Value Measurement*, defines fair value as the price that would be received to sell an asset or be paid to transfer a liability in an orderly transaction between market participants at the measurement date. The Company applies the following fair value hierarchy, which prioritizes the inputs used to measure fair value into three levels and bases the categorization within the hierarchy upon the lowest level of input that is available and significant to the fair value measurement. Level 1 inputs are quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date. Level 2 utilizes quoted market prices in markets that are not active, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency. Level 3 inputs are unobservable inputs for the asset or liability in which there is little, if any, market activity for the asset or liability at the measurement date. The carrying amount of certain of the Company's financial instruments approximate fair value due to their short maturities. As of June 30, 2021 and December 31, 2020, the carrying amounts of the Company's financial instruments approximate fair value due to their short maturities. There were no financial instruments classified as Level 3 in the fair value hierarchy during the three and six months ended June 30, 2021 and 2020.

## 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 June 30, 2021 and December 31, 2020, collaboration warrants to purchase 0 and 30,307 shares of common stock were outstanding. No collaboration warrants were granted or exercised in connection with collaboration or consulting services during the three and six months ended June 30, 2021. Collaboration warrants to purchase 30,307 shares expired during the three and six months ended June 30, 2021. No collaboration warrants were granted or exercised and none expired in connection with collaboration or consulting services during the three and six months ended June 30, 2020, respectively.

In addition, the Company has outstanding warrants to purchase an aggregate of 347,505 and 378,453 shares of common stock in connection with debt and equity financing arrangements as of June 30, 2021 and December 31, 2020, respectively. As of June 30, 2021, these warrants have an average weighted exercise price of \$36.74 per share and expiration dates ranging from July 2021 through September 2026. No debt and equity financing warrants were granted during the three and six months ended June 30, 2021 and 2020. During the six months ended June 30, 2021 and 2020, debt and equity financing warrants to purchase approximately 1,485 and 0.2 million shares of common stock, respectively, were exercised on a cashless one-for-one basis. No debt and equity financing warrants were exercised during the three months ended June 30, 2021 and 2020, respectively. In addition, approximately 0 and 29,000 debt and equity warrants expired during the three and six months ended June 30, 2021. No debt and equity warrants expired during the three and six months ended June 30, 2020.

## 9. Share-Based Expense

Total share-based expense related to stock options, restricted stock units ("RSUs") and common stock awards was approximately \$0.1 million during the three months ended June 30, 2021 and 2020 and approximately \$0.2 million and \$0.3 million for the six months ended June 30, 2021 and 2020, respectively.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Research and development expenses	\$ 19,026	\$ 12,936	\$ 29,736	\$ 26,294
General and administrative expenses	90,896	98,798	156,470	251,038
	<u>\$ 109,922</u>	<u>\$ 111,734</u>	<u>\$ 186,206</u>	<u>\$ 277,332</u>

### Employee Stock Options

During the six months ended June 30, 2021, the Company granted 200,000 stock option awards to purchase shares of common stock. The weighted average grant date fair value per option share was \$2.34. Key assumptions used in the Black-Scholes option pricing model for options granted during the six months ending June 30, 2021 were the Company's stock price, a risk free rate of 1.08%, an expected life of 5.88 years and an expected volatility rate of 134.47%. There were no employee stock options or RSUs granted or exercised during the six months ended June 30, 2020. The Company recognized a total of \$0.1 million of compensation expense related to employee stock options during the three months ended June 30, 2021 and 2020 and \$0.2 million and \$0.3 million during the six months ended June 30, 2021 and 2020, respectively.

### ***Non-Employee Stock Options***

The Company did not grant any non-employee stock options during the six months ended June 30, 2021 and 2020. The Company did not recognize any expense related to non-employee stock options during the three and six months ended June 30, 2021. The Company recognized approximately \$4,000 and \$7,000 of expense during the three and six months ended June 30, 2020, respectively.

