#### 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, 2020

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  $\boxtimes$  No  $\square$ 

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  $\boxtimes$  No  $\square$ 

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	X	Smaller reporting company	X
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 Exchange Act Rule 12b-2): Yes 🗆 No 🗵

As of August 7, 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 JUNE 30, 2020

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# **ITEM 1 - FINANCIAL STATEMENTS**

# XENETIC BIOSCIENCES, INC. CONDENSED CONSOLIDATED BALANCE SHEETS

		June 30, 2020 (Unaudited)	D	ecember 31, 2019
ASSETS				
Current assets:				
Cash	\$	8,066,460	\$	10,367,920
Prepaid expenses and other		1,049,339		722,079
Total current assets		9,115,799		11,089,999
Property and equipment, net		-		757
Indefinite-lived intangible assets		9,243,128		9,243,128
Other assets		704,431		1,213,042
Total assets	\$	19,063,358	\$	21,546,926
LIABILITIES AND STOCKHOLDERS' EQUITY Current liabilities: Accounts payable	\$	250,075	\$	931,128
Accrued expenses and other current liabilities	φ	537,253	φ	484,029
Total current liabilities		787.328		1,415,157
		787,528		1,413,137
Deferred tax liability		2,918,518		2,918,518
Total liabilities		3,705,846		4,333,675
Commitments (Note 10)				
Stockholders' equity:				
Preferred stock, 10,000,000 shares authorized				
Series B, \$0.001 par value: 1,804,394 shares issued and outstanding as of June 30, 2020 and December 31, 2019		1,804		1,804
Series A, \$0.001 par value: 970,000 shares issued and outstanding as of June 30, 2020 and December 31, 2019		970		970
Common stock, \$0.001 par value; 12,500,000 shares authorized as of June 30, 2020 and December 31, 2019; 6,323,218 and 6,092,432 shares issued as of June 30, 2020 and December 31, 2019, respectively; 6,296,227 and 6,065,441 shares				
outstanding as of June 30, 2020 and December 31, 2019, respectively		6,322		6,092
Additional paid in capital		188,517,553		188,240,451
Accumulated deficit		(168,141,691)		(166,008,620)
Accumulated other comprehensive income Treasury stock		253,734		253,734
•		(5,281,180)		(5,281,180)
Total stockholders' equity	<u>_</u>	15,357,512	<u>_</u>	17,213,251
Total liabilities and stockholders' equity	\$	19,063,358	\$	21,546,926

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

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

		THREE MON JUN			SIX MONTHS ENDED JUNE 30,						
		2020		2019		2020		2019			
Revenue:											
Royalty revenue	\$	112,927	\$	-	\$	169,676	\$	_			
Total revenue		112,927		_		169,676		_			
Operating costs and expenses:											
Research and development	\$	(307,900)	\$	(487,519)	\$	(667,551)	\$	(951,301)			
General and administrative		(787,486)		(890,779)		(1,715,366)		(1,754,152)			
Total operating costs and expenses		(1,095,386)		(1,378,298)		(2,382,917)		(2,705,453)			
Loss from operations		(982,459)		(1,378,298)		(2,213,241)		(2,705,453)			
Other income:											
Other income		192		735		58		490			
Interest income, net		28,625		163		80,112		313			
Total other income		28,817		898		80,170		803			
Net loss	\$	(953,642)	\$	(1,377,400)	\$	(2,133,071)	\$	(2,704,650)			
Deemed dividend								(3,879,447)			
Net loss applicable to common stockholders	\$	(953,642)	\$	(1,377,400)	\$	(2,133,071)	\$	(6,584,097)			
Desig and diluted loss per share	¢	(0.15)	¢	(1.56)	Φ.	(0.24)	<u>.</u>	(7.70)			
Basic and diluted loss per share	\$	(0.15)	\$	(1.56)	\$	(0.34)	\$	(7.79)			
Weighted-average shares of common stock outstanding, basic and diluted		6,288,351		882,107		6,260,841		844,749			

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

	Preferr	ed Sto	ck	Commo	on Ste	ock	Additional	Accumulated Other					Total		
	Number of Shares		ar Value \$0.001)	Number of Shares		Par Value (\$0.001)	Paid in Capital	Accumulated Deficit	Сог	nprehensive Income	1	Freasury Stock	Ste	ockholders' Equity	
Balance as of April 1, 2020	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)	
Balance as of June 30, 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	

# SIX MONTHS ENDED JUNE 30, 2020

									Ac	cumulated		
	Preferr	ed Stoc	k	Common Stock			Additional		Total			
	Number of	Pa	r Value	Number of	of Par Value		Paid in	Accumulated Compre		prehensive	Treasury	Stockholders'
	Shares	(\$	0.001)	Shares	(	(\$0.001)	Capital	Deficit		Income	Stock	Equity
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	-		-	-		-	277,332	-		-	-	277,332
Exercise of purchase warrants	-		-	229,598		229	(229)	-		-	-	-
Net loss	-		-	-		-	-	(2,133,071)		-	-	(2,133,071)
Balance as of June 30, 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

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

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

# THREE MONTHS ENDED JUNE 30, 2019

									Ac	cumulated				
	Preferr	ed St	ock	Commo	on S	Stock	Additional			Other				Total
	Number of Shares		2ar Value (\$0.001)	Number of Shares		Par Value (\$0.001)	Paid in Capital	Accumulated Deficit		nprehensive Income	1	Freasury Stock	St	ockholders' Equity
Balance as of April 1, 2019	2,774,394	\$	2,774	897,523	\$	898	\$ 171,103,147	\$ (154,560,845)	\$	253,734	\$	(5,281,180)	\$	11,518,528
Exercise of pre-funded warrants	_		_	42,417		42	467	_		_		_		509
Issuance of common stock to vendor	_		-	7,836		7	(7)	_		-		-		_
Issuance of common stock to adjust														
for reverse split rounding	_		_	1,442		1	(1)	_		_		_		_
Share-based expense	_		_	-		-	234,154	-		-		-		234,154
Common stock awards to vendors	_		_	-		-	15,000	_		_		_		15,000
Net loss	-		_	-		-	-	(1,377,400)		_		_		(1,377,400)
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

# SIX MONTHS ENDED JUNE 30, 2019

	Preferr Number of Shares	Pa	<u>ek</u> r Value 60.001)	Common Stock Number of Par Va Shares (\$0.00				Accumulated Deficit	Com	umulated Other prehensive ncome	Treasury Stock	Total Stockholders' Equity
Balance as of January 1, 2019	2,774,394	\$	2,774	810,856	/	311	\$ 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
Exercise of pre-funded warrants	-		-	42,417		42	467	-		-	-	509
Issuance of common stock to vendor	_		-	7,836		7	(7)	-		-	-	-
Issuance of common stock to adjust for reverse split rounding	_		_	1,442		1	(1)	_		_	_	_
Deemed dividend related to Series B Preferred Stock down round							2.050.445					2.050.445
provision Accretion of deemed dividend related to Series B Preferred Stock down	-		_	-		-	3,879,447	-		-	_	3,879,447
round provision	-		-	-		_	(3,879,447)	-		-	-	(3,879,447)
Share-based expense	-		-	-		-	450,667	-		-	-	450,667
Common stock awards to vendors	-		-	-		-	32,427	-		-	-	32,427
Net loss	_		-	-		_	-	(2,704,650)		-	-	(2,704,650)
Balance as of June 30, 2019	2,774,394	\$	2,774	949,218	\$ 9	948	\$ 171,352,760	\$ (155,938,245)	\$	253,734	\$ (5,281,180)	\$ 10,390,791

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

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

	Six Months Ended June 30,			ine 30,
		2020		2019
CASH FLOWS FROM OPERATING ACTIVITIES:				
Net loss	¢	(2,122,071)	¢	(2,704,(50))
	\$	(2,133,071)	\$	(2,704,650)
Adjustments to reconcile net loss to net cash used in operating activities: Depreciation		757		2.412
Amortization of right of use asset		13,765		10,179
Gain on sale of property and equipment		15,705		(2,000)
Gain on settlement with vendor		(143,639)		(2,000)
Share-based expense		277,332		450,667
Vendor share-based expense		277,332		32,427
Changes in operating assets and liabilities:		_		32,427
Prepaid expenses and other assets		167,586		(775,258)
Accounts payable, accrued expenses and other liabilities				680,767
		(484,190)		,
Net cash used in operating activities		(2,301,460)		(2,305,456)
CASH FLOWS FROM INVESTING ACTIVITIES:				
Proceeds from sale of property and equipment				2,000
Net cash provided by investing activities				2,000
Net easi provided by investing activities		_		2,000
CASH FLOWS FROM FINANCING ACTIVITIES:				
Net proceeds from issuance of common stock and warrants		_		2,699,559
Net cash provided by financing activities		_		2,699,559
				, ,
Net change in cash		(2,301,460)		396,103
Cash at beginning of period		10,367,920		638,115
		<u> </u>		
Cash at end of period	\$	8,066,460	\$	1,034,218
		<u> </u>		
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
				43,330
Issuance of common stock from cashless exercise of purchase warrants	\$	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  $XCART^{TM}$ , 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<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. 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.

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<sup>TM</sup>, PolyXen, ErepoXen<sup>TM</sup>, and ImuXen<sup>TM</sup>, 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. During 2019, the Company completed two stock offerings that resulted in \$16.1 million of net proceeds to the Company. The Company believes that it is 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 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 control.



#### 2. 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 encound 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. Inless 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 six months ended June 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.

#### 3. 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, 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 \$113,000 and \$170,000 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. There were no remaining performance obligations and all other revenue recognized as revenue related to the Serum Institute, Pharmsynthez or SynBio agreements during the three and six months ended June 30, 2020 and 2019.

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<sup>TM</sup>. 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 Technology (as defined in the Scripps Agreement) solely for 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.

## 4. Property and Equipment, net

Property and equipment, net consists of the following:

	June 30, 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)		(56,270)	
Property and equipment – net	\$	-	\$	757	

Depreciation expense was approximately \$200 and \$1,000 for the three months ended June 30, 2020 and 2019, respectively, and approximately \$800 and \$2,000 for the six months ended June 30, 2020 and 2019, respectively.

# 5. 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. The carrying value of the IPR&D was approximately \$9.2 million as of June 30, 2020 and December 31, 2019, respectively. IPR&D is required to be tested annually until the project is completed or abandoned. The IPR&D is not yet commercialized and, therefore, has not yet begun to be amortized as of June 30, 2020. The Company assesses IPR&D for impairment at least annually as of October 1 or when events or changes in circumstances indicate that the carrying value may be impaired. No impairment was recorded during the three and six months ended June 30, 2020 nor during the year ended December 31, 2019.

# 6. 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.

#### 7. 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, 2020 and December 31, 2019, collaboration warrants to purchase 30,307 and 32,412 shares of common stock were outstanding, respectively. During the three and six months ended June 30, 2020, collaboration warrants to purchase 2,105 shares expired. The outstanding warrants as of June 30, 2020 have an average weighted exercise price of \$124.74 and expiration dates ranging from April 27, 2021 through May 2021. No collaboration warrants were granted or exercised in connection with collaboration or consulting services during the three and six months ended June 30, 2020 and 2019, respectively.

In addition, the Company has outstanding warrants to purchase an aggregate of 428,959 and 658,557 shares of common stock in connection with debt and equity financing arrangements as of June 30, 2020 and December 31, 2019, respectively. These warrants have an average weighted exercise price of \$40.88 as of June 30, 2020 and expiration dates ranging from July 2020 through September 2026. There were no debt and equity financing warrants granted during the six months ended June 30, 2020 and warrants to purchase 129,084 shares of common stock were granted during the six months ended June 30, 2020, debt and equity financing warrants to purchase approximately 230,000 shares of common stock were exercised on a cashless one-for-one basis. No debt or equity financing warrants were exercised during the three and six months ended June 30, 2019.

#### 8. 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 June 30, 2020 and 2019, respectively, and approximately \$0.3 million and \$0.5 million for the six months ended June 30, 2020 and 2019, 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,				
		2020		2019		2020		2019
Research and development expenses	\$	12,936	\$	31,660	\$	26,294	\$	43,078
General and administrative expenses		98,798		217,494		251,038		440,016
	\$	111,734	\$	249,154	\$	277,332	\$	483,094

# **Employee Stock Options**

There were no employee stock options or RSUs granted or exercised during the six months ended June 30, 2020 and 2019, respectively. 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 June 30, 2020 and 2019, respectively, and \$0.3 million and \$0.5 million during the six months ended June 30, 2020 and 2019, respectively.

#### Non-Employee Stock Options

The Company did not grant any non-employee stock options during the six months ended June 30, 2020 and 2019, respectively. The Company recognized approximately \$4,000 and \$7,000 of expense during the three and six months ended June 30, 2020, respectively. The Company did not recognize any expense related to non-employee stock options during the three and six months ended June 30, 2019, respectively.

## **Common Stock Awards**

During the three and six months ended June 30, 2019, the Company granted 1,188 and 1,873 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 six months ended June 30, 2019, approximately \$15,000 and \$32,000 of expense related to common stock awards was recognized, respectively. There were no common stock awards granted during the three and six months ended June 30, 2020, the Company issued 1,188 shares related to these awards. As of June 30, 2020, there were 7,406 common stock awards authorized but not issued.



#### 9. Income Taxes

During the three and six months ended June 30, 2020 and 2019, 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 \$26.3 million and \$25.9 million as of June 30, 2020 and December 31, 2019, respectively.

As of June 30, 2020 and 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. This net deferred tax liability will continue to be reflected on the balance sheet until the related intangible assets are no longer held by the Company.

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

#### 10. Commitments

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

	x Months Ended June 30, 2020
Operating cash flow information:	
Cash paid for amounts included in the measurement of lease liabilities	\$ 13,765

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

	Balance Sheet Classification	June	30, 2020
Right-of-use assets	Prepaid expenses and other	\$	6,277
Current lease liabilities	Accrued expenses and other current liabilities	\$	6,277

#### 11. 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 \$0.1 million related to this agreement during the six months ended June 30, 2020. The Company during the three months ended June 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 June 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 \$25,000 of interest income related to this loan during the three and six months ended June 30, 2020, respectively. As of June 30, 2020, 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 is required to pay Pharmsynthez \$51,000 as an initial payment for trial startup costs, which amount is 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. No costs were incurred under the Work Order during the three and six months ended June 30, 2020, respectively.

#### 12. Subsequent Events

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

# 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 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 for subsequent commercialization of our drug candidates; but acquiding the reaceptor ("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

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 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<sup>TM</sup>, 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 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, 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 pharmacelogical 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- $101^{TM}$  (sodium cridanimod) for the treatment of progestin 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 six months ended June 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 August, 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 six 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 June 30, 2020 and 2019

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

Description	arter Ended 1ne 30, 2020	uarter Ended une 30, 2019	Increase (Decrease)	Percentage Change
Revenues:			 	
Royalty revenue	\$ 112,927	\$ _	\$ 112,927	100.0
Operating costs and expenses:				
Research and development	(307,900)	(487,519)	(179,619)	(36.8)
General and administrative	(787,486)	(890,779)	(103,293)	(11.6)
Total operating costs and expenses	(1,095,386)	 (1,378,298)	 (282,912)	(20.5)
Loss from operations	 (982,459)	 (1,378,298)	 (395,839)	(28.7)
Other income:				
Other income	192	735	(543)	(73.9)
Interest income, net	28,625	163	 28,462	17,461.3
Net loss	\$ (953,642)	\$ (1,377,400)	\$ (423,758)	(30.8)

#### Revenue

For the three months ended June 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 first quarter of 2020 were recorded as revenue by us during the three months ended June 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 June 30, 2019.

## **Research and Development Expenses**

Research & development ("R&D") expenses for the three months ended June 30, 2020 decreased by \$0.2 million, or 36.8% to \$0.3 million from \$0.5 million in the comparable quarter in 2019. The table below sets forth the R&D costs incurred by the Company by category of expense for the quarters ended June 30, 2020 and 2019:

	 Quarter Ended,		
Category of Expense	 June 30, 2020	Jı	une 30, 2019
Outside services and contract research organizations	\$ 150,668	\$	351,253
Salaries and wages	112,055		75,163
Share-based expense	12,936		31,660
Other	32,241		29,443
Total research and development expense	\$ 307,900	\$	487,519



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 three months ended June 30, 2020 as compared to the same period in the prior year. Costs related to the 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 was partially offset by an increase in costs associated with our XCART preclinical development efforts and increased employee related costs during the quarter.

# **General and Administrative Expenses**

General and administrative expenses for the three months ended June 30, 2020 was \$0.8 million, decreasing by approximately \$0.1 million, or 11.6%, compared to the same period in the prior year, primarily due to a decrease in 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 offset by an increase in investor relations costs due to increased investor outreach activities and slightly higher legal costs during the second quarter of 2020 compared to the same period in the prior year.

#### **Other Income**

Other income was approximately \$200 for the three months ended June 30, 2020 compared to approximately \$700 for the same period in 2019. This decrease was primarily related to changes in foreign currency exchange rates during the second quarter of 2020 as compared to the same period in 2019.

#### Interest Income, net

Interest income, net increased to approximately \$29,000 during the three months ended June 30, 2020 as compared to approximately \$200 for the same period in the prior year. This increase is primarily due to an increase in cash in the second quarter of 2020 as compared to the second quarter of 2019, due to the receipt of net proceeds of \$13.4 million from our July 2019 public offering.

