UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

		FORM 10-C	<u>. </u>	
(Mark One) QUARTERLY REPORT PURSUANT TO SECTION 13 O	D 15(d) OF THE	ECHDITIES EVOUAN	CE ACT OF 1024
		period ended Sep		GE ACT OF 1954
		OR		
	TRANSITION REPORT PURSUANT TO SECTION 13 O			GE ACT OF 1934
		sition period from		
	Commissi	ion File Number:	——————————————————————————————————————	
		sen Bio, I of registrant as specifie		
	Delaware		2	26-2025616
	(State or other jurisdiction of incorporation or organization)		(I. Ide	R.S. Employer entification No.)
	245 First Street, Suite 1800 Cambridge, MA			02142
	(Address of principal executive offices)			(Zip Code)
	(Registrant's te	(617) 444-8550 elephone number, inclu	ding area code)	
	(T	Not applicable.	:f -h	
	(Former name, former addres	s and former fiscal yea	r, if changed since last report)	
Securitie	s registered pursuant to Section 12(b) of the Act:			
		Trading		
	Title of each class Common Stock, \$0.001 par value	Symbol(s) SESN		change on which registered
Indicate	by check mark whether the registrant (1) has filed all report			daq Stock Market S(d) of the Securities Eychange Act of 1934
during th	the preceding 12 months (or for such shorter period that the lents for the past 90 days. Yes \boxtimes No \square			
	by check mark whether the registrant has submitted electron S-T during the preceding 12 months (or for such shorter p		-	-
emerging	by check mark whether the registrant is a large accelerate g growth company. See the definitions of "large accelerate" in Rule 12b-2 of the Exchange Act.	d filer, an acceler ted filer," "accel	ated filer, a non-acceler erated filer," "smaller r	ated filer, smaller reporting company or an eporting company," and "emerging growth
	Large accelerated filer \Box	Smaller	reporting company	\boxtimes
	Accelerated Filer \boxtimes Non-accelerated filer \Box		g growth company	
	erging growth company, indicate by check mark if the regis d financial accounting standards provided pursuant to Section			ransition period for complying with any new
Indicate	by check mark whether the registrant is a shell company (as	defined in Rule 1	2b-2 of the Exchange Ac	t). Yes □ No ⊠
There we	ere 129,339,617 shares of the registrant's common stock outs	standing as of Nov	ember 2, 2020.	

SESEN BIO, INC.

Quarterly Report on Form 10-Q for the Quarterly Period ended September 30, 2020

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SIGNATURES

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements.

SESEN BIO, INC. CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited; In thousands, except share and per share data)

	S	eptember 30, 2020	1	December 31, 2019
Assets				
Current assets:				
Cash and cash equivalents	\$	41,969	\$	48,121
Prepaid expenses and other current assets		7,072		6,326
Total current assets		49,041		54,447
Restricted cash		20		20
Property and equipment, net of accumulated depreciation of \$850 and \$758, respectively		154		238
Intangible assets		46,400		46,400
Goodwill		13,064		13,064
Other assets		349		196
Total Assets	\$	109,028	\$	114,365
Liabilities and Stockholders' Deficit				
Current liabilities:				
Accounts payable	\$	1,524	\$	1,902
Accrued expenses		7,703		6,169
Other current liabilities		481		446
Total current liabilities		9,708		8,517
Contingent consideration		103,200		120,020
Deferred tax liability		12,528		12,528
Other liabilities		145		_
Total Liabilities	\$	125,581	\$	141,065
Commitments and contingencies				
Stockholders' Deficit:				
Preferred stock, \$0.001 par value per share; 5,000,000 shares authorized at September 30, 2020 and December 31, 2019; no shares issued and outstanding at September 30, 2020 and December 31, 2019		_		_
Common stock, \$0.001 par value per share; 200,000,000 shares authorized at September 30, 2020 and December 31, 2019; 123,645,007 and 106,801,409 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively		123		107
Additional paid-in capital		284,236		266,717
Accumulated deficit		(300,912)		(293,524)
Total Stockholders' Deficit		(16,553)		(26,700)
Total Liabilities and Stockholders' Deficit	\$	109,028	\$	114,365
			_	

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

SESEN BIO, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(Unaudited; In thousands, except per share data)