### **10. Income Taxes**

During the three and six months ended June 30, 2021 and 2020, there was no provision for income taxes as the Company incurred losses during both periods. Deferred tax assets and liabilities reflect the net tax effect of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The Company records a valuation allowance against its deferred tax assets as the Company believes it is more likely than not the deferred tax assets will not be realized. The valuation allowance against deferred tax assets was approximately \$30.2 million and \$29.6 million as of June 30, 2021 and December 31, 2020, respectively.

As of June 30, 2021 and December 31, 2020, the Company did not record any unrecognized tax positions.

### **11. Commitments**

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

	<b>Six Months Ended June 30, 2021</b>
<b>Operating cash flow information:</b>	
Cash paid for amounts included in the measurement of lease liabilities	\$ 17,160

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

	<b>Balance Sheet Classification</b>	<b>June 30, 2021</b>
Right-of-use assets - ST	Prepaid expenses and other	\$ 37,408
Right-of-use assets - LT	Other assets	\$ 7,957
Current lease liabilities	Accrued expenses and other current liabilities	\$ 37,408
Non-current lease liabilities	Other long-term liabilities	\$ 7,957

### **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), 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, 2020, filed with the SEC on March 16, 2021, as amended on April 28, 2021.

During the fourth quarter of 2019, the Company entered into a loan agreement with Pharmsynthez (the “Pharmsynthez Loan”), pursuant to which the Company advanced Pharmsynthez an aggregate principal amount of up to \$500,000 to be used for the development of a specific product under the Company’s co-development agreement with SynBio. The Pharmsynthez Loan had a term of 15-months and accrued interest at a rate of 10% per annum. The Pharmsynthez Loan is guaranteed by all of the operating subsidiaries of Pharmsynthez, including SynBio and AS Kevelt, and is secured by all of the equity interests of the Company owned by Pharmsynthez and SynBio. The Company recognized approximately \$11,000 and \$23,000 of interest income related to this loan during the three and six months ended June 30, 2021, respectively. The Company recognized approximately \$13,000 and \$25,000 of interest income related to this loan during the three and six months ended June 30, 2020, respectively.

Effective January 23, 2021, the Company entered into a First Amendment to Loan Agreement and Other Loan Documents with Pharmsynthez, Kevelt and SynBio (the “Pharmsynthez Loan Extension”) to modify the repayment terms and maturity of the Pharmsynthez Loan to January 2022. The terms of the Pharmsynthez Loan Extension called for two (2) equal monthly principal payments of \$25,000 in each of January 23, 2021 and February 28, 2021 and the payment of all outstanding accrued interest in six (6) equal monthly installments from January 31, 2021 through June 30, 2021. In addition, the Pharmsynthez Loan Extension requires monthly interest payments and the repayment of the remaining principal amount in six (6) equal monthly installments from August 2021 through January 2022. All other terms of the Pharmsynthez Loan remain in effect. As of June 30, 2021, approximately \$0.5 million was included in Prepaid expenses and other on the condensed consolidated balance sheet. As of December 31, 2020, approximately \$0.5 million was classified within Prepaid expenses and other and approximately \$0.1 million was classified within Other assets on the consolidated balance sheet.

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 was refundable on pro rata basis if the project is terminated prematurely as a result of Pharmsynthez failing to perform the work. On June 12, 2020, the Company and Pharmsynthez entered into a Master Services Agreement (“MSA”) to advance the development of the Company’s XCART technology for B-cell malignancies. The MSA terminated and superseded the SRA. The Company expensed approximately \$10,000 and \$0.1 million related to work performed under these agreements during the three and six months ended June 30, 2021. The Company expensed approximately \$0.1 million related to work performed under these agreements during the six months ended June 30, 2020. No expense was recorded during the three months ended June 30, 2020. As of June 30, 2021, approximately \$40,000 was accrued and included in Accrued expenses and other current liabilities on the condensed consolidated balance sheet. As of December 31, 2020, approximately \$25,000 was recorded as an advanced payment and included in Prepaid expenses and other on the consolidated balance sheet.

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 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 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. Through June 30, 2021, all costs incurred under the MSA were credited against the amounts paid under the SRA. 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. As of June 30, 2021, approximately \$0.1 million of milestone payments has been paid.

### **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 there were no such events requiring recognition or disclosure in the financial statements except as described below.