# Comparison of Six Months Ended June 30, 2020 and 2019

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

Description		x Months Ended June 30, 2020		Six Months Ended June 30, 2019		Increase Decrease)	Percentage Change
Revenues:	¢	1(0)(7)	¢		¢	1(0,(7))	100.0
Royalty revenue	\$	169,676	\$		\$	169,676	100.0
Operating costs and expenses:							
Research and development expenses		(667,551)		(951,301)		(283,750)	(29.8)
General and administrative expenses		(1,715,366)		(1,754,152)		(38,786)	(2.2)
Total operating costs and expenses		(2,382,917)		(2,705,453)		(322,536)	(11.9)
Loss from operations		(2,213,241)		(2,705,453)		(492,212)	(18.2)
Other income:							
Other income		58		490		(432)	(88.2)
Interest income, net		80,112		313		79,799	25,494.9
Net loss	\$	(2,133,071)	\$	(2,704,650)	\$	(571,579)	(21.1)



#### Revenue

For the six months ended June 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 first quarter of 2020 were recorded as revenue by us during the six months ended June 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 quarters subsequent to the actual sales by the sublicensee. We did not recognize any revenue for the six months ended June 30, 2019.

#### **Research and Development Expenses**

R&D expenses decreased approximately \$0.3 million, or 29.8% to \$0.7 million for the six months ended June 30, 2020, from \$1.0 million for the six months ended June 30, 2019. The table below sets forth the R&D costs incurred by us, by category of expense, for the six months ended June 30, 2020 and 2019:

		Six Months Ended,		
Category of Expense	Jui	ne 30, 2020	Jun	ne 30, 2019
Outside services and contract research organizations	\$	374,289	\$	705,598
Salaries and wages		201,897		154,448
Share-based expense		26,294		43,078
Other		65,071		48,177
Total research and development expense	\$	667,551	\$	951,301

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 six months ended June 30, 2020 as compared to same period in the prior year. Costs related to the 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 partially offset by increased costs associated with our XCART pre-clinical development efforts. Salaries and wages increased during the six months ended June 30, 2020 due to slightly higher employee related costs.

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

General and administrative expenses decreased by approximately \$39,000, or 2.2% for the six months ended June 30, 2020, to \$1.7 million from \$1.8 million in the comparable period in 2019, primarily due to a decrease in 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 offset by an increase in investor relations costs due to increased investor outreach activities, slightly higher legal costs and increased employee costs during the six months ended June 30, 2020 compared to the same period in the prior year.

#### **Other Income**

Other income was approximately \$60 for the six months ended June 30, 2020 compared to approximately \$500 for the same period in 2019. This decrease was primarily related to a reduction in foreign currency transactions and related changes in foreign currency exchange rates during the six months ended June 30, 2020 as compared to the same period in 2019.



#### **Interest Income**

Interest income, net increased to approximately \$80,000 during the six months ended June 30, 2020 as compared to approximately \$300 for the same period in the prior year. This increase is primarily due to an increase in cash in the first half of 2020 as compared to the same period in 2019 due to the receipt of net proceeds of \$13.4 million from our July 2019 public offering.

# Liquidity and Capital Resources

We incurred a net loss of approximately \$2.1 million for the six months ended June 30, 2020. We had an accumulated deficit of approximately \$168.1 million at June 30, 2020 as compared to an accumulated deficit of approximately \$166.0 million at December 31, 2019. Working capital was approximately \$8.3 million at June 30, 2020 and \$9.7 million at December 31, 2019, respectively. During the six months ended June 30, 2020, our working capital decreased by \$1.4 million primarily due to our net loss for the six months ended June 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 long-term in order to continue the pursuit of our business plan.

Our principal source of liquidity consists of cash. At June 30, 2020, we had approximately \$8.1 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 June 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 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, 2020 of approximately \$2.3 million was primarily due to our net loss for the period, 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 used in operating activities for the six months ended June 30, 2019 totaled approximately \$2.3 million, which was primarily due to our net loss for the period, offset by non-cash charges associated with share-based expense.

# **Cash Flows from Investing Activities**

There were no cash flows from investing activities for the six months ended June 30, 2020. Cash flows provided by investing activities for the six months ended June 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 six months ended June 30, 2020. Cash flows provided by financing activities for the six months ended June 30, 2019 totaled approximately \$2.7 million representing net proceeds from our registered direct offering in March 2019.

# **Contractual Obligations and Commitments**

As of June 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 Report on Form 10-Q for the quarter ended March 31, 2020.

# Our financial condition, results of operations, business and cash flow may be negatively affected by a public health crises 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 first six 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.

# 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.

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# ITEM 6 – EXHIBITS

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

EXHIBIT	
NUMBER	DESCRIPTION
10.1*#	Research Funding and Option Agreement, dated May 15, 2020, between the Company and the Scripps Research Institute.
10.2*#	Master Service Agreement, dated June 12, 2020, between the Company and PJSC Pharmsynthez.
10.3*#	Work Order to Master Service Agreement, dated June 12, 2020, between the Company and PJSC Pharmsynthez.
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 June 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.
	Portions of this exhibit, marked by brackets and asterisks, have been omitted pursuant to Item 601(b)(10) of Regulation S-K under the Securities Act of
#	1933, as amended, because they are both (i) not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed. The registrant

undertakes to promptly provide an unredacted copy of the exhibit on a supplemental basis, if requested by the Commission or its staff.

# SIGNATURES

Pursuant to the requirements of 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.

August 12, 2020

By: /S/ JEFFREY F. EISENBERG

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

By: <u>/S/ JAMES PARSLOW</u>

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

## CERTAIN INFORMATION IDENTIFIED IN THIS DOCUMENT, MARKED BY BRACKETS AND ASTERISKS ("[\*\*\*]"), HAS BEEN EXCLUDED PURSUANT TO ITEM 601(B)(10) OF REGULATION S-K UNDER THE SECURITIES ACT OF 1933, AS AMENDED, BECAUSE IT IS (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED.

## **RESEARCH FUNDING AND OPTION AGREEMENT**

This Agreement is entered into May 12, 2020 (the "Effective Date"), by and between The Scripps Research Institute, a California nonprofit public benefit corporation located at 10550 North Torrey Pines Road, La Jolla, California 92037 ("TSRI"), and Xenetic Biosciences, Inc. ("Sponsor"), a for-profit corporation located at 40 Speen Street, Suite 102, Framingham, Massachusetts 01701, with respect to the facts set forth below.

# RECITALS

A. TSRI is engaged in fundamental scientific biomedical and biochemical research including research relating to methods for treatment of B cell malignancies using personalized medicine, as more particularly described herein.

B. Sponsor is engaged in research and development of personalized CAR T therapy for the treatment of hematological cancers.

C. Sponsor desires to provide certain funding as part of TSRI's research activities described above.

D. Subject to any non-exclusive rights of the U.S. Government, TSRI is willing to grant to Sponsor an option to acquire rights and licenses to certain intellectual property arising from the Research Program.

# AGREEMENT

NOW, THEREFORE, in consideration of the mutual covenants and conditions outlined herein, TSRI and Sponsor hereby agree as follows:

1. DEFINITIONS.

1.1 <u>Affiliate</u>. The term "Affiliate" shall mean any entity which directly or indirectly controls, or is controlled by Sponsor. The term "control" as used herein means (a) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or shares entitled to vote for the election of directors; or (b) in the case of non-corporate entities, direct or indirect ownership of at least fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entities. Unless otherwise specified, the term Sponsor includes Affiliates.

1.2 Agreement Number. This Agreement is TSRI number 2020-0140.

1.3 <u>Biological Materials</u>. The term "Biological Materials" shall mean any Technology in the form of tangible materials together with any progeny, mutants, or derivatives thereof developed in performance of the Research Program.

1.4 <u>Calendar Quarter</u>. The term "Calendar Quarter" shall mean that period of three months occurring from January through March (Quarter 1), April through June (Quarter 2), July through September (Quarter 3) and October through December (Quarter 4). For purposes of clarity, each of Quarter 1, Quarter 2, Quarter 3 and Quarter 4 is a Calendar Quarter under this Agreement.

1 . 5 <u>Confidential Information</u>. The term "Confidential Information" shall mean any and all proprietary information of TSRI or Sponsor, including, trade secrets, information relating to existing or contemplated products, services, technology, designs, processes, formulae, computer systems, computer software, research programs, algorithms and research or developments, which may be exchanged between the parties at any time and from time to time during the term hereof. The fact that a party may have marked or identified as confidential or proprietary any specific information shall be indicative that such party believes such information to be confidential or proprietary, but the failure to so mark information shall not conclusively determine that such information was or was not considered confidential information by such party. Neither Party shall modify, enhance, compile or assemble (or reverse compile or disassemble), or reverse engineer Confidential Information of the other or anything containing or embodying such Confidential Information. Neither Party shall use any Confidential Information of the other or anything containing or embodying such Confidential Information. Neither Party shall use any Confidential Information of the other party or the concepts therein for its own benefit or for the benefit of a third party or for any purpose other than for evaluating a possible business relationship. Neither Party shall remove any proprietary legends or notices, including copyright notices, appearing on or in the Confidential Information. Each Party shall take appropriate action with respect to each and every person permitted access to any Confidential Information to ensure that each person complies with the confidentiality provisions hereof. Confidential Information shall also include any information which, given the circumstances surrounding the disclosure, would be considered confidential by the disclosing party. Information shall not be considered confidential to the extent that it:

a. Is publicly disclosed through no fault of any party hereto, either before or after it becomes known to the receiving party; or

b. Was known to the receiving party prior to the Effective Date, which knowledge was acquired independently and not from the other party hereto (including such party's employees); or

c. Is subsequently disclosed to the receiving party in good faith by a third party who has a right to make such disclosure; or

Information.

- d. Was independently developed by or on behalf of the receiving party without use of or reference to the other party's Confidential
- 1.6 Field. The term "Field" shall mean treatment of a B-cell Malignancy using the Technology.

1.7 Joint Technology. The term "Joint Technology" shall mean any Technology developed by individuals associated with TSRI and Sponsor under the terms of this Agreement.

1.8 <u>Patent Rights</u>. The term "Patent Rights" shall mean:

(a) U.S. patents or patent application(s) directed to the Technology;

(b) Foreign counterpart patents or patent applications claiming and entitled to the priority date of the respective patents and patent application(s) referenced in sub-clause (a) above;

(c) Divisionals and continuations of any patents or patent applications referenced in sub-clauses (a) and (b) above;

(d) Any claim(s) of a continuation-in-part claiming and entitled to the priority date of the respective patents and patent application(s) referenced in sub-clause (a) above; and

(e) Reissues, reexaminations, renewals and patent term extensions of the patents referenced in sub-clauses (a) - (d) above.

1 . 9 <u>Principal Investigator</u>. The term "Principal Investigator" shall mean Dr. Lerner, together with such replacement persons selected in accordance with the provisions of Section 2.2 hereof.

1.10 <u>Research Program</u>. The term "Research Program" shall mean the research program to be undertaken by TSRI under the direction and control of the Principal Investigator as expressly set forth on Exhibit A hereto.

1.11 <u>Research Tool</u>. The term "Research Tool" shall mean any Technology which is designed or utilized for basic research purposes or internal drug discovery purposes and which is not utilized to produce, or incorporated into, a product.

1.12 <u>Technology</u>. The term "Technology" shall mean any invention, discovery, know-how, Biological Material, software, information and data, whether patentable or not, first conceived and reduced to practice during and as a result of the performance of the Research Program.

1.13 <u>Technology Rights</u>. The term "Technology Rights" shall mean any Technology, including TSRI Technology and Joint Technology developed pursuant to the work conducted under this Agreement.

1.14 <u>TSRI Technology</u>. The term "TSRI Technology" shall mean any Technology developed solely by TSRI under the principles of what constitutes an inventor under the patent laws of the United States of America.

## 2. CONDUCT OF RESEARCH PROGRAM.

2.1 <u>Conduct of Research Program</u>. TSRI hereby agrees to use diligent and reasonable efforts to perform the Research Program subject to the provisions of this Agreement. Notwithstanding the foregoing, TSRI makes no warranties or representations regarding its ability to achieve, nor shall it be bound to accomplish, any particular research objective or results.

2.2 <u>Supervision of Research Program</u>. TSRI agrees that the Research Program at TSRI shall be conducted by or under the direct supervision of the Principal Investigator. In the event that the Principal Investigator leaves TSRI, or terminates his/her involvement in the Research Program, TSRI shall use its best efforts to find a replacement Principal Investigator for whom Sponsor provides its written acceptance, which written acceptance shall not be unreasonably withheld. In the event that TSRI shall to appoint a replacement Principal Investigator reasonably acceptable to Sponsor, Sponsor shall have a right to terminate this Agreement upon delivery to TSRI of written notice of intent to terminate pursuant to this Section 2.2, which notice must be delivered to TSRI not less than thirty (30) days nor more than ninety (90) days after delivery by TSRI to Sponsor of the name of the replacement Principal Investigator.

2.3 <u>Reports.</u> TSRI agrees that within forty-five (45) days following the last day of each Calendar Quarter during the term of this Agreement, TSRI shall furnish Sponsor with a written report summarizing the results of the research included within the scope of the Research Program conducted by TSRI, during the immediately preceding Calendar Quarter, including but not limited to all data, conclusions, results, analysis, observations and a detailed description of all procedures, including all materials used for each procedure. All such reports shall be treated as Confidential Information by Sponsor

## 2.4 Financial and Staffing Obligations

(a) <u>Contributions of Parties to Research Program</u>. Contributions in the form of financial support, equipment, personnel, technology and other necessary components for the conduct of the Research Program shall be made by the parties in accordance with the terms set forth on Exhibit B. All payments due to TSRI by Sponsor shall be payable in U.S. Dollars in quarterly installments in advance, within thirty (30) days of the dates set forth in the following payment schedule:



1st invoice: \$300,013.50 (USD)	To be submitted: Effective Date
2nd invoice: \$300,013.50 (USD)	To be submitted: 90 days after Effective Date
3rd invoice: \$300,013.50 (USD)	To be submitted: 180 days after Effective Date
4th invoice: \$300,013.50 (USD)	To be submitted: 270 days after Effective Date
5th invoice: \$300,013.50 (USD)	To be submitted: 1 year anniversary of Effective Date
6th invoice: \$300,013.50 (USD)	To be submitted: 450 days after Effective Date
7th invoice: \$300,013.50 (USD)	To be submitted: 540 days after Effective Date
8th invoice: \$300,013.50 (USD)	To be submitted: 630 days after Effective Date
9th invoice: \$299,820.50 (USD)	To be submitted: 2 year anniversary of Effective Date
10th invoice: \$299,820.50 (USD)	To be submitted: 810 days after Effective Date

All invoices shall be sent to Sponsor via e-mail at AP@xeneticbio.com. Each invoice and payment must reference the Research Project title, Agreement Number and Principal Investigator for purposes of identification. Payments under this Section 2.4(a) shall be sent to:

The Scripps Research Institute 10550 North Torrey Pines Road, TPC-7 La Jolla, California 92037 Attn: Senior Director, Sponsored Programs

TSRI shall not be obligated to perform any of the research specified herein or to take any other action required under this Agreement if the funding is not provided as set forth in Exhibit B and in accordance with the payment schedule as set forth in this Section 2.4(a). Furthermore, should Sponsor fail to make the first payment to TSRI in accordance with this Section 2.4(a), TSRI shall have the right to immediately terminate this Agreement and this Agreement shall be null and void *ab initio*.

(c) <u>Indirect Cost Adjustment.</u> TSRI shall have the right to adjust the payments payable under Section 2.4(a) above to reflect changes in the indirect cost rate negotiated between TSRI and the U.S. Government that is in effect during the quarter that the work is performed. TSRI will notify Sponsor in writing of any change in the indirect cost rate before the effective date of such change. The corresponding direct costs will remain fixed as specified in Exhibit B.

#### 3. OPTION, LICENSE AND PROSECUTION.

#### 3.1 Grant of License . Patent Rights and Technology Rights TSRI hereby grants to Sponsor the following:

(a) A license within the Field to any Patent Rights or Technology under the terms of the License Agreement Between Opko Pharmaceuticals, LLC and TSRI with an Effective Date of February 25, 2019 (the "License Agreement"), which was later assigned to Sponsor by Opko Pharmaceuticals, LLC on March 1, 2019. The Patent Rights or Technology Rights licensed under this section 3.1(a) will be added to Exhibit A of the License Agreement with a notation that the scope of the license is limited to the Field.

(b) an exclusive option (the "Option") to acquire an exclusive, worldwide license, including the right to sublicense, under TSRI's rights in the Technology or Patent Rights not already licensed under 3.1(a). In the event that a product, process or Biological Material utilizes a Research Tool, such Research Tool shall be made available for Sponsor's sole use on a non-exclusive, royalty-free, non-transferable basis solely in connection with Sponsor's exercise of its license rights to the Patent Rights granted hereunder.

(c) a non-exclusive, royalty-free, non-transferable license, without the right to grant sublicenses, to make and use TSRI Technology solely for Sponsor's internal research purposes during the performance of the Research Program. Any transfer of materials to Sponsor under this Section 3.1(c) shall require the execution of a Material Transfer Agreement.

3.2 <u>Disclosure of Technology Subject to Option</u>. After the Principal Investigator submits an invention disclosure covering any Technology to TSRI's Office of Technology Development, TSRI shall disclose such Technology in writing to Sponsor (the "Technology Disclosure"). TSRI shall use reasonable efforts to provide a Technology Disclosure that contains sufficient detail to (i) enable both parties to determine whether or not the particular Technology is TSRI Technology or Joint Technology; and (ii) enable Sponsor to evaluate the advisability of exercising the Option granted hereunder with respect to such Technology. All such Technology Disclosures shall be maintained in confidence by Sponsor as Confidential Information of TSRI.