	Three Months ended September 30,					nded 80,			
		2020		2019		2020	2019		
License revenue	\$	11,236	\$	_	\$	11,236	\$	_	
Operating expenses:									
Research and development		10,196		6,613		23,625		19,243	
General and administrative		4,115		3,238		10,882		8,910	
Change in fair value of contingent consideration		18,400		3,600		(16,820)		46,600	
Total operating expenses		32,711		13,451		17,687		74,753	
Loss from operations		(21,475)		(13,451)		(6,451)		(74,753)	
Other income (expense), net:									
Other income (expense), net		(1)		319		195		806	
Net Loss and Comprehensive Loss Before Taxes	·	(21,476)		(13,132)		(6,256)		(73,947)	
Provision for income taxes		(1,132)		_		(1,132)		_	
Net Loss and Comprehensive Loss After Taxes	\$	(22,608)	\$	(13,132)	\$	(7,388)	\$	(73,947)	
Deemed dividend on adjustment of exercise price on certain warrants	\$		\$	_		(147)	\$	_	
Net Loss and Comprehensive Loss Attributable to Common Shareholders	\$	(22,608)	\$	(13,132)	\$	(7,535)	\$	(73,947)	
Net loss per common share - basic and diluted	\$	(0.19)	\$	(0.13)	\$	(0.07)	\$	(0.85)	
Weighted-average common shares outstanding - basic and diluted	=	117,886		101,266		113,437		86,575	

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

SESEN BIO, INC. CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT) (Unaudited; In thousands, except share data)

	Common Stock		Additional Paid-in Capital		Accumulated Deficit		S	tockholders' Equity	
Polonicat Provide 21, 2010	Shares		Amount	Φ.	Capital	ф.		ф	(Deficit)
Balance at December 31, 2019	106,801,409	\$	107	\$	266,717	\$	(293,524)	Þ	(26,700)
Net income (loss)	_		_		_		41,564		41,564
Share-based compensation	_		_		407		_		407
Sales of common stock under 2014 ESPP	2,785		_		1		_		1
Issuance of common stock under ATM Offering, net of issuance costs of \$0.1 million	3,187,359		3		3,176		_		3,179
Balance at March 31, 2020	109,991,553	\$	110	\$	270,301	\$	(251,960)	\$	18,451
,				_					
Net income (loss)	_		_		_		(26,344)		(26,344)
Share-based compensation	_		_		491		_		491
Issuance of common stock under ATM Offering, net of issuance costs of \$0.1 million	6,636,100		6		4,768		_		4,774
Balance at June 30, 2020	116,627,653	\$	116	\$	275,560	\$	(278,304)	\$	(2,628)
		_					<u> </u>		
Net income (loss)	_		_		_		(22,608)		(22,608)
Share-based compensation	_		_		453		_		453
Sales of common stock under 2014 ESPP	25,401		_		9				9
Issuance of common stock under ATM Offering, net of issuance costs of \$0.3 million	6,991,953		7		8,214		_		8,221
Balance at September 30, 2020	123,645,007	\$	123	\$	284,236	\$	(300,912)	\$	(16,553)

	Common Stock				Additional Paid-in	A	Accumulated	Stockholders'	
	Shares		Amount		Capital		Deficit		Equity
Balance at December 31, 2018	77,456,180	\$	77	\$	230,154	\$	(186,024)	\$	44,207
Net income (loss)	_		_		_		(6,480)		(6,480)
Share-based compensation	_		_		326		_		326
Sales of common stock under 2014 ESPP	8,601		_		7		_		7
Balance at March 31, 2019	77,464,781	\$	77	\$	230,487	\$	(192,504)	\$	38,060
Net income (loss)	_		_		_		(54,335)		(54,335)
Share-based compensation	_		_		356		_		356
Exercise of stock options	30,000		_		45		_		45
Exercise of common stock warrants	3,361,115		4		3,430		_		3,434
Issuance of common stock and common stock warrants, net of issuance costs of \$2.2 million	20,410,000		20		27,789		_		27,809
Balance as of June 30, 2019	101,265,896	\$	101	\$	262,107	\$	(246,839)	\$	15,369
Net income (loss)	_		_		_		(13,132)		(13,132)
Share-based compensation	_		_		229		_		229
Sales of common stock under the 2014 ESPP	1,682		_		1		_		1
Balance at September 30, 2019	101,267,578	\$	101	\$	262,337	\$	(259,971)	\$	2,467

 $\label{thm:companying} \textit{notes are an integral part of these condensed consolidated financial statements}.$

SESEN BIO, INC. CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited; In thousands)

Nine Months ended September 30, 2020 2019 **Cash Flows from Operating Activities:** (7,388) \$ Net loss \$ (73,947)Adjustments to reconcile net loss to net cash used in operating activities: Depreciation 92 164 Share-based compensation 1,351 911 Change in fair value of contingent consideration (16,820)46,600 Changes in operating assets and liabilities: Prepaid expenses and other assets (899)(421)Accounts payable 1,216 (378)Accrued expenses and other liabilities 1,714 1,761 **Net Cash Used in Operating Activities** (22,328)(23,716) **Cash Flows from Investing Activities: Net Cash Used in Investing Activities** (8)(137)**Cash Flows from Financing Activities:** Proceeds from issuance of common stock under ATM Offering, net of issuance costs 16,174 Proceeds from sales of common stock under 2014 ESPP 10 8 Proceeds from exercises of stock options 45 Proceeds from the issuance of common stock and common stock warrants, net of issuance costs 27,809 Proceeds from the exercise of common stock warrants 3,434 **Net Cash Provided by Financing Activities** 16,184 31,296 Net Increase (Decrease) in Cash, Cash Equivalents and Restricted Cash 7,443 (6,152)Cash, Cash Equivalents and Restricted Cash - Beginning of Period 48,141 50,442 41,989 57,885 Cash, Cash Equivalents and Restricted Cash - End of Period Supplemental disclosure of non-cash operating activities: Right-of-use assets related to the adoption of ASC 842 \$ \$ 236 Right-of-use assets obtained in exchange for lease obligations 290 \$ \$ 113 Cash paid for amounts included in the measurement of lease liabilities \$ 115 Supplemental disclosure of non-cash financing activities: Deemed dividend on adjustment of exercise price on certain warrants \$ \$ 147