#### ***Financing***

On July 26, 2021, the Company entered into a securities purchase agreement in connection with a private placement (the “Purchase Agreement”) with the purchaser named on the signature page thereto (“Purchaser”), pursuant to which the Company agreed to issue and sell to the Purchaser, in a private placement priced at-the-market under Nasdaq rules, (i) 950,000 shares of the Company’s common stock, par value \$0.001 per share (the “Shares”), (ii) warrants to purchase an aggregate of 4,629,630 shares of the Company’s common stock, with an exercise price of \$3.30 per share (the “Series A Warrants”) which expire three and one half years from the earlier of (a) the six month anniversary of the initial exercise date and (b) the date that the registration statement registering all of the warrant shares underlying the Series A Warrants is declared effective, and (iii) pre-funded warrants to purchase up to 3,679,630 shares of the Company’s common stock, with an exercise price of \$0.001 per share (the “Series B Warrants” and together with the Series A Warrants, the “Warrants”) with no expiration (the “Private Placement”), at a purchase price of \$2.70 per one Share and one Series A Warrant and \$2.699 per one Series B Warrant and one Series A Warrant. The Company received aggregate gross proceeds from the Private Placement of approximately \$12.5 million, before deducting placement agent fees and offering expenses, and excluding the exercise of any Warrants.

## 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; our expectations regarding the timing for proposed submissions of regulatory filings, including, but not limited to, any Investigational New Drug filing or any New Drug Application; the nature, timing and extent of collaboration arrangements; the expected results pursuant to collaboration arrangements including the receipts of future payments that may arise pursuant to collaboration arrangements; the outcome of our plans to obtain regulatory approval of our drug candidates; the outcome of our plans for the commercialization of our drug candidates; our plans to address certain markets, engage third party manufacturers, and evaluate additional drug candidates for subsequent commercial development, 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.

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:

- failure to realize the anticipated potential of the XCART or PolyXen technology;
- our ability to implement our business strategy;
- the failure of the holder to exercise the warrants issued in the Private Placement;
- our use of proceeds from the Private Placement and warrant exercise;
- 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;
- the impact of natural disasters or public health emergencies, such as the COVID-19 global pandemic (including any new variant strains of the underlying virus), on our financial condition and results of operations; and
- other factors set forth in the Risk Factors section of our Annual Report on Form 10-K and in subsequent filings with the Securities and Exchange Commission (“SEC”).

These factors are not necessarily all of the important factors that could cause actual results to differ materially from those expressed in the forward-looking statements in this Quarterly Report. Other unknown or unpredictable factors also could have material adverse effects on our future results, including, but not limited to, those discussed in the section titled “Risk Factors.” The forward-looking statements in this Quarterly Report are made only as of the date of this Quarterly Report, and we do not undertake any obligation to publicly update any forward-looking statements to reflect subsequent events or circumstances. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995.

## **BUSINESS OVERVIEW**

We are a biopharmaceutical company focused on 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, including with Scripps Research and Pharmsynthez.

Additionally, we are leveraging our proprietary drug delivery platform, PolyXen<sup>®</sup>, 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 Food and Drug Administration 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<sup>™</sup> (sodium cridanimid) for the treatment of progesterin resistant endometrial cancer. We commenced a Phase 2 trial under an Investigational New Drug filing in 2017, for the potential treatment of progesterone receptor negative endometrial cancer in conjunction with progesterone therapy, with the 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 six months ended June 30, 2021 was on advancing the development of our XCART platform 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, 2020 filed with the SEC on March 16, 2021, as amended on April 28, 2021.