3.3 Option Period. Sponsor shall have a period of ninety (90) days from receipt of the Technology Disclosure from TSRI (the "Option Period") within which to exercise its Option with respect to the particular Technology disclosed therein. Upon delivery of written notice that Sponsor waives its Option, or upon the failure of Sponsor to exercise its Option in writing during the Option Period, Sponsor shall have no further rights to the particular TSRI Technology, and TSRI may license the TSRI Technology to third parties as it sees fit.

3.4 <u>Exercise of Option</u>. Sponsor shall exercise its Option by delivering to TSRI a written notice within the Option Period which specifies the particular Technology for which the Option is being exercised. Upon such notification, Sponsor and TSRI shall have a period of one-hundred and eighty (180) days within which to negotiate a definitive license agreement. Additionally, in the event that the Parties require additional time to negotiate the definitive agreement, the Parties shall have the option to extend the period for negotiation on a month by month basis, with the understanding that such extension requires the mutual written consent of both Parties, which consent shall not to be unreasonably withheld or delayed.

3.5 Prosecution of Patent Rights, TSRI shall direct and control the preparation, filing and prosecution of patent applications and patents within the Patent Rights. TSRI will provide to Sponsor a copy of any communication to be filed with a patent office anywhere in the world and TSRI shall reasonably consider any comments provided by Sponsor related to the content of the communication. As consideration for the Option, Sponsor shall pay all reasonable fees and costs, and any and all reasonable future fees and costs associated with work performed by TSRI's Office of Patent Counsel and any independent counsel engaged by TSRI related to the preparation, filing, prosecution and maintenance of the Patent Rights. Payment shall be made within thirty (30) days after Sponsor receives an invoice therefor. Failure of Sponsor to pay patent fees and expenses as set forth above shall immediately relieve TSRI from its obligation to incur any further patent fees and expenses with regard to the Technology that is the subject matter of the patents for which such fees and expenses are payable. Sponsor's obligation to pay all patent fees and costs incurred pursuant to this Agreement shall survive the termination or expiration of this Agreement. Both parties hereto agree that TSRI may, at its sole discretion, utilize TSRI's Office of Patent Counsel in lieu of or in addition to independent counsel for patent prosecution and maintenance of patent application(s). Sponsor shall have full rights of consultation with the patent attorneys so selected on all matters relating to patent application(s), provided that TSRI shall have the final determination in all such matters.

3.6 Joint Technology. The parties hereby agree that in the event that the disclosed Technology is Joint Technology not in the Field and that Sponsor either does not exercise its Option or does not sign a license agreement with TSRI, both parties shall (i) have no further obligations to each other with respect to such Joint Technology and any Patent Rights that relate thereto; and (ii) be free to independently license or otherwise dispose of their rights to such Joint Technology and any Patent Rights that relate thereto; and (ii) be free to independently license or otherwise dispose of their rights to such Joint Technology and any Patent Rights that relate thereto on a worldwide basis without accounting to the other party.

# 4. INTERESTS AND RIGHTS IN INTELLECTUAL PROPERTY.

4.1 <u>Title</u>. TSRI shall retain sole ownership and title to TSRI Technology and to all intellectual property rights related thereto. TSRI shall, in the good faith exercise of its discretion, undertake reasonable efforts to preserve and maintain its ownership and title in and to the TSRI Technology as TSRI deems appropriate. Ownership of and title to Joint Technology shall be vested jointly in TSRI and Sponsor, with each owning an undivided interest therein. Ownership of Patent Rights shall follow inventorship under principles arising under U.S. patent law.

4.2 <u>Governmental Interest</u>. TSRI and Sponsor acknowledge that TSRI has received, and expects to continue to receive, funding from the United States Government in support of TSRI's research activities. TSRI and Sponsor acknowledge and agree that their respective rights and obligations pursuant to this Agreement shall be subject to the rights of the United States Government, existing and as amended, which may arise or result from TSRI's receipt of research support from the United States Government, including but not limited to, 37 CFR 401, the NIH Grants Policy Statement and the NIH Guidelines for Obtaining and Disseminating Biomedical Research Resources.

4.3 <u>Reservation of Rights</u>. All rights that are not expressly granted under this Agreement are hereby reserved. Without limiting the foregoing, TSRI reserves the right to use for any research or educational purposes any Patent Rights, Biological Materials, or Research Tools, without TSRI being obligated to pay Sponsor any royalties or other compensation. In addition, TSRI reserves the right to grant non-exclusive research and educational use licenses to other nonprofit or academic institutions to Patent Rights, Biological Materials, or Research Tools, without the other non-profit entity being obligated to pay Sponsor any royalties or other compensation.

# 5. CONFIDENTIALITY AND PUBLICATION.

5.1 <u>Treatment of Confidential Information</u>. The parties agree that during the term of this Agreement, and for a period of five (5) years after this Agreement terminates, a party receiving Confidential Information of the other party will (a) maintain in confidence such Confidential Information to the same extent such party maintains its own proprietary information; (b) not disclose such Confidential Information to any third party without the prior written consent of the other party; and (c) not use such Confidential Information for any purpose except those permitted by this Agreement.

If Confidential Information is required to be disclosed by law or court order, the Party required to make such disclosure shall limit the same to the minimum required to comply with the law or court order, and shall use reasonable efforts to attempt to seek confidential treatment for that disclosure, and prior to making such disclosure that Party shall notify the other party, not later than ten (10) days (or such shorter period of time as may be reasonably practicable under the circumstances) before the disclosure in order to allow that other Party to comment and/or to obtain a protective or other order, including extensions of time and the like, with respect to such disclosure.

5.2 <u>Publications</u>. Sponsor acknowledges that it is the general policy of TSRI to encourage publication of research results in technical or scientific journals; and Sponsor agrees that TSRI shall have a right to publish in accordance with its general policy. TSRI shall submit to Sponsor copies of proposed publications which describe Technology and afford Sponsor a period of thirty (30) days to review the publication to ascertain whether Sponsor's Confidential Information would be disclosed by the publication. If such proposed publication would disclose Sponsor's Confidential Information, then upon Sponsor to protect its Confidential Information by filing a patent application(s). Absent receipt by TSRI of any written instruction by Sponsor within the thirty (30) day period, TSRI shall be free to publish the proposed publication.

5.3 <u>Publicity</u>. Except as otherwise provided herein or required by law, no party shall originate any publication, news release or other public announcement, written or oral, whether in the public press, stockholders' reports, or otherwise, relating to this Agreement or to the performance hereunder without the prior written approval of the other party, which approval shall not be unreasonably withheld or delayed. TSRI agrees that Sponsor shall have the right to make those disclosures that are legally required under the laws of the United States of America, the State of Nevada or the State of Massachusetts for a publicly traded company on a recognized stock exchange. Scientific publications published in accordance with Section 5.2 of this Agreement shall not be construed as publicity governed by this Section 5.3.

# 6. WARRANTY AND DISCLAIMER.

TSRI hereby represents and warrants that it has full right and power to enter into this Agreement. TSRI MAKES NO OTHER WARRANTIES CONCERNING THE CONDUCT OR RESULTS OF THE RESEARCH PROGRAM, PATENT RIGHTS, TECHNOLOGY, RESEARCH TOOLS, BIOLOGICAL MATERIALS OR ANY OTHER MATTER WHATSOEVER, INCLUDING WITHOUT LIMITATION, ANY EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OF THIRD PARTY RIGHTS, OR ARISING OUT OF COURSE OF CONDUCT OR TRADE CUSTOM OR USAGE, AND TSRI DISCLAIMS ALL SUCH EXPRESS OR IMPLIED WARRANTIES. TSRI MAKES NO WARRANTY OR REPRESENTATION AS TO THE VALIDITY OR SCOPE OF PATENT RIGHTS, OR THAT ANY PRODUCT, PROCESS, SERVICE, BIOLOGICAL MATERIAL, OR RESEARCH TOOL WILL BE FREE FROM AN INFRINGEMENT ON PATENTS OR OTHER INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR THAT NO THIRD PARTIES ARE IN ANY WAY INFRINGING UPON ANY PATENT RIGHTS, TECHNOLOGY , RESEARCH TOOLS OR BIOLOGICAL MATERIALS COVERED BY THIS AGREEMENT. FURTHER, TSRI HAS MADE NO INVESTIGATION AND MAKES NO REPRESENTATION THAT THE PATENT RIGHTS, RESEARCH TOOLS OR BIOLOGICAL MATERIALS ARE SUITABLE FOR SPONSOR'S PURPOSES.

IN NO EVENT SHALL TSRI BE LIABLE FOR ANY INDIRECT, SPECIAL, INCIDENTAL, EXEMPLARY OR CONSEQUENTIAL DAMAGES (INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOSS OF PROFITS OR EXPECTED SAVINGS OR OTHER ECONOMIC LOSSES, OR FOR INJURY TO PERSONS OR PROPERTY) ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT OR ITS SUBJECT MATTER. TSRI'S AGGREGATE LIABILITY, IF ANY, FOR ALL DAMAGES OF ANY KIND RELATING TO THIS AGREEMENT OR ITS SUBJECT MATTER SHALL NOT EXCEED THE AMOUNT PAID BY SPONSOR TO TSRI UNDER THIS AGREEMENT. THE FOREGOING EXCLUSIONS AND LIMITATIONS SHALL APPLY TO ALL CLAIMS AND ACTIONS OF ANY KIND AND ON ANY THEORY OF LIABILITY, WHETHER BASED ON CONTRACT, TORT (INCLUDING, BUT NOT LIMITED TO NEGLIGENCE OR STRICT LIABILITY), OR ANY OTHER GROUNDS, AND REGARDLESS OF WHETHER TSRI HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, AND NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED REMEDY. THE PARTIES FURTHER AGREE THAT EACH WARRANTY DISCLAIMER, EXCLUSION OF DAMAGES OR OTHER LIMITATION OF LIABILITY HEREIN IS INTENDED TO BE SEVERABLE AND INDEPENDENT OF THE OTHER PROVISIONS SINCE THEY EACH REPRESENT SEPARATE ELEMENTS OF RISK ALLOCATION BETWEEN THE PARTIES.

#### 7. TERM AND TERMINATION.

vears.

- 7.1 Term. Unless terminated sooner, the initial term of this Agreement shall commence on the Effective Date and shall continue for three (3)
- ars.
- 7.2 Termination by Sponsor. Sponsor may terminate this Agreement by giving thirty (30) days advance written notice of termination to TSRI.

7.3 <u>Termination Upon Non-Payment</u>. In the event that Sponsor fails to pay to TSRI any payment within the time frame set forth in Section 2.4(a), TSRI shall not be obligated to perform any of the research specified herein or to take any other action required under this Agreement. Sponsor shall be provided thirty (30) days to make the payment owed after receiving written notification from TSRI of failure to make a required payment within the time frame set forth in Section 2.4(a). If Sponsor fails to make the required payment within the thirty (30) days following receipt of written notification from TSRI, TSRI may terminate this Agreement immediately upon such nonpayment. Termination pursuant to this Section 7.3 shall not relieve Sponsor of any liability under this Agreement. 7.4 Termination Upon Default. Except as specified in Sections 7.3 and 7.5, the failure of a party to perform any obligation required of it to be performed hereunder and the failure to cure within sixty (60) days after receipt of notice from the other party specifying in reasonable detail the nature of such default, shall constitute an event of default hereunder. Upon the occurrence of an event of default, the non-defaulting party may deliver to the defaulting party written notice of intent to terminate, such termination to be effective upon the date set forth in such notice. Such termination rights shall be in addition to and not in substitution for any other remedies that may be available to the non-defaulting party serving such notice against the defaulting party. Termination pursuant to this Section 7.4 shall not relieve the defaulting party of liability and damages to the non-defaulting party for breach of this Agreement. Waiver by any party of a single default or a succession of defaults shall not deprive such party of any right to terminate this Agreement arising by reason of any subsequent default.

7.5 <u>Termination Upon Insolvency</u>. This Agreement may be terminated as to any party ("Insolvent Party") by another party giving written notice of termination to the Insolvent Party upon the filing of bankruptcy or bankruptcy of the Insolvent Party or the appointment of a receiver of any of the Insolvent Party's assets, or the making by the Insolvent Party of any assignment for the benefit of creditors, or the institution of any proceedings against the Insolvent Party under any bankruptcy law. Termination shall be effective upon the date specified in this notice.

# 7.6 Effect of Expiration or Termination

a. <u>Termination Upon Default of Sponsor</u>. Upon the termination of this Agreement by reason of a default by Sponsor, neither party shall have any further rights or obligations with respect to this Agreement, other than the obligation of Sponsor to make any and all final payments accrued prior to the date of termination, the obligation of the parties to make all reports required hereunder, and except as provided below. Upon such termination of this Agreement, the parties shall continue to abide by their non-disclosure obligations as described in Section 5.1 and each party hereto shall fulfill any other obligations incurred prior to such termination. Any such termination of this Agreement shall not constitute the termination of any license or any other agreements between the parties which are then in effect except as expressly provided therein. In addition, upon such termination, Sponsor's Option under Section 3.1 shall be deemed automatically cancelled, and Sections 4, 6, 7 and 9 shall survive any such termination.

b. Expiration or Termination upon Default of TSRI. Upon the expiration of this Agreement at its regularly scheduled expiration date, or upon a termination of this Agreement on account of a default by TSRI, then TSRI shall make the disclosures required by Section 3.2 for TSRI Technology conceived or reduced to practice up to the date of said expiration or termination; and Sponsor shall have the right to exercise its Option with respect to said TSRI Technology in accordance with the schedule and procedures specified in Sections 3.3 and 3.4 above; and any non-exclusive licenses that have been granted under Section 3.1 shall survive. Additionally, each party shall perform all other obligations up to the date of said expiration or termination; and the parties shall continue to abide by their non-disclosure obligations described in Section 5.1; and any previously existing license agreements or other agreements between the parties shall continue in effect. In addition, upon such expiration or termination, Sections 4, 6, 7 and 9 shall survive.

## 8. ASSIGNMENT; SUCCESSORS.

8.1 <u>Assignment</u>. Any and all assignments by Sponsor of this Agreement or any rights granted hereunder without the prior written consent of TSRI are void except for assignments to an Affiliate of Sponsor.

8.2 <u>Binding Upon Successors and Assigns</u>. Subject to the limitations on assignment set forth herein, this Agreement shall be binding upon and inure to the benefit of any successors in interest and assigns of TSRI and Sponsor. Any such successor to or assignee of a party's interest shall expressly assume in writing the performance of all the terms and conditions of this Agreement to be performed by such party and such written assumption shall be delivered to the other Party.

## 9. GENERAL PROVISIONS.

9.1 <u>Independent Contractors</u>. The relationship between TSRI and Sponsor is that of independent contractors. TSRI and Sponsor are not joint venturers, partners, principal and agent, master and servant, employer or employee, and have no other relationship other than independent contracting parties. TSRI and Sponsor shall have no power to bind or obligate each other in any manner, other than as is expressly set forth in this Agreement.

9.2 <u>Dispute Resolution</u>. Any dispute or claim between the parties arising out of or relating to this Agreement, including without limitation the breach thereof, shall be resolved according to the following dispute resolution procedures:

Agreement.

(a) Such dispute shall be first addressed by the representatives of TSRI and Sponsor who have primary responsibility for managing this

(b) If the dispute is not resolved by such representatives within fifteen (15) days after the date either party gives written notice that such dispute exists, then the dispute shall be referred to and addressed by the senior management of each party.

(c) If such dispute is not resolved by the parties' senior management within thirty (30) days after the date the dispute is referred to them, then the dispute shall be submitted to mediation. The mediator shall be a retired judge or other neutral third party mutually selected by TSRI and Sponsor who has at least ten (10) years experience in mediating or arbitrating cases in the bio-pharmaceutical industry and regarding the same or substantially similar legal and subject matter as the dispute between Sponsor and TSRI. If the parties are unable to agree on such mediator within twenty (20) days after they exchange initial lists of potential mediators, a mediator with the same qualifications will be selected by the JAMS office in State of New York, New York City (after consultation with the parties).

(d) The location of the mediation shall be in the State of New York, New York City. TSRI and Sponsor hereby irrevocably submit to the exclusive jurisdiction and venue of the mediator mutually selected by the parties for purposes of the mediation, and to the exclusive jurisdiction and venue of the federal and state courts located in the State of New York, New York City for any action or proceeding regarding this Agreement in the event mediation is unsuccessful as provided in sub-clause (e) below, or as provided in sub-clause (f) below, and waive any right to contest or otherwise object to such exclusive jurisdiction or venue, including without limitation any claim that such exclusive venue is not a convenient forum.

York, New York City.

(e) If the dispute is not resolved through mediation, either party may refer the dispute to a court of competent jurisdiction in State of New

(f) Notwithstanding anything to the contrary in this Agreement, prior to or while a mediation proceeding is pending, either party has the right to seek and obtain injunctive and other equitable relief from a court of competent jurisdiction to enforce that party's rights hereunder.

9.3 <u>Entire Agreement; Modification</u>. This Agreement and all of the attached Exhibits set forth the entire agreement and understanding between the parties as to the subject matter hereof, and supersede all prior or contemporaneous written or oral agreements. There shall be no amendments or modifications to this Agreement, except by a written document which is signed by both parties.

9.4 <u>New York Law</u>. This Agreement shall be construed and enforced in accordance with the laws of the State of New York notwithstanding any conflicts or choice of laws provisions.

9.5 <u>No Use of Name</u>. The use of the name "The Scripps Research Institute", "Scripps", "TSRI" or any variation thereof in connection with the advertising, sale or performance of Products, Processes, Services, Biological Materials or Research Tools is prohibited, unless Sponsor is provided written agreement for the use of the name.

9.6 <u>Headings</u>. The headings for each article and section in this Agreement have been inserted for the convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular article or section.

9.7 <u>Severability</u>. Should any one or more of the provisions of this Agreement be held invalid or unenforceable by a court of competent jurisdiction, it shall be considered severed from this Agreement and shall not serve to invalidate the remaining provisions thereof. The parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by them when entering this Agreement may be realized.

9.8 <u>No Waiver</u>. Any delay in enforcing a party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such party's rights to the future enforcement of its rights under this Agreement, excepting only as to an express written and signed waiver as to a particular matter for a particular period of time.

9.9 <u>Notices</u>. Any notices required by this Agreement shall be in writing, shall specifically refer to this Agreement and shall be sent by registered or certified airmail, postage prepaid, or by telefax, telex or cable, charges prepaid, or by overnight courier, postage prepaid, and shall be forwarded to the respective addresses set forth below unless subsequently changed by written notice to the other party:

FOR TSRI:	The Scripps Research Institute 10550 North Torrey Pines Road, TPC-9 La Jolla, California 92037 ATTN: Alliances
With a copy to:	otd@scripps.edu
FOR SPONSOR:	Xenetic Biosciences, Inc. 40 Speen Street, Suite 102 Framingham, Massachusetts 01701 Attn: Chief Executive Officer
With a copy to:	info@xeneticbio.com

Notices shall be deemed delivered upon the earlier of (i) when received; (ii) three (3) days after deposit into the U.S. mail; (iii) the date notice is sent via telefax, telex or cable; or (iv) the day immediately following delivery to an overnight courier guaranteeing next-day delivery (except Sunday and holidays).
9.10 <u>Compliance with U.S. Laws</u>. Nothing contained in this Agreement shall require or permit TSRI or Sponsor to do any act inconsistent with the requirements of any United States law, regulation or executive order as the same may be in effect from time to time.

9.11 Export Controls. It is TSRI's policy to remain fully in compliance at all times with all U.S. export control regulations, including but not limited to the Export Administration Regulations; International Traffic in Arms Regulations; and embargo sanctions under the Office of Foreign Assets Control (OFAC). All activities and/or transactions contemplated or hereby agreed to within this Agreement shall be strictly predicated on full compliance with all U.S. and international export control regulations including but not limited to restricted party prohibitions; export license requirements. In the event that Sponsor will be providing export-controlled material to TSRI, Sponsor must first notify TSRI of its intention to provide this material in advance of shipment. Further, diversion of any kind of any item provided to Sponsor contrary to U.S. laws is strictly prohibited. In the event that such diversion occurs, TSRI shall not be held liable for any consequential liability, penalties, or enforcement actions undertaken by a U.S. Government agency or any other party in relation to such action.

9.12 Indemnity, Sponsor shall indemnify, defend (by counsel reasonably acceptable to TSRI) and hold harmless TSRI and any parent, subsidiary or other affiliated entity of TSRI and their trustees, directors, officers, employees, scientists, agents, successors, assigns and other representatives (collectively, the "Indemnitees") from and against all claims, suits, actions, damages, liabilities, losses and other expenses, including without limitation reasonable attorney's fees, expert witness fees and costs incurred by or asserted against the Indemnitees, whether or not a lawsuit or other proceeding is filed (collectively "Claim"), that arise out of or relate to any allegations regarding Sponsor's use of Technology. Sponsor shall not enter into any settlement of such Claims that imposes any obligation on TSRI, that does not unconditionally release TSRI from all liability or that would have an adverse effect on TSRI's reputation or business without TSRI's prior written consent. Notwithstanding the above, Indemnitees, at their expense, shall have the right to retain separate independent counsel to assist in defending any such Claims. In the event Sponsor fails to promptly indemnify and defend such Claims and/or pay Indemnitees' expenses as provided above, Indemnitees shall have the right to defend themselves, and in that case, Sponsor shall reimburse Indemnitees for all of their reasonable attorney's fees, costs and damages incurred in settling or defending such Claims within thirty (30) days of each of the Indemnitees' written requests. This indemnity shall be a direct payment obligation and not merely a reimbursement obligation of Sponsor to Indemnitees.

### [SIGNATURES ON FOLLOWING PAGE]

IN WITNESS WHEREOF, the parties have executed this Agreement by their duly authorized representatives as of the date set forth above.

TSRI:

THE SCRIPPS RESEARCH INSTITUTE

By:<u>/s/ Nikki Alvarez</u> Name: Nikki Alvarez Title: Director, Alliances SPONSOR:

XENETIC BIOSCIENCES, INC.

By: <u>/s/ Jeffrey F. Eisenberg</u> Name: Jeffrey F. Eisenberg Title: Chief Executive Officer



# EXHIBIT A: RESEARCH PROGRAM

# Overall Period of Performance: 5/1/2020 – 10/31/2022 [\*\*\*]

### Study Introduction

Xenetic Biosciences is developing a CAR T platform (termed 'XCART') for the treatment of certain non-Hodgkin Lymphoma (NHL) subtypes, by targeting a patient- and tumor- specific lymphoma neoantigen, namely the unique B-cell receptor (BCR) displayed by a given malignant B-cell clone.

XCART will utilize a universal 'CAR cassette', into which neoantigen-specific, antigen-binding domains (ABDs) can be inserted to create a patient-specific CAR. The resulting CAR construct can then be engineered into an autologous CAR T product for treatment of the patient's lymphoma.

[\*\*\*]

# **EXHIBIT B: BUDGET**

	Xenetic Biosciences, I	nc.			
Principal Investigator/Program Director (Last, First, Middle):	[***	1			
BUDGET May 1, 2020 – Oct, 31, 2022					
PERSONNEL (Applicant organization only)	%	YEAR 1	YEAR 2	YEAR 3	
Personnel		[***]	[***]	[***]	
SUPPLIES (Itemize by category)					
[***]		[***]	[***]	[***]	
TRAVEL					
[***]		[***]	[***]	[***]	
OTHER EXPENSES (Itemize by category)					
[***]		[***]	[***]	[***]	
DIRECT COSTS		[***]	[***]	[***]	
INDIRECT COSTS @ [***]		[***]	[***]	[***]	
TOTAL COSTS		[***]	[***]	[***]	
GRAND TOTAL					
		[***]			

### CERTAIN INFORMATION IDENTIFIED IN THIS DOCUMENT, MARKED BY BRACKETS AND ASTERISKS ("[\*\*\*]"), HAS BEEN EXCLUDED PURSUANT TO ITEM 601(B)(10) OF REGULATION S-K UNDER THE SECURITIES ACT OF 1933, AS AMENDED, BECAUSE IT IS (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED.

# MASTER SERVICES AGREEMENT

This Master Services Agreement ("Agreement") is made effective June 12, 2020 between Xenetic Biosciences, Inc. a Nevada corporation having its place of business at 40 Speen Street, Suite 102, Framingham, Massachusetts 01701 ("Sponsor") and PJSC Pharmsynthez, a Russian public joint stock company having an address of Ne134, Liter 1, Poselok Kuzmolovsky, St. Kapitolovo, Vsevolozhsky Raion, Leningradskaya Oblast, 188663, Russia ("Pharms"). When signed by both Parties, this Agreement will set forth the terms and conditions under which Pharms agrees to provide certain services to Sponsor as set forth herein. This Agreement shall be effective as of the date of last signature ("Effective Date"). Individually, each of Sponsor and Pharms is a "Party" and collectively, "Parties."

### **Recitals:**

A. Sponsor is in the business of developing, manufacturing and/or distributing pharmaceutical products, medical devices and/or biotechnology products. Pharms is in the business of developing, manufacturing and/or distributing pharmaceutical products, medical devices and/or biotechnology products, and in providing clinical trial services, research, and other services for the pharmaceutical device and biotechnology industries.

B. Sponsor and Pharms entered into a Sponsored Research Agreement ("SRA") on August 12, 2019 that the Parties intend to terminate coincident with the entry of Sponsor and Pharms into this Agreement. The SRA is attached as Exhibit C to this Agreement.

C. The Parties agree that prior to termination of the SRA, Sponsor had paid \$350,000 United States Dollars ("USD") to Pharms. The Parties also agree that the funds paid by Sponsor will be credited against amounts due under this Agreement and shall be used by Pharms for payment of any costs and expenses incurred by Pharms or a third party engaged by Pharms pursuant to the terms of this Agreement.

D. Sponsor and Pharms further agree and understand that the terms, obligations and rights of this Agreement shall supercede any terms, obligations and rights either Party previously bore under the SRA, which has now been terminated by the Parties.

Sponsor and Pharms desire to enter into this Agreement to provide the terms and conditions upon which Sponsor may engage Pharms from time-to-time to provide services for individual studies or projects by executing individual Work Orders (as defined below) specifying the details of the services, which are generally set forth in the Program Summary attached as Exhibit A, and the related terms and conditions.

#### Agreement:

### 1.0 Scope of the Agreement; Work Orders; Nature of Services; Change Orders.

- 1.1 <u>Scope of Agreement</u>. As a "master" form of contract, this Agreement allows the parties to contract for multiple projects through the issuance of multiple Work Orders (as discussed in Section 1.3 below), without having to re-negotiate the basic terms and conditions contained herein. This Agreement covers the provision of services by Pharms and Pharms's corporate affiliates (see Section 1.5) and, accordingly, this Agreement represents a vehicle by which Sponsor can efficiently contract with Pharms and its corporate affiliates for a broad range of services.
- 1.2 <u>Nature of Services</u>. The services covered by this Agreement may include expert consultation, clinical trial services, data processing, data management, clerical, project management, and other research and development services requested by Sponsor from time-to-time and agreed to by Pharms as set forth in the relevant Work Order (collectively, the "Services").
- 1.3 Work Orders. The specific details of each project under this Agreement (each "Project" or "Study") shall be separately negotiated and specified in writing on terms and in a form acceptable to the parties (each such writing, a "Work Order"). A sample Work Order is attached hereto as Exhibit B. Each Work Order will include, as appropriate, the scope of work, timeline, and budget and payment schedule. Each Work Order shall be subject to all of the terms and conditions of this Agreement, in addition to the specific details set forth in the Work Order. To the extent any terms or provisions of a Work Order conflict with the terms and provisions of this Agreement, the terms and provisions of this Agreement shall control, except to the extent that the relevant Work Order expressly and specifically states an intent to supersede this Agreement on a specific matter. All Work Orders and other exhibits hereto shall be deemed to be incorporated herein by reference. The terms and conditions of this Agreement shall apply to all work performed on each Project, including work performed prior to the effective date of the Project at the request of Sponsor.
- 1.4 <u>Change Orders</u>. Any change in the details of a Work Order or the assumptions upon which the Work Order is based (including, but not limited to, changes in an agreed starting date for a Project or suspension of the Project by Sponsor) may require changes in the budget and/or timelines, and shall require a written authorization of Sponsor. The changes and associated costs will be captured in a written amendment to the Work Order (a "Change Order"). Each Change Order shall detail the requested changes to the applicable task, responsibility, duty, budget, timeline or other matter. The Change Order will become effective upon the execution of the Change Order by both parties, and Pharms will be given a reasonable period of time within which to implement the changes. Both parties agree to act in good faith and promptly when considering a Change Order requested by the other party. Without limiting the foregoing, Sponsor agrees that it will not unreasonably withhold approval of a Change Order, even if it involves a fixed price contract, if the proposed changes in budgets or timelines result from, among other appropriate reasons, forces outside the reasonable control of Pharms or changes in the assumptions upon which the initial budget or timelines were based, including, but not limited to, the assumptions set forth in the budget or timelines.
- 1.5 Affiliates and CRO Partners. Sponsor agrees that Pharms may use the services of its CRO partners and affiliates ("Subcontractors") to fulfill Pharms's obligations under this Agreement or any Work Order and Pharms shall remain responsible for all such Services performed by its Subcontractors. To the extent that Pharms uses the services of its CRO partners or affiliates to fulfill any obligation under this Agreement or any Work Order, Pharms shall provide a copy of any CRO partner or affiliate agreement to Sponsor prior to entry for review and comment and Pharms shall not enter into an agreement with a CRO partner or affiliate without first obtaining Sponsor's written consent. Sponsor shall also be provided a copy of the final, signed agreement entered into under this Section 1.5 with a CRO partner or affiliate. The terms, conditions and rights in this Agreement shall be incorporated into the Work Order and such affiliate, notwithstanding the foregoing, shall be solely responsible for the performance of the Services under such Work Order. The term "affiliate" shall mean all entities controlling, controlled by or under common control with Pharms or Sponsor, as the case may be. The term "control" shall mean the ability to vote more than fifty percent (50%) of the voting securities of any entity or otherwise having the ability to direct the management and policies of an entity. Any Subcontractors utilized to perform Services will be named in the Work Order.



### 2.0 Payment of Fees and Expenses; Taxes; Currency Management; Investigator Payments.

- 2.1 <u>Project Budget</u>. Sponsor will pay Pharms the reasonable fees, expenses and pass-through costs incurred in providing the Services in accordance with the budget and payment terms contained in each Work Order. Reasonable pass-through costs will be estimated in the budget and Sponsor shall pay the actual costs incurred.
- 2.2 Invoices. Pharms will invoice Sponsor in accordance with the budget and payment schedule for Pharms's fees, and monthly for its expenses and pass-through costs incurred in performing the Services. All invoice payments shall be made to Pharms within thirty (30) days of receipt except for prepayment, advances and investigator invoices, which are due and payable upon receipt. All invoices shall be deemed received three (3) business days after the date postmarked if sent by mail, on the date sent if they are sent electronically or by facsimile, and three (3) days after the date they are sent if delivered by a reputable overnight delivery service. Expenses and pass-through costs will be supported by a detailed summary sheet. If any portion of an invoice is disputed, then Sponsor shall pay the undisputed amounts as set forth above and the parties shall use good faith efforts to reconcile the disputed amount as soon as practicable.
- 2.3 <u>Taxes</u>. Pharms shall be responsible for paying for all taxes due that are related to any work conducted by Pharms. To the extent that any taxes constitute a cost that is reimbursable by Sponsor under this Agreement, such tax shall be invoiced on the invoice for the month following payment of the tax.
- 2.4 <u>Foreign Currency Exchange</u> Unless otherwise specified in the Work Order, the currency to be used for invoice and payment will be in US Dollars (the "Contracted Currency"). If a currency referenced within the budget ceases to become legal tender, the applicable replacement currency will be substituted for such currency for purposes of this provision at an established conversion rate.
  - 2.4.1 <u>Pass-Through Costs</u>. If Pharms incurs pass-through costs in a currency other than the Contracted Currency, then Sponsor shall reimburse Pharms's actual costs in the Contracted Currency based on the Oanda foreign currency exchange rate (Oanda.com) for the applicable currencies on the last business day of the month immediately preceding the month in which such pass-through costs are submitted.
- 2.5 Investigator Payments. If Pharms will be paying Investigators and a site where the work performed under this Agreement is conducted on behalf of Sponsor, the parties will agree in the relevant Work Orders as to a schedule of the amounts to be paid to Investigators. Sponsor acknowledges and agrees that payments for Investigators' services are pass-through payments to third parties and are separate from payments for Pharms's Services. Sponsor agrees that it will not withhold Investigator payments except to the extent that it has reasonable questions about the services performed by a particular Investigator.
- 2.6 <u>Milestones</u>. In the event that milestones shall be provided under a Work Order under this Agreement, and such milestones shall involve one or more payments by Sponsor to Pharms, the Parties agree that a table shall be attached to the Work Order that sets forth the milestone event that triggers the payment and the amount of the payment to be made in USD or shares of Sponsor's common stock. To the extent that the milestone payment is made in shares of the Sponsor, the shares shall be priced at a cost of one and 5/100 USD/Share (\$1.05 USD/share). The Parties additionally agree that the decision whether to pay the milestone payment in cash or in shares shall be at the sole discretion of the Sponsor. Further, if the milestone payment is provided in shares of Sponsor stock, the shares shall be sisued in the name of those individuals that Pharms identifies in writing to Sponsor prior to the issuance of the shares, subject in all respects to compliance with Section 2.7. In the event of any change in the number or kind of outstanding shares of the Company's common stock by reason of a stock split, stock dividend, recapitalization or reorganization, the number of any shares subject to issuance under this Agreement as set forth under a Work Order shall be appropriately adjusted by the Sponsor in its sole discretion, and the decision of the Sponsor regarding any such adjustment shall be final, binding and conclusive.

2.7 Securities Laws. Notwithstanding any provision of this Agreement to the contrary, the issuance of any shares under this Agreement will be subject to compliance with all applicable requirements of federal, state, or foreign law with respect to such securities and with the requirements of any stock exchange or market system upon which the shares may then be listed. No shares will be issued hereunder if such issuance would constitute a violation of any applicable federal, state, or foreign securities laws or other law or regulations or the requirements of any stock exchange or market system upon which the Stock may then be listed. In addition, no shares will be issued hereunder unless such shares may be issued in accordance with the terms of an applicable exemption from the registration requirements of the Securities Act of 1933, as amended (the "Securities Act"). As a condition to any issuance hereunder, the Sponsor may require Pharms, or any persons designated by Pharms to receive any shares, to satisfy any qualifications that may be necessary or appropriate to evidence compliance with any applicable law or regulation, including the Securities Act and the provisions of Regulation D and Regulation S promulgated thereunder, and to make any representation or warranty with respect to such compliance as may be requested by the Sponsor.