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

During March 2020, a global pandemic was declared by the World Health Organization related to the rapidly growing outbreak of a novel strain of coronavirus, or COVID-19. The pandemic has significantly affected economic conditions in the U.S., accelerating during the first half of March 2020 and continuing into 2021, 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 three and six months ended June 30, 2021 despite social distancing and other measures taken in response to the pandemic, the ultimate impact of the COVID-19 pandemic on our results of operations and financial condition is dependent on future developments, including the duration of the pandemic and the related extent of its severity, the pace and rate at which vaccines are administered, 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 June 30, 2021 and 2020

The comparison of our historical results of operations for the fiscal quarter ended June 30, 2021 to the fiscal quarter ended June 30, 2020 is as follows:

Description	Quarter Ended June 30, 2021	Quarter Ended June 30, 2020	Increase (Decrease)	Percentage Change
Revenues:				
Royalty revenue	\$ 287,603	\$ 112,927	\$ 174,676	154.7%
Operating costs and expenses:				
Research and development	(524,550)	(307,900)	216,650	70.4
General and administrative	(890,704)	(787,486)	103,218	13.1
Total operating costs and expenses	(1,415,254)	(1,095,386)	319,868	29.2
Loss from operations	(1,127,651)	(982,459)	145,192	14.8
Other income:				
Other income	238	192	46	24.0
Interest income, net	20,735	28,625	(7,890)	(27.6)
Net loss	\$ (1,106,678)	\$ (953,642)	\$ 153,036	16.1

### Revenue

Revenue for the three months ended June 30, 2021 increased by \$0.2 million, or 154.7%, to \$0.3 million from approximately \$0.1 million for the three months ended June 30, 2020. This increase represents an increase in royalty revenue related to our sublicense agreement with Takeda Pharmaceuticals Co. Ltd. as compared to the same period in 2020, as the sublicensee continued its worldwide launch of the product.

### Research and Development Expenses

Research & development (“R&D”) expenses for the three months ended June 30, 2021 increased by \$0.2 million, or 70.4% to \$0.5 million from \$0.3 million in the comparable quarter in 2020. The table below sets forth the R&D costs incurred by the Company by category of expense for the quarters ended June 30, 2021 and 2020:

Category of Expense	Quarter Ended,	
	June 30, 2021	June 30, 2020
Outside services and contract research organizations	\$ 358,389	\$ 150,668
Salaries and wages	108,747	112,055
Share-based expense	19,026	12,936
Other	38,388	32,241
Total research and development expense	\$ 524,550	\$ 307,900

The increase in outside services and contract research organizations expense was primarily due to increased spending related to our XCART platform technology during the three months ended June 30, 2021 as compared to the same period in the prior year. Costs related to our XCART program were higher in 2021 as compared to the same period in 2020 as we continued to invest in our pre-clinical developments efforts. This increase was partially offset by a decrease in spending on our XBIO-101 Phase 2 clinical trial, which was closed during the first quarter of 2021.

#### General and Administrative Expenses

General and administrative expenses for the three months ended June 30, 2021 was \$0.9 million, increasing \$0.1 million, or 13.1%, compared to the same period in the prior year. The increase was primarily due to a gain on settlement of certain vendor amounts to close out our XBIO-101 trial that reduced general and administrative expenses by \$0.1 million during the three months ended June 30, 2020.

#### Other Income

Other income was approximately \$200 for both the three months ended June 30, 2021 and 2020. Other income relates to changes in foreign currency exchange rates during both periods.

#### Interest Income, net

Interest income decreased to approximately \$21,000 during the three months ended June 30, 2021 as compared to approximately \$29,000 for the same period in the prior year. This decrease is primarily due to a decrease in interest income on invested funds due to lower interest rates during the second quarter of 2021 compared to the same period in 2020.

#### Comparison of Six Months Ended June 30, 2021 and 2020

The comparison of our historical results of operations for the six months ended June 30, 2021 to the six months ended June 30, 2020 is as follows:

Description	Six Months Ended June 30, 2021	Six Months Ended June 30, 2020	Increase (Decrease)	Percentage Change
Revenues:				
Royalty revenue	\$ 478,819	\$ 169,676	\$ 309,143	182.2%
Operating costs and expenses:				
Research and development	(1,154,279)	(667,551)	486,728	72.9
General and administrative	(1,821,282)	(1,715,366)	105,916	6.2
Total operating costs and expenses	(2,975,561)	(2,382,917)	592,644	24.9
Loss from operations	(2,496,742)	(2,213,241)	283,501	12.8
Other income:				
Other income	1,122	58	1,064	1,834.5
Interest income, net	42,997	80,112	(37,115)	(46.3)
Net loss	\$ (2,452,623)	\$ (2,133,071)	\$ 319,552	15.0

## Revenue

Revenue for the six months ended June 30, 2021 increased by \$0.3 million, or 182.2%, to \$0.5 million from approximately \$0.2 million for the six months ended June 30, 2020. This increase represents an increase in royalty revenue related to our sublicense agreement with Takeda Pharmaceuticals Co. Ltd. as compared to the same period in 2020, as the sublicensee continued its worldwide launch of the product.