### 3.0 Term; Termination.

- 3.1 <u>Term</u>. This Agreement shall commence on the date it has been signed by all parties and shall continue for a period of five (5) years from the date of execution, or until terminated by either party in accordance with this Section 3.0; provided, however, that the Agreement shall continue to apply to the extent that any Work Order previously executed under this Agreement is still active and shall apply for the duration of the Services performed under such Work Order.
- 3.2 <u>Termination without Cause</u>. Sponsor may terminate this Agreement or any Work Order without cause at any time during the term of the Agreement on thirty (30) days' prior written notice to Pharms.
- 3.3 <u>Termination for Cause</u>. Either party may terminate this Agreement or any Work Order for material breach, which shall include Sponsor's non-payment to Pharms, upon thirty (30) days' prior written notice specifying the nature of the breach, if such breach has not been substantially cured within the thirty (30) day period following the receipt of written notification for a material breach unless the non-breaching party agrees in writing to extend the 30-day cure period.
- 3.4 <u>Bankruptcy</u>. Either party may terminate this Agreement or any Work Orders immediately upon provision of written notice if the other party becomes insolvent or files for bankruptcy.
- 3.5 Identification of Work Order. Any written termination notice shall identify the specific Work Order or Work Orders that are being terminated.
- 3.6 Payment. Sponsor shall pay Pharms for all Services performed in accordance with this Agreement and any relevant Work Order and reimburse Pharms for all costs and expenses incurred in performing those Services, including all non-cancelable costs incurred prior to termination but paid after the termination date, even if the parties' original payment schedule spreads out payments for certain services or defers payments for certain services until the end of the Study. If payments are unit or milestone based, and the Agreement or a Work Order is terminated after costs have been incurred toward achieving portions of one or more incomplete units or milestones, Sponsor will pay for actual work performed toward those incomplete units or milestones up to the date of termination, in addition to paying for completed units or milestones. All costs and expenses that are included by Pharms shall be individually documented in an invoice for reimbursement and Pharms shall provide to Sponsor any and all documentary evidence for the cost and expense, including any and all receipts.
- 3.7 <u>Closeout</u>. Upon termination of a Work Order, the parties shall promptly meet to prepare a close-out schedule, and Pharms shall cease performing all work not necessary for the orderly close-out of the Services or required by laws or regulations. Sponsor shall pay for all actual costs, including reasonable time as mutually agreed spent by Pharms personnel, incurred to complete activities associated with the termination and close-out of affected Projects, including the fulfillment of any regulatory requirements.

### 4.0 Confidentiality.

- 4.1 <u>Confidential Information</u>. Sponsor and its affiliates possess certain confidential and proprietary data and information, including without limitation Sponsor Property (as defined in Section 5.1 below) ("Sponsor Confidential Information"), and Pharms and its affiliates possess certain confidential and propriety information pertaining to its operations, methods and pricing ("Pharms Confidential Information") (Sponsor Confidential Information"). "Confidential Information" ("Pharms Confidential Information") ("Sponsor Confidential Information"). "Confidential Information" does not include information that is (i) already in the receiving party's possession; (ii) part of the public domain through no fault of the receiving party; (iii) received from a third party authorized to provide it; (iv) independently developed by the receiving party; or (v) required by law to be disclosed provided each party shall notify the other party prior to making any required disclosure.
- 4.2 <u>Obligations</u>. The Confidential Information shall be used by the receiving party, its affiliates, and their employees only for purposes of performing the receiving party's obligations hereunder. Each party agrees that it will not reveal, publish or otherwise disclose the Confidential Information of the other party to any third party without the prior written consent of the disclosing party, except for the receiving party's respective affiliates, officers, directors, representatives, agents, employees, independent contractors, consultants, firms or outside attorneys ("Representatives") as provided below. The receiving party may disclose the disclosing party's Confidential Information to its Representatives who have a need to know such Confidential Information in connection with the Services or potential services, provided that each of the foregoing must be subject to written confidentiality obligations covering the disclosing party's Confidential Information to the same or greater extent as the receiving party is obligated by this Agreement, and that the receiving party remains responsible for all disclosures made to and by its Representatives. These obligations of confidentiality and nondisclosure shall remain in effect for a period of five years after the completion or termination of the applicable Work Order, whichever is later. Neither Party shall modify, enhance, compile or assemble (or reverse compile or disassemble), or reverse engineer Confidential Information of the other Party or the concepts therein for its own benefit or for the benefit of a third party or for any purpose other than for evaluating a possible business relationship. Neither Party shall remove any proprietary legends or notices, including copyright notices, appearing on or in the Confidential Information.
- 4.3 <u>Return of Confidential Information</u>. Upon termination of this Agreement or a Work Order and request by the other party, each party will return to the other party Confidential Information that are held by that party or its employees, agents or contractors in accordance with Section 6.2 (Record Retention) or destroy them, if permissible, following the written request of the party that owns such Confidential Information.

### 5.0 **Ownership and Inventions; No License.**

- 5.1 <u>Sponsor Property</u>. All data and information generated or derived by Pharms as the result of Services performed by Pharms under this Agreement and which are provided by Pharms to Sponsor as deliverables under this Agreement shall be and remain the exclusive property of Sponsor ("Sponsor Property"). Any inventions that may evolve from the data and information delivered to Sponsor as the result of services performed by Pharms under this Agreement shall belong to Sponsor and Pharms agrees to assign its rights in all such inventions and/or related patents to Sponsor.
- 5.2 <u>No License</u>. Neither anything contained herein, nor the delivery of any information to a party hereto, shall be deemed to grant the receiving party any right or license under any patents or patent applications or to any know-how, technology or inventions of the disclosing party.



### 6.0 Records and Materials.

- 6.1 <u>Record Storage</u>. During the term of each Work Order, Pharms shall maintain all materials, information and all other data obtained or generated by Pharms in the course of providing the Services hereunder, including all computerized records and files, in a secure area reasonably protected from fire, theft and destruction. For global trials, the relevant hard copy Trial Master Files ("TMF") will be stored in the location(s) where the work is performed. The hard copy files throughout the Project for review or other audit purposes will not be shipped to a separate location unless specifically requested by Sponsor. If such records are requested to be shipped, Sponsor shall have sole responsibility for the costs of shipping the materials referred to herein, and Sponsor shall retain and be responsible for the performance of any carrier designated by Sponsor for the shipping of materials. When parties use an electronic TMF, Pharms will only maintain the image of the wet ink signatures, and hard copies of such documents will not be maintained.
- 6.2 <u>Record Retention</u>. At the completion of the Services by Pharms, all materials, information and all other data owned by Sponsor, regardless of the method of storage or retrieval, shall be (i) delivered to Sponsor in such form as is then currently in the possession of Pharms or (ii) disposed of, at the direction and written request of Sponsor. Sponsor shall pay the costs associated with any of the above options. In the event of early termination, Pharms will follow Pharms procedures for document transfers. If the TMF is held in multiple Pharms locations, it will be consolidated and shipped to the Sponsor. Sponsor shall have sole responsibility for the costs of shipping of the materials and data referred to herein for the carrier designated by Pharms. Sponsor shall retain and be responsible for the costs of shipping and performance of any carrier designated by Sponsor for the shipping of materials and data. Pharms will forward all final paper and electronic Project-related records to the Sponsor's responsibility to maintain the records per the appropriate regulations and retention periods. After three calendar months from the date the final shipment of the TMF is sent to the Sponsor, Pharms will ensure that the TMF documentation that was stored electronically at Pharms is purged. Pharms will not maintain duplicate Project-related records. Notwithstanding the foregoing, Pharms, however, reserves the right to retain, at its own cost and subject to the confidentiality provisions herein, copies of all materials and data that may be needed to satisfy regulatory requirements, for insurance purposes, marketing application support, or to demonstrate the performance of its obligations hereunder.

### 7.0 Relationship of the Parties.

7.1 <u>Independent Contractor</u>. For the purposes of this Agreement, the parties hereto are independent contractors and nothing contained in this Agreement shall be construed to place them in the relationship of partners, principal and agent, employer/employee or joint venturers. Neither party shall have the power or right to bind or obligate the other party, and neither party shall hold itself out as having such authority.

# 8.0 Regulatory Compliance.

8.1 <u>General</u>. Pharms agrees that its Services will be conducted in compliance with all applicable laws, rules and regulations and with the standard of care customary in the contract research organization industry. Sponsor agrees that its obligations in connection with the clinical trial will be conducted in compliance with all applicable laws rules and regulation in the clinical trial industry. Pharms's standard operating procedures will be used in performance of the Services, unless otherwise specifically stated in the applicable Work Order. Pharms certifies that it has not been debarred under the United States Generic Drug Enforcement Act or any applicable law in any other country and that it will not knowingly employ any person or entity that is so debarred to perform any Services under this Agreement. Sponsor further represents that it will cooperate with Pharms in taking any actions that Pharms reasonably believes are necessary to comply with the regulatory obligations that have been transferred to Pharms.

8.2 <u>Privacy</u>. To the extent applicable, Pharms and Sponsor agree to comply with all applicable national and international privacy laws and regulations.



- 8.3 <u>Data Protection</u>. Pharms shall at all times abide by its privacy policies and Sponsor's instructions on data protection when processing personal data under this Agreement.
- 8.4 Informed Consent Forms. Sponsor will review and approve all ICF templates and any substantive changes required by the Investigators.

# 9.0 Audits, Regulatory Inspections and Third Party Legal Proceedings.

- 9.1 Sponsor Audits. During the term of the applicable Work Order, Pharms will permit Sponsor's representatives (provided that (a) such representatives are not competitors of Pharms); and (b) prior to any audit Sponsor shall procure that its non-employee representative enter into a confidentiality agreement with Pharms on terms at least as stringent as the confidentiality terms herein) to examine or audit the work performed hereunder and the facilities at which the work order specifications and that the facilities are adequate. Sponsor agrees that it shall not disclose to any third party any information ascertained by Sponsor in connection with any such audit or examination, except to the extent required by law or regulation. Pharms will not provide Third Party audit reports to the Sponsor unless it is a contracted audit in the Work Order for the Sponsor.
- 9.2 <u>Regulatory Inspections</u>. Each party acknowledges that the other party may respond independently to any regulatory correspondence or inquiry in which such party or its affiliates is named. Pharms shall whenever possible notify Sponsor and shall provide Sponsor the opportunity to comment on any response to such regulatory correspondence or inquiry in so far as it directly concerns a Study or Project of Sponsor for which Pharms is providing Services, wherein, such comment shall be reasonably considered. Sponsor shall whenever possible notify Pharms and shall provide Pharms the opportunity to comment on any response to such regulatory correspondence or inquiry in so far as it directly concerns a Study or Project of Sponsor for which Pharms, its affiliates, Subcontractors or Third Parties is providing Services, wherein, such comment shall be reasonably considered. In addition, each party shall notify the other party promptly of any FDA or other governmental or regulatory inspection, inquiry or findings concerning any Study or Project of Sponsor in which Pharms is providing Services. During any such inspection or inquiry, the parties agree to make reasonable efforts to disclose only the information required to be disclosed.
- 9.3 <u>Third Party Legal Proceedings</u>. In the event that Pharms or any of its affiliates, and its and their employees or agents is served with or becomes subject to any subpoena, order, judgment, discovery, proceeding, enforcement or other legal process (each, a "Legal Proceeding") and, which Legal Proceeding seeks from Pharms disclosure of any documents or information related to the Services, to the extent such Legal Proceeding is not related to Section 13.2 or a breach of any term of this Agreement, then Sponsor shall bear and/or reimburse Pharms for all reasonable third party fees, costs and expenses including reasonable attorneys' fees associated with such Legal Proceeding.

### 10.0 Third Parties; Investigators; Non-Solicitation

- 10.1 Third Party Agreements. If the applicable Work Order provides that Pharms will enter into agreements with Investigators or any other third parties to procure goods or services for the applicable Project as a pass-through expense to Sponsor under the applicable Work Order (each, a "Third Party" and collectively, "Third Parties"), such Third Parties shall be independent contractors and shall not be considered the employees, agents, or subcontractors of Pharms or Sponsor. To the extent included in the scope of work and budget in applicable Work Order, Pharms will manage a Third Party related to the applicable Study (i.e. monitor and verify Project timeline adherence, include in team meetings to the extent applicable, highlight and escalate performance issues, recommend corrective actions, if any, related to performance, and include progress in status reports); with the understanding that Pharms shall be responsible for the goods or services provided by any Third Parties that provide goods or services under this Section 10.1.
- 10.2 Indemnification. If such Third Parties request an indemnification for loss or damage caused by the Sponsor's Project, then Sponsor shall negotiate any such indemnification directly with the Third Party. Pharms shall not sign such indemnifications on Sponsor's behalf.



- 11.0 Anti-Bribery. Each party undertakes to the other party that:
- 11.1 it will not, and will procure that each of its employees, directors, officers, affiliates, subcontractors and agents will not, (i) offer, promise or give an advantage to another person, or (ii) request, agree to receive or accept a financial or other advantage in violation of any anticorruption laws, rules, regulations and decrees applicable to the respective party (collectively, "Legislation"), including the United States Foreign Corrupt Practices Act, as amended (the "FCPA"), the United Kingdom Bribery Act 2010 (the "Bribery Act") and any implementing legislation under the OECD Convention Against the Bribery of Foreign Government Officials in International Business Transactions ("OECD Convention"). It is each party's responsibility to be familiar with, and comply with, the provisions of the applicable Legislation; and
- 11.2 from time to time, at the reasonable request of the other party, it will confirm in writing that it has complied with its undertakings under subsection (i) above and will provide any information reasonably requested by the other party in support of such compliance.

### 12.0 Limitation of Liability.

12.1 <u>Consequential Damages</u>. Neither party, nor its affiliates, nor any of their respective directors, officers, employees, subcontractors or agents shall have any liability (including without limitation, contract, negligence and tort liability) for any loss of profits, opportunities or goodwill or any type of indirect, incidental, punitive, exemplary, special or consequential damages in connection with this Agreement or any Work Order or the Services performed by Pharms.

### 13.0 Indemnification.

- 13.1 Sponsor Indemnity. Sponsor shall indemnify, defend and hold harmless (collectively "indemnify") Pharms and its affiliates, and its and their directors, officers, members, managers, employees, subcontractors and agents (each, a "Pharms Indemnified Party"), from and against any and all losses, damages, liabilities, fines, reasonable attorney fees, court costs, and expenses (collectively "Losses"), joint or several, resulting or arising from any third-party claims, actions, proceedings, investigations or litigation relating to or arising from any third party claims, actions, proceedings, investigations or litigation relating to or arising from or in connection with this Agreement, any Work Order, or the Services contemplated herein (including, without limitation, any Losses arising from or in connection with any Study, test, device, product or potential product to which this Agreement or any Work Order relates and any Project related services provided by Pharms at the request of Sponsor yet prior to finalization and execution of the relevant Work Order), except to the extent such Losses are determined to have resulted solely from the gross negligence or intentional misconduct of the Pharms Indemnified Party seeking indemnity hereunder.
- 13.2 <u>Pharms Indemnity</u>. Pharms shall indemnify, defend and hold harmless (collectively "indemnify") Sponsor and its affiliates and their directors, officers, members, managers, subcontractors, employees and agents ("Sponsor Indemnified Party") from and against any and all Losses, damages, liabilities, fines, reasonable attorney fees, court costs, and expenses, joint or several, resulting or arising from any third party claims, actions, proceedings, investigations or litigation relating to or arising from or in connection with this Agreement, any Work Order, or the Services contemplated herein, to the extent such Losses are determined to have resulted from the gross negligence or intentional misconduct of a Pharms Indemnified Party or Pharms breach of this Agreement.
- 13.3 Indemnification Procedure. A party seeking indemnification or reimbursement hereunder shall give the other party prompt notice of any such claim or lawsuit (including a copy thereof) served upon it and shall fully cooperate with the indemnifying party and its legal representatives in the investigation of any matter the subject of indemnification. The party seeking indemnification shall not unreasonably withhold its approval of the settlement of any claim, liability, or action covered by Section 13.1 or Section 13.2, as applicable, will cooperate with counsel of the indemnifying or reimbursing party, and reserves the right to engage its own counsel to assist in the defense at the expense of the indemnifying party.



### 14.0 Sponsor Cooperation; Disclosure of Hazards.

14.1 <u>Sponsor Cooperation</u>. Sponsor shall forward to Pharms in a timely manner all documents, materials and information in Sponsor's possession or control necessary for Pharms to conduct the Services. Pharms shall not be liable to Sponsor nor be deemed to have breached this Agreement for errors, delays or other consequences arising from Sponsor's failure to timely provide documents, materials or information or to otherwise cooperate with Pharms in order for Pharms to timely and properly perform its obligations, and any such failure by Sponsor shall automatically extend any timelines affected by a time period reasonably commensurate to take into account such failure, unless Sponsor agrees in writing to pay any additional costs that would be required to meet the original timeline.

### 15.0 Conflict of Agreements; No Obligation of Exclusivity.

- 15.1 <u>Conflict of Agreements</u>. Pharms represents to Sponsor that it is not a party to any agreement which would prevent it from fulfilling its obligations under this Agreement and that during the term of this Agreement, Pharms agrees that it will not enter into any agreement to provide services which would in any way prevent it from providing the Services contemplated under this Agreement. Sponsor agrees that it will not enter into an agreement with a third party that would alter or affect the regulatory obligations delegated to Pharms in any Study or Project without the written consent of Pharms, which will not be unreasonably withheld.
- 15.2 <u>No Obligation of Exclusivity</u>. Neither party shall have any obligation of exclusivity of any nature to the other. Each party shall be free to provide services or conduct or sponsor clinical or research studies involving other parties, so long as a party's agreement with any such third party does not prevent it from performing its obligations under this Agreement.
- 16.0 Change in Law or Rules Governing Clinical Trials. In the event the U.S. Food, Drug, and Cosmetic Act, or any rule or regulation governing any Services including without limitation any Good Clinical Practice regulation is amended revised or revoked during the term of this Agreement, the parties will discuss the effect of such change on the Agreement and/or on Services being provided under this Agreement and work together in good faith to implement any necessary changes to the Services.
- 17.0 Force Majeure. In the event either party shall be delayed or hindered in or prevented from the performance of any act required hereunder by reasons of strike, lockouts, labor troubles, inability to procure materials or services, lack or failure of public transportation facilities, failure of power or restrictive government or judicial orders, or decrees, riots, insurrection, war, terrorism or acts of public enemies, blockage or embargo, Acts of God, holiday closings or vacations in the European Union, inclement weather, epidemic, fire or other reason or cause beyond that party's control, then performance of such act (except for the payment of money owed) shall be excused for the period of such delay. A party may claim relief if such circumstances exist as to its subcontractor and the delay in performance of the subcontractor will cause or contribute to a delay in performance by the party. The party claiming relief under this provision shall notify the other of the circumstances giving rise to its application, provide an estimate of the impact on its performance, and take reasonable steps to remove or mitigate the impediment.
- 18.0 Notices and Deliveries. Any notice required or permitted to be given hereunder by either party hereunder shall be in writing and shall be deemed given on the date received if delivered personally, by a reputable overnight delivery service, or three (3) days after the date postmarked if sent by regular, registered or certified mail, return receipt requested, postage prepaid to the following addresses:

If to Pharms:

PJSC Pharmsynthez Attention: CEO №134, Liter 1, Poselok Kuzmolovsky, St. Kapitolovo, Vsevolozhsky Raion Leningradskaya Oblast, 188663 If to Sponsor:

Xenetic Biosciences, Inc. Attention: Chief Scientific Officer 40 Speen St., Ste. 102 Framingham, MA 01701

If Sponsor delivers, ships, or mails materials or documents to Pharms, or if Pharms delivers, ships, or mails materials or documents to Sponsor or to third parties, then the expense and risk of loss for such deliveries, shipments, or mailings shall be borne by Sponsor. Pharms disclaims any liability for the actions or omissions of thirdparty delivery services or carriers. All information transmitted by Pharms pursuant to this Agreement will be sent by the standard transmission method selected by Pharms (telephone, facsimile, mail, personal delivery or email). Sponsor hereby consents and authorizes Pharms to send facsimiles relating to the Services, or relating to potential future services, to any office of Sponsor or Sponsor's affiliates.

### 19.0 Insurance.

- 19.1 Pharms. For the term required under the federal and local laws where the clinical trial is to be conducted, Pharms shall obtain insurance or ensure that its respective CRO Partners or affiliates who carry out the work obtain insurance to cover any harm to the life and/or health of a patient that occurs as a result of a clinical trial conducted pusuant a Statement of Work under this Agreement. Pharms shall obtain an insurance coverage or ensure that its respective CRO Partners or affiliates who carry out the work obtain insurance that is no less than the minimum required under the federal and local laws where the clinical trial is to be conducted and the rules of the institution where the clinical trial is conducted. In the case where the clinical trial is conducted within the legal borders of Russia, the insurance coverage and conditions shall comply with the requirements of Federal Law of 12.04.2010 N 61-FZ "On the Circulation of Medicines", as amended. Pharms represents and warrants that it will use reasonable efforts to name Sponsor as an additional insurance upon request. In no event shall the obligations set out in this Section 19 in any way limit or reduce any of either party's other obligations under this Agreement, including, without limitation, either party's indemnification obligations set out in Section 13.
- 20.0 **Binding Agreement and Assignment**. This Agreement shall be binding upon and inure to the benefit of Sponsor and Pharms and their respective successors and permitted assigns. Except as stated above in Section 1.5, neither party may assign or delegate this Agreement or any Work Order or any of its rights or obligations thereunder to any party without the express, written consent of the other party.
- 21.0 Project Steering Committee. To facilitate communication between the Parties and the review of the strategic decisions under this Agreement, the Parties shall appoint a Project Steering Committee. The Project Steering Committee shall be comprised of appropriate representatives of both Parties, initially consisting of two (2) representatives from each of Sponsor and Pharms. Each Party shall appoint a Project Steering Committee liaisons for the Parties. Employees of each Party who are not on the Project Steering Committee may attend meetings of the Project Steering Committee, as required to further the efforts set forth in the Work Order. The initial team leader and Party representatives shall be identified in each Work Order that is entered into pursuant to the terms of this Agreement.

Any representative of the Project Steering Committee may designate another individual from such representative's Party to attend a meeting of the Project Steering Committee in his or her place. In such case, the representative shall notify the other Party's representative in writing prior to the applicable meeting. A representative of a Project Steering Committee may be changed by a Party at any time following written confirmation of the change to the other Party.

The Project Steering Committee shall plan and manage the project and associated activities to be conducted in connection with the work set forth in each Work Order and to facilitate communication on the project between the Parties. The Project Steering Committee shall also be responsible for the sharing of certain data relating to the Parties' project efforts in connection with each Work Order.

Modification to, and implementation of, the work set forth in each Work Order and other day-to day clinical and development activities shall be managed by the Project Steering Committee. The Project Steering Committee shall meet no less frequently than once a month in person, by teleconference, web-conference or video conference as agreed upon by the Parties.

Notwithstanding anything herein to the contrary, the Project Steering Committee shall operate by consensus with representatives of Sponsor having one collective vote and representatives of Pharms having one collective vote. In the event of any disagreements between the Parties, and the inability of the Parties to reasonably resolve the disagreements within thirty (30) days of when the dispute was presented to the Project Steering Committee, then the dispute shall be referred to the senior management representatives of each Party. For purposes of the Project Steering Committee, Sponsor's senior management representative shall be its Chief Executive Officer and Pharm's senior management representative shall be its Chairman. If the senior management is not able to reasonably settle the dispute, the Sponsor shall have the deciding vote. If required, the Project Steering Committee shall be responsible for discussing in good faith and agreeing on issues relating to forecasting and contingency planning with regard to a Work Order.

- 21.0 Choice of Law, Waiver and Enforceability. This Agreement shall be construed, governed, interpreted, and applied in accordance with the laws of the State of Delaware, exclusive of its conflicts of law provisions. The failure to enforce any right or provision herein shall not constitute a waiver of that right or provision. Any waiver of a breach of a provision shall not constitute a waiver of any subsequent breach of that provisions herein are found to be unenforceable on the grounds that they are overly broad or in conflict with applicable laws, it is the intent of the parties that such provisions be replaced, reformed or narrowed so that their original business purpose can be accomplished to the extent permitted by law, and that the remaining provisions shall not in any way be affected or impaired thereby.
- 22.0 **Survival**. The rights and obligations of Sponsor and Pharms, which by intent or meaning have validity beyond such termination (including, but not limited to, rights with respect to inventions, confidentiality, discoveries and improvements, indemnification and liability limitations) shall survive the termination of this Agreement or any Work Order.
- 23.0 Entire Agreement, Headings and Modification. This Agreement, together with the relevant Work Orders, contains the entire understandings of the parties with respect to the subject matter herein, and supersedes all previous agreements (oral and written), negotiations and discussions. The descriptive headings of the sections of this Agreement are inserted for convenience only and shall not control or affect the meaning or construction of any provision hereof. Any modifications to the provisions herein must be in writing and signed by the parties.
- 24.0 **Counterparts**. This Agreement may be executed in any number of counterparts, each of which when executed and delivered, shall constitute an original, but all of which together shall constitute one agreement binding on all parties, notwithstanding that all parties are not signatories to the same counterpart. Transmission by fax or by electronic mail of an executed counterpart of this Agreement shall be deemed to constitute due and sufficient delivery of such counterpart. This Agreement and any Work Order, Change Order, amendment or modification may not be denied legal effect or enforceability solely because it is in electronic form, or because an electronic signature or electronic record was used in its formation.
- 25.0 Authority. Each party represents and warrants that it has the power and authority to enter and perform its obligations under this Agreement without conflict with, default under, or violation of any law, regulation, or agreement binding upon it. Each party represents and warrants that this Agreement has been duly and validly executed and delivered by it and constitutes its legally valid and binding obligation, enforceable in accordance with its terms, except as enforcement may be limited by law or in equity.

Remainder of page intentionally left blank; signature follow on next page



IN WITNESS WHEREOF, this Agreement has been executed by the parties hereto through their duly authorized officers on the date(s) set forth below.

# ACKNOWLEDGED, ACCEPTED AND AGREED TO:

PJSC Pharmsynthez

By: <u>/s/ Efim Prilezhaev</u> (signature)

Print Name: Efim Prilezhaev

Title: CEO

Date: June 12, 2020

Xenetic Biosciences, Inc.

By: <u>/s/ Jeffrey F. Eisenberg</u> (signature)

Print Name: Jeffrey F. Eisenberg

Title: Chief Executive Officer

Date: June 12, 2020

### EXHIBIT A PROGRAM SUMMARY

# **Introduction**

Xenetic Biosciences is developing a CAR T platform (termed 'XCART') for the treatment of certain non-Hodgkin Lymphoma (NHL) subtypes, by targeting a patientand tumor- specific lymphoma neoantigen, namely the unique B-cell receptor (BCR) displayed by a given malignant B-cell clone.

XCART will utilize a universal 'CAR cassette', into which neoantigen-specific, antigen-binding domains (ABDs) can be inserted to create a patient-specific CAR. The resulting CAR construct can then be engineered into an autologous CAR T product for treatment of the patient's lymphoma. [\*\*\*]

### EXHIBIT B SAMPLE WORK ORDER

### WORK ORDER

This Work Order ("Work Order") is between Xenetic Biosciences, Inc., 40 Speen St., Ste 102, Framingham, MA 01701 ("Sponsor") and PJSC Pharmsynthez, N134, Liter 1, Poselok Kuzmolovsky, St. Kapitolovo, Vsevolozhsky Raion, Leningradskaya Oblast, 188663, Russia ("Pharms") and relates to the Master Services Agreement dated as of June 12, 2020 (the "Agreement"), which is incorporated by reference herein. Pursuant to the Agreement, Pharms has agreed to perform certain services in accordance with written Work Orders, such as this one, entered into from time-to-time. This Work Order sets forth the obligations of the parties with regard to conducting a Stage 1 study (as described in the Attachments to this Work Order) of Sponsor's XCART technology, under a protocol (the "Protocol") to be prepared and agreed by the Project Steering Committee (as described below). Once the final Protocol is prepared, such Protocol, including any amendments thereto, is incorporated herein by reference.

### The parties hereby agree as follows:

1 . <u>Work Order</u>. This document constitutes a "Work Order" under the Agreement and this Work Order and the services contemplated herein are subject to the terms and provisions of the Agreement.

2 . <u>Services and Payment of Fees and Expenses</u>. The specific services contemplated by this Work Order (the "Services") and the related payment terms and obligations are set forth on the following attachments, which are incorporated herein by reference:

PROJECT ASSUMPTIONS	ATTACHMENT 1
SCOPE OF WORK/BUDGET	ATTACHMENT 2
TIMELINE	ATTACHMENT 3
PAYMENT SCHEDULE	ATTACHMENT 4
MILESTONE//PAYMENTS	ATTACHMENT 5
THIRD PARTY VENDORS	ATTACHMENT 6

3. <u>Term</u>. The term of this Work Order shall commence on the date of execution and shall continue until the Services described in Attachment 2 are completed, unless this Work Order is terminated in accordance with the Agreement. If the Agreement is terminated or expires, but this Work Order is not terminated or completed, then the terms of the Agreement shall continue to apply to this Work Order until the Work Order is either terminated or completed.

4. <u>Amendments</u>. No modification, amendment, or waiver of this Work Order shall be effective unless in writing and duly executed and delivered by each party to the other.

5. <u>Standard Operating Procedures</u>. Pharms shall conduct the Study according to the formats and procedures set forth in Pharms's Standard Operating Procedures ("SOPs").

6. <u>Third Parties</u>. The Third Party vendors who will be performing services on the Study are set forth in Attachment 6. Sponsor has provided its written consent and approves such Third Party vendors listed and referred to within this Agreement.

7. Project Steering Committee Members. The initial team leader and Party representatives for the work conducted under this Work Order are:

Sponsor: 1 Curtis Lockshin, CSO; 2 Jeffrey Eisenberg, CEO

Pharms: 1 Dmitry Genkin, Member & Chairman of the Board of Directors; 2 Kirill Surkov, CEO's science advisor

ACKNOWLEDGED, ACCEPTED AND AGREED TO:

PJSC Pharmsynthez	Xenetic Biosciences, Inc.	
By:(signature)	By:(signature)	
Print Name:	Print Name:	
Title:	Title:	
Date:	Date:	



# **ATTACHMENT 1: PROJECT ASSUMPTIONS**

[\*\*\*]

# ATTACHMENT 2: SCOPE OF WORK/PROJECT BUDGET

[\*\*\*]

# **ATTACHMENT 3: TIMELINE**

[\*\*\*]

# ATTACHMENT 4: PAYMENT SCHEDULE

[\*\*\*]

# ATTACHMENT 5: MILESTONES SCHEDULE AND PAYMENTS (Stages defined in Exhibit A –Program Summary)

Table 1

Milestone Event	Payment in USD Payment in Shares	
[***]	\$52,500	50,000 shares
[***]	\$472,500	450,000 shares
[***]	\$525,000	500,000 shares

# ATTACHMENT 6: THIRD PARTY AGREEMENTS

Shemyakin and Ovchinnikov Institute of Bioorganic Chemistry (Moscow)

Belarussian Research Center for Pediatric Oncology, Hematology and Immunology

Institute of Bioorganic Chemistry of NASB

Viciebsk Regional Clinical Oncological Center

### EXHIBIT C

# SPONSORED RESEARCH AGREEMENT BETWEEN XENETIC AND PHARMSYNTHEZ

# SPONSORED RESEARCH AGREEMENT

This Sponsored Research Agreement (the "Agreement"), is entered into and effective as of August 12, 2019 (the "Effective Date") by and between PJSC «Pharmsynthez», a Russian public joint stock company having an address of N2134, Liter 1, Poselok Kuzmolovsky, St. Kapitolovo, Vsevolozhsky Raion, Leningradskaya Oblast, 188663, Russia ("Institution"), and Xenetic Biosciences, Inc. having an address of 40 Speen Street, Ste. 102, Framingham, MA 01701 ("Sponsor"). For the purposes of this Agreement, Sponsor and Institution may each be referred to as a "Party" and together as the "Parties."

WHEREAS, Sponsor desires to sponsor a Research Project (defined below) at the Institution under a Principal Investigator selected by the Institution and approved by the Sponsor;

WHEREAS, Sponsor desires to have the Principal Investigator perform the Research Project on behalf of Sponsor, which shall relate to CAR-T Technology (the "Purpose");

WHEREAS, the research will be conducted pursuant to one or more Work Orders, which the Parties shall agree upon prior to the initiation of the work and which shall be subject to the terms of this Agreement; and

WHEREAS, Institution is willing to (a) undertake the Research Project, and (b) grant to Sponsor certain rights under terms and conditions set forth herein.

#### **ARTICLE 1: DEFINITIONS**

1.1 "Affiliate" means any person, corporation, company, partnership, joint venture and/or finn which controls, is controlled by or is under common control with Sponsor. As used herein, "control" shall mean direct or indirect ownership of at least fifty percent (50%) of the stock or shares having the right to vote for the election of directors.

1.2 "Budget" means the indicative budget that shall be set forth in each Work Order and shall detail the payments to be made by Sponsor for the conduct of the Research Project, including the amounts due, payment schedule, the location where invoices should be sent, and the manner and location where payments should be made, with the understanding that the total budget for all work to be conducted pursuant to this Agreement and all Work Orders entered into by the Parties shall not exceed three hundred fifty thousand United States Dollars (\$350,000 USD).

1.3 "Invention" shall mean any discovery, improvement or invention, whether patentable or not, developed, conceived, or reduced to practice during performance of, or in relation to, the Research Project that relates to, is based upon or arises as a result of use of, the Sponsor Materials, Sponsor Confidential Information, and/or the Research Results.

1.4 **"Project Participant"** means any employee, contractor or agent of Principal Investigator or Institution who may participate in the Research Project, including, but not limited to, scientists, post-doctoral fellows, students, and technicians.

1.6 "Research Parties" shall collectively refer to Institution and Principal Investigator.

1.7 "Research Project" shall mean the Research Project conducted pursuant to one or more Work Orders to carry out the Purpose.

1.8 "Results" shall mean any, and all data, information and results generated or produced in the performance of, or related to, the Research Project by the Principal Investigator and Project Participants.

1.9 **"Sponsor Material"** means any products, product candidates, compound, biomaterial or other substance of Sponsor delivered to Institution and that may be used as part of the Research Project, together with its derivatives, progeny, parts, analogs and homologs, modifications, and any other new chemical entity, developed by, or for, or otherwise obtained by Sponsor, including, but not limited to CAR-T Technology.

1.20 "Work Order" means any work order entered into by mutual agreement of the Parties to conduct the work for the Research Project, with the understanding that Sponsor shall be under no obligation to enter into any particular Work Order or to advance funds for any specific research or activities under the Research Project other than pursuant to a signed Work Order.

# **ARTICLE 2: RESEARCH PROJECT**

2.1 **General.** Institution, under the direction and supervision of the Principal Investigator, shall perform the Research Project in accordance with (a) the one or more Work Orders entered into by the Parties, (b) the terms and conditions of this Agreement, (c) all instuctions relating to the storage of Sponsor Material, and (d) all applicable international, federal, state and local laws, rules, regulations as well as other requirements of any applicable governmental authority in the performance of the Research Project. Institution shall proceed diligently with the work set forth in the Research Project by using its good faith efforts to allocate sufficient time, effort, equipment and facilities for the conduct of the activities thereunder and using Project Participants with sufficient skills and experience as are required to accomplish the objectives of the research activities set forth in the Research Project.