## Research and Development Expenses

R&D expenses increased approximately \$0.5 million, or 72.9% to \$1.2 million for the six months ended June 30, 2021, from \$0.7 million for the six months ended June 30, 2020. The table below sets forth the R&D costs incurred by us, by category of expense, for the six months ended June 30, 2021 and 2020:

Category of Expense	Six Months Ended,	
	June 30, 2021	June 30, 2020
Outside services and contract research organizations	\$ 811,013	\$ 374,289
Salaries and wages	238,795	201,897
Share-based expense	29,736	26,294
Other	74,735	65,071
Total research and development expense	<u>\$ 1,154,279</u>	<u>\$ 667,551</u>

The increase in outside services and contract research organizations expense was primarily due to increased spending related to our XCART platform technology during the six months ended June 30, 2021 as compared to the same period in the prior year. Costs related to our XCART program were higher in 2021 as compared to the same period in 2020 as we continued to invest in our pre-clinical developments efforts. This increase was partially offset by a decrease in spending on our XBIO-101 Phase 2 clinical trial, which was closed during the first quarter of 2021. Salaries and wages increased during the six months ended June 30, 2021 due to slightly higher employee related costs.

## General and Administrative Expenses

General and administrative expenses for the six months ended June 30, 2021 was \$1.8 million, increasing \$0.1 million, or 6.2%, compared to the same period in the prior year. Increases in employee related and consulting costs during the six months ended June 30, 2021 compared to the same period in 2020 were substantially offset by lower share-based expense and legal and accounting costs. In addition, general and administrative expenses for the six months ended June 30, 2020 were lower than the same period in 2021 due to a \$0.1 million gain on settlement of certain vendor amounts to close out our XBIO-101 trial recognized during 2020.

## Other Income

Other income was approximately \$1,000 for the six months ended June 30, 2021 compared to approximately \$100 for the same period in 2020. This increase was primarily related to changes in foreign currency exchange rates during the six months ended June 30, 2021 as compared to the same period in 2020.

## Interest Income

Interest income decreased to approximately \$43,000 during the six months ended June 30, 2021 as compared to approximately \$80,000 for the same period in the prior year. This decrease is primarily due to a decrease in interest income on invested funds due to lower interest rates during 2021 compared to the same period in 2020.

## **Liquidity and Capital Resources**

We incurred a net loss of approximately \$2.5 million for the six months ended June 30, 2021. We had an accumulated deficit of approximately \$179.4 million at June 30, 2021 as compared to an accumulated deficit of approximately \$176.9 million at December 31, 2020. Working capital was approximately \$9.2 million at June 30, 2021 and \$11.4 million at December 31, 2020, respectively. During the six months ended June 30, 2021, our working capital decreased by \$2.2 million primarily due to our net loss for the six months ended June 30, 2021. We expect to continue incurring losses for the foreseeable future and may need to raise additional capital or pursue other strategic alternatives in the long-term in order to continue the pursuit of our business plan.

Our principal source of liquidity consists of cash. At June 30, 2021, we had approximately \$9.3 million in cash and \$1.0 million in current liabilities. At December 31, 2020, we had approximately \$11.5 million in cash and \$0.9 million in current liabilities. We have historically relied upon sales of our equity securities to fund our operations. We expect the majority of our funding through equity or equity-linked instruments, debt financings, corporate collaborations, related party funding and/or licensing agreements to continue as a trend for the foreseeable future.

Management evaluates whether there are conditions or events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that the financial statements are issued. We have incurred substantial losses since our inception, and we expect to continue to incur operating losses in the near-term. These factors raise substantial doubt about our ability to continue as a going concern. We believe that we have access to capital resources through possible public or private equity offerings, debt financings, corporate collaborations, related party funding, or other means to continue as a going concern. On December 4, 2020, we closed on a \$6.0 million registered direct Common Stock offering resulting in \$5.4 million of net proceeds to us. On July 28, 2021, we completed a \$12.5 million private placement of our Common Stock resulting in approximately \$11.4 million of net proceeds to us. We believe that these financings, coupled with our existing resources, will be adequate for us to continue as a going concern. However, we anticipate we may need additional capital in the long-term to pursue our business initiatives. The terms, timing and extent of any future financing will depend upon several factors, including the achievement of progress in our clinical development programs, our ability to identify and enter into licensing or other strategic arrangements, and factors related to financial, economic and market conditions, many of which are beyond our control.

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

Cash flows used in operating activities for the six months ended June 30, 2021 totaled approximately \$2.2 million, which was primarily due to our net loss for the period, partially offset by non-cash charges associated with share-based expense. Cash flows used in operating activities for the six months ended June 30, 2020 totaled approximately \$2.3 million, which was primarily due to our net loss for the period, partially offset by non-cash charges associated with share-based expense, and settlement of certain amounts payable to a vendor related to the close-out of our XBIO-101 trial.

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

There were no cash flows from investing activities for the six months ended June 30, 2021 and 2020.

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

There were no cash flows from financing activities for the six months ended June 30, 2021 and 2020.

### **Contractual Obligations and Commitments**

As of June 30, 2021, 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, 2020, filed with the SEC on March 16, 2021, as amended on April 28, 2021.

### **Off Balance Sheet Arrangements**

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

### **Recent Accounting Standards**

See Note 3 in our Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 16, 2021, as amended on April 28, 2021, 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, 2020, filed with the SEC on March 16, 2021, as amended on April 28, 2021.

### **ITEM 3 – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We are not required to provide the information required by this Item because we are a “smaller reporting company” (as defined in Rule 12b-2 of the Exchange Act).

### **ITEM 4 – CONTROLS AND PROCEDURES**

#### **Evaluation of Disclosure Controls and Procedures**

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

Based on this evaluation, our management, including our Chief Executive Officer and Chief Financial Officer, concluded that as of the end of the period covered by this Quarterly Report, our disclosure controls and procedures are designed at a reasonable assurance level and are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

#### **Changes in Internal Control over Financial Reporting**

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

## PART II – OTHER INFORMATION

### ITEM 1 – LEGAL PROCEEDINGS

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

### ITEM 1A – RISK FACTORS

There have been no material changes to the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 16, 2021, as amended on April 28, 2021.

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

None.

### ITEM 3 – DEFAULTS UPON SENIOR SECURITIES

None.

### ITEM 4 – MINE SAFETY DISCLOSURES

Not applicable.

### ITEM 5 – OTHER INFORMATION

None.

### ITEM 6 – EXHIBITS

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

EXHIBIT NUMBER	DESCRIPTION
31.1*	<a href="#">Certification of Jeffrey F. Eisenberg, Principal Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
31.2*	<a href="#">Certification of James Parslow, Principal Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
32.1**	<a href="#">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.</a>
101*	The following financial statements from the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, formatted in inline XBRL, include: (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statements of Stockholders' Equity, (iv) Condensed Consolidated Statements of Cash Flows and (v) the Notes to the Condensed Consolidated Financial Statements.
104*	Cover Page Interactive Data File (formatted in inline XBRL and included in Exhibit 101).
*	Filed herewith.
**	Exhibit 32.1 is being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall such exhibits be deemed to be incorporated by reference in any registration statement or other document filed under the Securities Act of 1933, as amended or the Securities Exchange Act of 1934, as amended, except as otherwise stated in such filing.

**SIGNATURES**

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

**XENETIC BIOSCIENCES, INC.**

August 12, 2021

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: August 12, 2021

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: August 12, 2021

By: /s/ JAMES PARLOW  
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 June 30, 2021, 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: August 12, 2021

**IN WITNESS WHEREOF**, the undersigned have set their hands hereto as of the 12th day of August 2021.

/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.”