2.2 **Participants.** The Research Project shall be conducted solely by Principal Investigator and Project Participants at the Institution. In the event that the Principal Investigator becomes unable or unwilling to continue the Research Project at the Institution, Sponsor shall have the option to: (a) continue the Research Project with a substitute researcher proposed by the Institution and approved by the Sponsor (who shall thereafter be deemed to be the Principal Investigator for purposes of this Agreement); or (b) to terminate this Agreement pursuant to Section 5.3.

2.3 **Records.** Institution and Principal Investigator and all Project Participants shall keep and maintain accurate scientific records fully and properly that reflect all work done and Research Results achieved in the performance of the Research Project and shall make such records, including, without limitation, all records related to the Research Project and Research Results available to Sponsor to audit and inspect following reasonable notification requesting an audit. It is understood that such records shall include laboratory notebooks sufficient to document any patentable inventions developed, conceived or reduced to practice during the course of the Research Project. Upon request by Sponsor and at Sponsor's expense, Principal Investigator shall within a reasonable period of time provide copies of all such records to Sponsor. Such records shall be maintained by Institution during the term of this Agreement and for three (3) years thereafter or such time as required by applicable laws, rules and regulations, with the understanding that if Sponsor shall the Institution maintain the records beyond the three (3) years or such additional time as required, to the extent Institution agrees to such additional time, Sponsor shall be responsible for the cost to maintain the records.

2.4 **Funding.** As consideration for conducting the Research Project, Sponsor shall make available for the Institution the sums set forth in the Budget for each Research Project. If the Research Project is terminated prematurely, the amount due hereunder shall be an amount equal to the pro-rata portion of the actual work performed and reimbursement for any costs actually incurred by Institution prior to termination.

If Sponsor requests, and Institution agrees, to make changes to the scope of the Research Project and/or it becomes apparant that to carry out the Research Project revisions will be required as to the amount of the Institution (FTEs or consumables) resources necessary to carry out the Research Project, Institution shall provide Sponsor with a revised Indicative Budget, which shall be reflected in subsequent invoices from Institution and payments by Sponsor pursuant to the terms of the revised Indicative Budget.

2.5 **Financial Reporting.** Institutionand Principal Investigator acknowledge that Sponsor may be required by law or trade association rules of which Sponsor is a member, related to the collection and reporting of any payments or transfers of value to certain healthcare providers and teaching hospitals (collectively, "Financial Transparency Laws"), including, but not limited to, the U.S. Physician Payment Sunshine Act, 42 U.S.C. § 1320a-7h, and the regulations implemented thereunder, to disclose to certain government agencies or other entities payments made to the Research Parties or Project Participants under this Agreement. Institution and Principal Investigator hereby consent to Sponsor's disclosure of such information, and acknowledge that such information may become available to the public. Institution and Principal Investigator shall cooperate with Sponsor in its compliance with Financial Transparency Laws in connection with this Agreement. Institution shall promptly provide Sponsor, in the format Sponsor requests, with all information that Sponsor believes it needs to comply with Financial Transparency Laws in connection with this Agreement.

2.6 Reports. Within twenty (20) business days following the end of each calendar quarter, the Party conducing the Research Project shall provide a comprehensive summary of the findings, results, data and other information that are generated by the Research parties as a result of the Research (the <u>"Results"</u>) to Sponsor. During conduct of the Research Project, Institution will inform Sponsor promptly of any unexpected events or results that arise related to the Sponsor Materials, including, but not limited to any toxicity issues identified. Sponsor shall own the Results that are generated. Only Sponsor for any purpose without further obligation or liability to the Institution including, without limitation, for further research and development activities, as well as for submissions to the FDA, EMA or other regulatory authorities. For the avoidance of doubt, the Institution and Principal Investigator shall not be permitted to use the Results for any purpose or third party research or study without the prior written approval of the Sponsor.

2.7 **Regulatory Requests.** After the completion of the Research Project, the Research Parties shall provide any information and assistance reasonably requested by Sponsor for any regulatory filing or regulatory compliance activities relating to the Research Project including any request for information from a regulatory agency. The Research Parties agree that time is of the essence with regard to these matters and will take all steps necessary to respond to Sponsor in a timely manner.

# **ARTICLE 3: INTELLECTUAL PROPERTY RIGHTS**

3.1 **Ownership; Limited License.** The Research Parties acknowledges that the Sponsor Materials are, and shall at all times remain, the sole property of Sponsor. Sponsor hereby grants to the Research Parties, during the term of this Agreement, effective upon delivery of the Sponsor Materials to the Principal Investigator, a nontransferable, non-exclusive license, with no right of sublicense, to use the Materials solely for performance of the Research under the terms of this Agreement.

3.2 **Invention Disclosure.** Institution shall promptly and fully disclose to Sponsor in writing and with detailed specificity any Invention related to the Research Project that is developed, conceived and/or reduced to practice by a Research Party or Project Participant, within twenty (20) days of Institution becoming aware any such Invention Disclosure"). Each Invention Disclosure provided under the preceding sentence will include a description of the Inventions and a reference to this Agreement. All Invention Disclosures shall be the Confidential Information of Sponsor. Sponsor shall solely own all Inventions, including those set forth in an Invention Disclosure pursuant to this Section 3.2.

3.3 **Raw Data and Results.** Institution and Sponsor appreciate and understand that through the work of Institution in conducting the research plan, certain raw data and results shall be generated, which shall constitute Sponsor Confidential Information and relate to, use or incorporate or are generated from Sponsor's information, documents, work product and any other Sponsor Materials that are delivered by Sponsor to Institution to be evaluated by Sponsor as set forth in the research plan. The Institution and Sponsor agree that such raw data and results shall be owned solely by the Sponsor.

3.4 **Deliverables.** Sponsor is, and shall be, the sole and exclusive owner of all right, title and interest to all information, documents, work product and any other materials that are delivered by Institution to Sponsor hereunder or identified in a Work Order and incorporated by reference, or any other written document describing research or services to be performed by the Principal Investigator under the terms of this Agreement ("Deliverables"), including all intellectual property rights therein.

3.5 **Exclusive Rights to All Inventions and Results. The** Research Parties agree that all Inventions created by and through the Research Project under this Agreement and all Results are solely owned by Sponsor and Institution has no rights, other than those Sponsor may grant to Institution to such Inventions and Results.

3.6 **No Other Licenses.** Except as expressly set forth in this Section 3, no other right, title or interest of any nature whatsoever is granted by either Party to the other Party under this Agreement, and neither the delivery of Material nor the disclosure of Confidential Information shall be deemed to grant any rights or license to Institution except for the limited license to use the Materials in Research during the term of this Agreement, as expressly set forth in Section 3.1.

3.7 **No Third Party Rights.** Neither Institution nor Principal Investigator has entered into any agreements with any third party providing material or funding for the Research Project that could result in a claim by such third party that it has commercial rights to any Inventions made by Institution under this Agreement. Institution will not involve any third party in the Research Project, nor use material provided by a third party commercial entity in the Research Project, without first (a) providing to Institution a copy of the proposed agreement governing Institution's obligations to such third party regarding the Research Project and (b) obtaining Sponsor's written consent to such third party's involvement in the Research Project, such consent to not be unreasonably withheld.

3.8 **Protection of Inventions.** Sponsor at its sole discretion shall have the sole right to file for protection of any Inventions, including through patent protection. To the extent that Sponsor files for a patent, Institution shall cause all Institution inventors of an Invention to cooperate with Sponsor to provide assistance and execute any documentation necessary to perfect assignment. Sponsor shall have all rights and final decisions as to the filing, prosecution and/or maintenance of all patents or patent applications covering an Invention. Institution will and shall cause all Institution inventors and others who are necessary to cooperate with Sponsor in any such filing, prosecution or maintenance.

# **ARTICLE 4: CONFIDENTIALITY**

4.1 **Confidential Information.** For purposes of this Agreement, the term "Confidential Information" means (a) all information of a confidential, secret, and/or proprietary nature provided by or on behalf of on party or any of its Affiliates to the other party in connection with this Agreement, designated as "confidential." Confidential Information may include, without limitation: trade secrets; know-how; inventions; technical data; results specifications; protocols; procedures; information related to chemical or biological compounds, including but not limited to information on structure and activity; testing methods; business or financial information; information related to products, product candidates or research and development programs; the results of research and development activities, including but not limited to clinical trial results; product and marketing plans; customer and supplier information, and all information, reports, evaluations and copies generated or derived by either Party from any of the foregoing. Confidential Information may also include information obtained from collaborators, customers, suppliers or vendors of Sponsor or any of its Affiliates or other third parties who have entrusted their confidential information to Sponsor or such Affiliates.

4.2 **Restrictions on Disclosure and Use. The** Party receiving Confidential Information agrees that it will maintain all Confidential Information in strict confidence, and shall disclose Confidential Information only to those employees, officers, directors and other representatives of the receiving Party who are obligated to maintain the confidential Information and who have a need to know such Confidential Information in connection with performance of the Research. Institution will not disclose Confidential Information to any other person or entity without the prior written consent of Sponsor. The receiving Party will not use Confidential Information to except for purposes of performing the Research. Notwithstanding anything to the contrary in this Agreement, the receiving Party shall be entitled to disclose Confidential Information to the extent required by applicable law or court order, *provided* that the receiving Party furnishes the disclosure so as to provide to the disclosure Party with a reasonable opportunity to seek to prevent disclosure or to obtain a protective order for the Confidential Information. The Parties will consult with each other prior to the receiving Party making any such required disclosure.



4.3 **Exceptions.** The obligations of non-disclosure and non-use under this Agreement will not apply to information which the receiving Party can clearly demonstrate, by written records, falls within any of the following categories:

(a) information that was generally known to the public prior to disclosure or being generated under this Agreement or later becomes generally known to the public through no fault of the receiving Party;

(b) information that was already known to the receiving Party prior to disclosure or being generated under this Agreement;

(c) information obtained by the receiving Party from a third party other than on behalf of the disclosing Party and provided such third party is lawfully in possession of and has the right to disclose the same without limitation upon further disclosure; and

(d) information that was independently developed by the receiving Party without reference to the Confidential Information and other than as part of the Research.

4.4 **Safekeeping.** Institution shall maintain all the Materials and other Confidential Information disclosed to it in a secure place with access limited to those persons who are specifically authorized to have access to such Confidential Information pursuant to this Agreement. Institution shall promptly notify Sponsor of any unauthorized use or disclosure of Materials or other Confidential Information of which it becomes aware or has knowledge and will take all reasonable steps to assist Sponsor in attempting to minimize any potential or actual damages or losses resulting from such unauthorized use or disclosure.

4.5 **Return of Materials and other Confidential Information.** Within thirty (30) days following the termination or expiration of this Agreement, Institution shall, as directed by Sponsor, return to Sponsor or destroy any remaining Materials, including Sponsor Materials and all other Confidential Information, including all reproductions and copies thereof, and shall delete all references to such Confidential Information stored electronically or otherwise. At such time, Institution shall also notify Sponsor in writing as to how much Material, including Sponsor was used in connection with the Research Project and how much Material was returned or destroyed under the preceding sentence.

4.6 **Injunctive Relief.** The receiving Party acknowledges and agrees that any violation of the terms of this Agreement relating to the disclosure or use of Confidential Information may result in irreparable injury and damage to the disclosing Party not adequately compensable in money damages, and for which the disclosing Party may have no adequate remedy at law. The receiving Party acknowledges and agrees that, if the disclosure or use restrictions contained in this Agreement are violated, the disclosing Party may need to obtain injunctions, orders, or decrees in order to protect Confidential Information and will be entitled to do so, in addition to any other remedies available for breach at law or in equity, without having to post a bond or show harm.

4.7 **Publication.** Institution may only publish or otherwise publicly disclose the Research Results with the prior written approval from Sponsor, wherein such written approval shall not be unreasonably withheld.

4.3 **Publicity.** No Party will use the name of another, nor of any of its employees, agents or representatives, in any promotion or advertising without the prior written approval of an authorized representative of the other Party. The Parties may, however, acknowledge Sponsor's support, the existence of this Agreement and the general nature of the research being pursued hereunder for such purposes as Sponsor may consider appropriate or as required by law. In any such statement, the relationship of the Parties hereunder shall be accurately and appropriately described.

### **ARTICLE 5: TERM AND TERMINATION**

5.1 **Term.** The term of this Agreement shall commence upon the Effective Date and continue in full force and effect until the earlier of a) completion of the Research Project and b) July 31, 2020, unless terminated prior to such date in accordance with this Article 5.

5.2 **Termination for Breach.** Either Party may terminate this Agreement, effective immediately, if the other Party materially breaches any provision of this Agreement and fail(s) to remedy such breach within thirty (30) days after receipt of notice in writing of such breach from the other Party.

5.3 **Sponsor Termination.** If Principal Investigator is unable or unwilling to continue to conduct the research or otherwise perform the obligations under this Agreement in connection with the Research Project, or if Principal Investigator fails to use reasonably diligent efforts to conduct the Research Project, Sponsor may terminate this Agreement upon thirty (30) days prior written notice to Institution and shall be under no further obligation to make monetary payments to the Parties under this Agreement.

5.4 **Effect of Termination and Expiration.** Upon expiration or any termination of this Agreement, (i) the Principal Investigator shall finalize the Results that have been compiled to such date, and shall prepare and submit a final report with respect to such Results to Sponsor; and (ii) the Institution shall return to Sponsor all unused Sponsor Materials and any Sponsor Confidential Information within twenty (20) days of Sponsor's request. In the event of Sponsor termination, any funds paid to Institution by Sponsor under this Agreement which have not been expended or irrevocably committed upon the effective date of termination shall be refunded to Sponsor within twenty (20) days after the effective date of termination.

5.5 **Survival.** The following sections of this Agreement shall survive expiration or any termination of this Agreement: Articles 3, 4, 6, 7 and 8 and Sections 2.3, 2.5-2.7, 5.4 and 5.5.

# ARTICLE 6: REPRESENTATIONS, WARRANTIES AND COVENANTS

### 6.1 Representations and Warranties of the Research Parties. The Institution represents and warrants to Sponsor that:

(a) The execution, delivery and performance of this Agreement does not and will not conflict with or result in breach of any term, condition, obligation or restriction of any other agreement with any third party;

(b) Principal Investigator's and Institution's participation in the Research Project and execution hereof, including the assignment of Inventions and Deliverables to Sponsor set forth in Sections 2 and 3, shall not conflict with any obligations of Principal Investigator to Institution or ally obligation of the Institution to any other person or entity;

6.2 **Debarment.** Institution and Principal Investigator represent and warrant that neither they nor any Project Participant or any other person retained to perform the Research Project pursuant to this Agreement, (a) is under investigation by the FDA for a debarment action or is presently debarred pursuant to the Generic Drug Enforcement Act of 1992, as amended (21 U.S.C. §301 et seq.), (b) is under investigation by the FDA for debarment action or is presently debarred pursuant to Section 306(a) or (b) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 335a (a) or (b)), (c) has a disqualification hearing pending or has been disqualified by the FDA pursuant to 21 C.F.R. Section 312.70 or its successor provisions, or (d) has been convicted of, or is currently charged with, a felony for conduct relating to the regulation or handing of any drug product. In addition, Institution and Principal Investigator represents and warrants to Sponsor that neither they nor any Project Participant or any other person retained to perform the Research Project pursuant to this Agreement Institution, Principal Investigator or activity which could lead to any of the above mentioned disqualification, debarment, felony or other actions. If during the term of this Agreement Institution, Principal Investigator or any Project Participants or any other person retained to perform the Research Project pursuant (w) comes under investigation by FDA for a debarment action or disqualification, (x) is debarred or disqualified, (y) is convicted of, or is currently charged with, a felony for conduct or activity which could lead to any of the above mentioned disqualified, (y) is convicted of, or is currently charged with, a felony for conduct or activity which could lead to any of the above mentioned disqualified, (y) is convicted of, or is currently charged with, a felony for conduct relating to the regulation or handing of any drug product or (z) engages in any conduct or activity which could lead to any of the above mentioned disqualified in t



6.3 **NO WARRANTY; DISCLAIMER.** INSTITUTION ACKNOWLEDGES AND AGREES THAT THE MATERIALS ARE EXPERIMENTAL IN NATURE AND PROVIDED TO INSTITUTION "AS IS." SPONSOR MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND WHATSOEVER, EXPRESSED OR IMPLIED, WITH RESPECT TO THE MATERIALS. IN PARTICULAR, SPONSOR MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND WITH RESPECT TO THE PURITY, TOXICITY, STABILITY, MERCHANTABILITY, TITLE, NON-INFRINGEMENT, OR FITNESS FOR A PARTICULAR PURPOSE OF THE MATERIALS. ACCORDINGLY, SPONSOR SHALL NOT BE LIABLE FOR ANY CLAIMS INSTITUTION MAY HAVE AGAINST SPONSOR FOR ANY DAMAGES ARISING OUT OF INSTITUTION'S HANDLING, USE, STORAGE AND DISPOSAL OF THE MATERIALS, EXCEPT TO THE EXTENT THAT SAID DAMAGES RESULT FROM THE GROSS NEGLIGENCE OR WILLFUL MISCONDUCT OF SPONSOR. SPONSOR DOES NOT ENCOURAGE VIOLATION OF ANY **THIRD** PARTY'S INTELLECTUAL PROPERTY RIGHTS.

6.4. **Sponsor Indemnification of Principal Investigator and Institution.** Sponsor will indemnify and hold harmless Principal Investigator, Institution and their Affiliates and each of their respective directors, officers, agents and employees from and against any damages, judgments, liabilities, penalties, losses, costs, and expenses, including, but not limited to, reasonable attorney's fees, (collectively, the "Losses") incurred in connection with any third party claim arising out of any adverse event caused or resulting from an issue with the Sponsor Materials itself that has been provided to the Institution by Sponsor or breach of any term of this Agreement, except insofar as such Losses result from Institution's gross negligence or willful misconduct. Institution shall notify Sponsor promptly of Institution's receipt of notice of any claim, proceeding or investigation for which indemnification may be sought. Notwithstanding the foregoing, the failure to give notice shall not impact Institution right to indemnity under this Section unless Sponsor has been prejudiced by such failure. Sponsor shall have the right, but not the obligation, to control the defense of any claim for which Institution without any such claim without Institution prior written consent unless such settlement fully releases Institution without any admission of fault or wrong-doing on Institution part. The indemnification set forth in this Section shall include amounts paid in settlement; *provided, however*, that no such settlement shall be entered into by Institution without Sponsor's consent.

6.5 **Institution Indemnification of Sponsor.** Institution will indemnify and hold harmless Sponsor and its Affiliates and each of their respective directors, officers, agents and employees from and against any damages, judgments, liabilities, penalties, losses, costs, and expenses, including, but not limited to, reasonable attorney's fees, (collectively, the <u>"Losses"</u>) incurred in connection with any third party claim arising out of any misuse of the Sponsor Materials by Institution the Principal Investigator or any employee or other individual acting on behalf of the Institution and/or Principal Investigator or breach of any term of this Agreement, except insofar as such Losses result from Sponsor's gross negligence or willful misconduct. Sponsor shall notify Institution promptly of Sponsor's receipt of notice of any claim, proceeding or investigation for which indemnification may be sought. Notwithstanding the foregoing, the failure to give notice shall not impact Sponsor's right to indemnification unless Institution shab been prejudiced by such failure. Sponsor shall have the right, but not the obligation, to control the defense of any claim for which Sponsor is seeking indemnification, provided Sponsor will not settle any such claim without Institution's prior written consent unless such settlement fully releases Institution without any admission of fault or wrong-doing on Institution's part.

6.6 Representations and Warranties of Sponsor. Sponsor represents and warrants that Sponsor has the legal right, authority and power to enter into this Agreement.

6.7 **Payments.** The Parties agree and acknowledge that the compensation contemplated under the terms of this Agreement (a) constitutes fair market value for the Research Project. The Research Parties represent and warrant that the Research Project accurately specifies the research to be provided by the Research Parties; the Research Project performed under the Agreement does not involve the counseling or promotion of a business arrangement or other activity that violates any law, rule or regulation; and the work specified under the Research Project does not exceed what is reasonably necessary to accomplish its purpose.

6.8 **AAALAC.** If the Research Project includes work that involves animal research, Institution each represent and warrant that, before commencement of activities under the Research Project, it will either attain AAALAC accreditation or obtain Sponsor's written approval of the applicable procedures and standards to be used in connection with the Research Project. Institution shall use its best efforts to maintain AAALAC accreditation (if applicable) for the duration of the Research Project and shall notify Sponsor promptly if Institution loses such accreditation during the Research Project, and provide with any such notice an explanation in reasonable detail describing the circumstances surrounding the loss of such accreditation. The Research Parties agree to comply with AAALAC standards or such other standards approved by Sponsor in writing, as the case may be, in respect of all activities conducted under the Research Project.

6.9 **Export Control Laws.** Institution agrees not to export or re-export any Materials or Confidential Information unless Institution has obtained in advance all required licenses, agreements or other authorizations from the U.S. and Russian Governments. No information or Materials provided to Institution under this Agreement shall be exported, re-exported, transferred, or disclosed contrary to the applicable laws and regulations of the United States and Russia, or to any country, entity or party which is ineligible to receive such information or materials under United States and Russian laws and regulations, including the U.S. Department of Commerce and the U.S. Department of Treasury and their Russian counterparts. Exports include, without limitation, the sending or taking of products, materials, items or technical data out of the United States or Russia in any manner, disclosing or transferring technical data to a foreign person *(i.e.,* any person who is not a lawful permanent resident of the U.S. or is not a protected individual as defined by 8 U.S.0 sections 1101 and 1324) whether in the United States or abroad, or performing services for a foreign client, whether in the United States or abroad.

6.10 **Limitations.** EXCEPT AS EXPRESSLY PROVIDED IN THIS ARTICLE 6, NO PARTY TO THIS AGREEMENT MAKES ANY WARRANTY, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, RELATING TO THE RESEARCH PROJECT OR OTHERWISE UNDER THIS AGREEMENT, AND EACH PARTY TO THIS AGREEMENT SPECIFICALLY DISCLAIMS ANY IMPLIED WARRANTY OF MERCHANTABILITY, TITLE, NON-INFRINGEMENT OR WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE. SOME JURISDICTIONS DO NOT ALLOW LIMITATIONS ON IMPLIED WARRANTIES, SO THE ABOVE LIMITATIONS MAY NOT APPLY TO A PARTY IN SUCH JURISDICTIONS.

### **ARTICLE 7: MATERIAL TRANSFER**

7.1 **Transfer.** From time to time, Sponsor will use reasonable efforts to deliver to Principal Investigator such quantity of Sponsor Material (or portion thereof) as needed to conduct the Research Project. All Sponsor Material, and all title, interests, and rights therein, shall remain the sole property of Sponsor.

7.2 Use of Material. The Research Parties shall, and shall ensure that Project Participants, use the Sponsor Material solely in the conduct of the Research Project and for no other purpose. The Research Parties shall not, and shall ensure that Project Participants do not, use any Material for their own or others' benefit or for any purpose not exc 1 usively related to the Research Project, including without limitation for any direct or indirect commercial purpose or for research, testing, diagnosis or treatment involving human subjects, and shall not disclose, distribute, sell or otherwise transfer the Sponsor Material to any other commercial or non-commercial third party without Sponsor's prior written consent. The Research Parties agree not to make any modifications of any Sponsor Material, and agree that any invention or discovery made in violation of the foregoing shall vest automatically and exclusively in the Sponsor. The Research Parties agree not to sequence, analyze or otherwise determine the chemical structure or physical properties of any Sponsor Material, unless specifically agreed to by the Sponsor and contemplated by the Research Project.

7.3 **Storage & Handling.** All Sponsor Material shall be stored in a restricted area and handled, used and disposed of in accordance with all applicable federal, state and local laws, rules and regulations. Upon conclusion of the Research Project or upon request by Sponsor, the Principal Investigator and Institution shall discontinue use of all Sponsor Material and will arrange, at Sponsor's option, for the return to Sponsor or for the lawful disposal of all unused Sponsor Material (and shall provide written certification of same).

### **ARTICLE 8: GENERAL PROVISIONS**

8.1 **Independent Contractors.** The relationship of Sponsor, on the one hand, and Principal Investigator and Institution, on the other hand, established by this Agreement is that of independent contractors, and nothing contained in this Agreement shall be construed to give either Party hereto the power to direct or control the day-today activities of the other Party hereto, or constitute the Parties as partners, joint ventures, co-owners or otherwise as participants in a joint or common undertaking. The Parties agree that neither the Principal Investigator, nor any Project Participants is an employee of Sponsor.

8.2 **Assignment.** This Agreement shall be binding upon and inure to the benefit of the Parties hereto, their respective successors, assigns, legal representatives and heirs. Sponsor may assign or transfer Sponsor's rights and obligations under this Agreement to an Affiliate or a successor to all or substantially all of Sponsor's assets or business relating to this Agreement, whether by sale, merger, operation of law or otherwise, upon written notice to Institution. This Agreement shall not otherwise be assignable by Institution without the prior written consent of Sponsor and any such assignment which does not receive such prior consent shall be void.

8.3 Entire Agreement. This Agreement constitutes the entire and only agreement between the Parties relating to the subject matter hereof, and all prior negotiations, representations, agreements and understandings relating to the subject matter hereof are superseded hereby, provided that Research Parties agree and acknowledge that Sponsor may enter into consulting type arrangements with certain individuals at the Institution relating to the Research Project.

8.4 **Notices.** All notices required or permitted under this Agreement will be in writing and will be given by addressing the same to the address or fax number for the Sponsor or Institution set forth on the signature page of this Agreement or at such other address or fax number as the Sponsor or Institution may specify in writing under this procedure. Notices will be deemed to have been given (a) three (3) business days after deposit in the U.S. mail with proper postage for first class registered or certified mail prepaid, return receipt requested; (b) one (1) business day after fax transmission, with receipt of transmission confirmed in writing and confirmation copy sent by mail; or (c) one (1) business day after sending by a nationally recognized courier service for next day delivery.

8.5 Modification. This Agreement may not be modified except by a written agreement signed by each of the Parties hereto.

8.6 **Waiver**. No waiver of any rights shall be effective unless agreed to in writing by the Party waiving such right, and the waiver of any breach or default shall not constitute a waiver of any other right hereunder or any subsequent breach or default.

8.7 **Subcontracting.** Institution shall not subcontract or otherwise engage or consult with any other person or entity, other than Principal Investigator, to perform any of the Research Project without the advance written consent of Sponsor, which written consent shall not be unreasonably withheld or delayed. Notwithstanding the foregoing, Institution may subcontract with the Shemyakin-Ovchinnikov Institute of Bioorganic Chemistry, Russian Academy of Sciences for all or part of the work to be performed hereunder.

8.7.1 **Permitted Subcontractor.** Sponsor's written approval of any subcontractor ("Permitted Subcontractor") shall not relieve the Principal Investigator or the Institution of its obligations under the Agreement, and the Principal Investigator and Institution shall remain fully responsible for ensuring the performance of each such Permitted Subcontractor and its employees and for their compliance with the relevant provisions of the Agreement including but not limited to intellectual property, confidentiality, and publication provisions;

(a) The Principal Investigator and Institution each represents and warrants that the Permitted Subcontractor shall perform its obligations hereunder in accordance with the Law, the terms of this Agreement and any Research Project issued hereunder; and

(b) Require each Permitted Subcontractor to be bound in writing by clauses substantially similar to the confidentiality provisions herein and require each Permitted Subcontractor to assign intellectual property assignment or license provisions of this Agreement to Sponsor, unless Sponsor agrees otherwise in writing.

(c) Each of the Principal Investigator and Institution is responsible for all Institution Permitted Subcontractor(s) and for the payment of their compensation, including, if applicable, withholding of income taxes, and the payment and withholding of social security and other payroll taxes, unemployment insurance, workers' compensation insurance payments and disability benefits.

8.8 **Headings.** The headings of the Articles and sections of this Agreement are intended for convenience of reference only and are not intended to be a part of, or to affect the meaning or interpretation of, this Agreement.

8.9 **Severability.** if, under applicable law or regulation, ally provision of this Agreement is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement ("Severed Clause"), it is mutually agreed that this Agreement shall endure except for the Severed Clause. The Parties shall consult and use their best efforts to agree upon a valid and enforceable provision which shall be a reasonable substitute for such Severed Clause in light of the intent of this Agreement.

8.10 **Construction.** The Parties agree that they have participated equally in the drafting of this Agreement and that the language herein contained should not be presumptively construed against any of them.

8. 11 **Counterparts.** This Agreement may be executed in any number of counterparts, each of which will be deemed to be an original and all of which together will constitute one and the same instrument. Signature pages to this Agreement may be exchanged electronically as a portable document format (.pdf) file and such signature pages shall be deemed originals.

8.12 **Choice of Law and Venue.** This Agreement shall be governed by and construed in accordance with the laws of the United States. Further, the Parties irrevocably agree that any legal action or proceedings brought by or against them with respect to this Agreement shall be brought in the courts of the United States, and ill particular, the Federal and State Courts of the State of Massachussets and, by execution and delivery hereof, the Parties irrevocably submit to such jurisdiction and hereby irrevocably waive any and all objections which they may have with respect to venue in any of the above courts.

[Signatures on following page]

IN WITNESS WHEREOF, each Party has executed this Agreement by a duly authorized individual effective as of the Effective Date.

netic Biosciences, Inc. PJSC < <pharmasynthez>&gt;</pharmasynthez>	
By: /s/ Jeffrey F. Eisenberg	By: /s/ Peter Kruglyakov
Name: Jeffrey F. Eisenberg	Name: Peter Kruglyakov
Title: CEO	Title: CEO
	7/8/19

# PRINCIPAL INVESTIGATOR'S CERTIFICATION

I acknowledge that I have read the foregoing Agreement. I will comply with the terms and conditions of the Agreement both as an individual and as an employee or agent of Institution and I hereby certify that the representations and warranties by me as the Principal Investigator in the Agreement are true and correct on the date hereof.

Principal Investigator

/s/ Surkov Kirill Signature

Name: Surkov Kirill

Title

### CERTAIN INFORMATION IDENTIFIED IN THIS DOCUMENT, MARKED BY BRACKETS AND ASTERISKS ("[\*\*\*]"), HAS BEEN EXCLUDED PURSUANT TO ITEM 601(B)(10) OF REGULATION S-K UNDER THE SECURITIES ACT OF 1933, AS AMENDED, BECAUSE IT IS (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED.

### WORK ORDER

This Work Order ("Work Order") is between Xenetic Biosciences, Inc., 40 Speen St., Ste 102, Framingham, MA 01701 ("Sponsor") and PJSC Pharmsynthez, Nº134, Liter 1, Poselok Kuzmolovsky, St. Kapitolovo, Vsevolozhsky Raion, Leningradskaya Oblast, 188663, Russia ("Pharms") and relates to the Master Services Agreement dated as of June 12, 2020 (the "Agreement"), which is incorporated by reference herein. Pursuant to the Agreement, Pharms has agreed to perform certain services in accordance with written Work Orders, such as this one, entered into from time-to-time. This Work Order sets forth the obligations of the parties with regard to conducting a Stage 1 study (as described in the Attachments to this Work Order) of Sponsor's XCART technology, under a protocol (the "Protocol") to be prepared and agreed by the Project Steering Committee (as described below). Once the final Protocol is prepared, such Protocol, including any amendments thereto, is incorporated herein by reference.

The parties hereby agree as follows:

1. Work Order. This document constitutes a "Work Order" under the Agreement and this Work Order and the services contemplated herein are subject to the terms and provisions of the Agreement.

Services and Payment of Fees and Expenses. The specific services contemplated by this Work Order (the "Services") and the related payment terms and 2. obligations are set forth on the following attachments, which are incorporated herein by reference:

PROJECT ASSUMPTIONS	ATTACHMENT 1
SCOPE OF WORK/BUDGET	ATTACHMENT 2
TIMELINE	ATTACHMENT 3
PAYMENT SCHEDULE	ATTACHMENT 4
MILESTONE//PAYMENTS	ATTACHMENT 5
THIRD PARTY VENDORS	ATTACHMENT 6

Term. The term of this Work Order shall commence on the date of execution and shall continue until the Services described in Attachment 2 are completed, unless this Work Order is terminated in accordance with the Agreement. If the Agreement is terminated or expires, but this Work Order is not terminated or completed, then the terms of the Agreement shall continue to apply to this Work Order until the Work Order is either terminated or completed.

Amendments. No modification, amendment, or waiver of this Work Order shall be effective unless in writing and duly executed and delivered by each party to 4 the other.

5. <u>Standard Operating Procedures</u>. Pharms shall conduct the Study according to the formats and procedures set forth in Pharms's Standard Operating Procedures ("SOPs").

6. <u>Third Parties</u>. The Third Party vendors who will be performing services on the Study are set forth in Attachment 6. Sponsor has provided its written consent and approves such Third Party vendors listed and referred to within this Agreement.

7. Project Steering Committee Members. The initial team leader and Party representatives for the work conducted under this Work Order are:

Sponsor: 1 Curtis Lockshin, CSO; 2 Jeffrey Eisenberg, CEO

Pharms: 1 Dmitry Genkin, Member & Chairman of the Board of Directors; 2 Kirill Surkov, CEO's science advisor

ACKNOWLEDGED, ACCEPTED AND AGREED TO:

PJSC Pharmsynthez

By: <u>/s/ Efim Prilezhaev</u> (signature)

Print Name: Efim Prilezhaev

Title: CEO

Date: June 12, 2020

Xenetic Biosciences, Inc.

By: <u>/s/ Curtis Lockshin, PhD.</u> (signature)

Print Name: Curtis Lockshin, PhD

Title: Chief Scientific Officer

Date: June 12, 2020

# **ATTACHMENT 1: PROJECT ASSUMPTIONS**

[\*\*\*]

# ATTACHMENT 2: SCOPE OF WORK/PROJECT BUDGET

[\*\*\*]

# **ATTACHMENT 3: TIMELINE**

[\*\*\*]

# ATTACHMENT 4: PAYMENT SCHEDULE

[\*\*\*]

# ATTACHMENT 5: MILESTONES SCHEDULE AND PAYMENTS (Stages defined in Exhibit A –Program Summary)

Table 1

Milestone Event	Payment in USD	Payment in Shares
[***]	\$52,500	50,000 shares
[***]	\$472,500	450,000 shares
[***]	\$525,000	500,000 shares

# ATTACHMENT 6: THIRD PARTY AGREEMENTS

Shemyakin and Ovchinnikov Institute of Bioorganic Chemistry (Moscow)

Belarussian Research Center for Pediatric Oncology, Hematology and Immunology

Institute of Bioorganic Chemistry of NASB

Viciebsk Regional Clinical Oncological Center

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;
- 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, 2020

By: <u>/s/ JEFFREY F. EISENBERG</u> Jeffrey F. Eisenberg Chief Executive Officer (Principal Executive Officer)

**EXHIBIT 31.2** 

I, James Parslow, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of Xenetic Biosciences, Inc.;
- 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, 2020

By: <u>/s/ JAMES PARSLOW</u> 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, 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: August 12, 2020

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

<u>/s/ Jeffrey F. Eisenberg</u> Jeffrey F. Eisenberg Chief Executive Officer <u>/s/James Parslow</u> 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."