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

SESEN BIO, INC. NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

1. DESCRIPTION OF BUSINESS

Sesen Bio, Inc. ("Sesen" or the "Company"), a Delaware corporation formed in February 2008, is a late-stage clinical company developing targeted fusion protein therapeutics ("TFPTs") for the treatment of patients with cancer. The Company's most advanced product candidate, VicineumTM, also known as VB4-845, is a locally-administered targeted fusion protein composed of an anti-epithelial cell adhesion molecule ("EpCAM") antibody fragment tethered to a truncated form of *Pseudomonas exotoxin A*. The Company has an ongoing single-arm, multi-center, open-label Phase 3 clinical trial of Vicineum as a monotherapy in patients with high-risk, bacillus Calmette-Guérin ("BCG")-unresponsive non-muscle invasive bladder cancer ("NMIBC") (the "VISTA Trial"). The VISTA Trial completed enrollment in April 2018 with a total of 133 patients, and in December 2019, the Company initiated submission of the Biologics License Application ("BLA") for Vicineum to the United States Food and Drug Administration ("FDA") under Rolling Review, which enables individual modules to be submitted and reviewed on an ongoing basis, rather than waiting for all sections to be completed before submission. The Company operates in one segment under the direction of its Chief Executive Officer (chief operating decision maker).

Viventia Acquisition

In September 2016, the Company entered into a Share Purchase Agreement with Viventia Bio, Inc., a corporation incorporated under the laws of the Province of Ontario, Canada ("Viventia"), the shareholders of Viventia named therein (the "Selling Shareholders") and, solely in its capacity as seller representative, Clairmark Investments Ltd., a corporation incorporated under the laws of the Province of Ontario, Canada ("Clairmark") (the "Share Purchase Agreement"), pursuant to which the Company agreed to and simultaneously completed the acquisition of all of the outstanding capital stock of Viventia from the Selling Shareholders (the "Viventia Acquisition"). In connection with the closing of the Viventia Acquisition, the Company issued 4.0 million shares of its common stock to the Selling Shareholders, which at that time represented approximately 19.9% of the voting power of the Company as of immediately prior to the issuance of such shares. Clairmark is an affiliate of Leslie L. Dan, a director of the Company until his retirement in July 2019.

In addition, under the Share Purchase Agreement, the Company is obligated to pay to the Selling Shareholders certain post-closing contingent cash payments upon the achievement of specified milestones and based upon net sales, in each case subject to the terms and conditions set forth in the Share Purchase Agreement, including: (i) a one-time milestone payment of \$12.5 million payable upon the first sale of Vicineum (the "Purchased Product") in the United States; (ii) a one-time milestone payment of \$7.0 million payable upon the first sale of the Purchased Product in any one of certain specified European countries; (iii) a one-time milestone payment of \$3.0 million payable upon the first sale of the Purchased Product in Japan; and (iv) quarterly earn-out payments equal to 2% of net sales of the Purchased Product during specified earn-out periods. Such earn-out payments are payable with respect to net sales in a country beginning on the date of the first sale in such country and ending on the earlier of (i) December 31, 2033 and (ii) fifteen years after the date of such sale, subject to early termination in certain circumstances if a biosimilar product is on the market in the applicable country (collectively, the "Contingent Consideration"). Under the Share Purchase Agreement, the Company, its affiliates, licensees and subcontractors are required to use commercially reasonable efforts for the first seven years following the closing of the Viventia Acquisition, to achieve marketing authorizations throughout the world and, during the applicable earn-out period, to commercialize the Purchased Product in the United States, France, Germany, Italy, Spain, United Kingdom, Japan, China and Canada. Certain of these payments are payable to individuals or affiliates of individuals that were previously employees or members of the Company's board of directors.

Liquidity and Going Concern

As of September 30, 2020, the Company had cash and cash equivalents of \$42 million, net working capital of \$39.3 million and an accumulated deficit of \$300.9 million. The Company incurred negative cash flows from operating activities of \$37.5 million for the year ended December 31, 2019 and \$22.3 million for the nine months ended September 30, 2020. Since its inception, the Company has received no revenue from sales of its products, and management anticipates that operating losses will continue for the foreseeable future as the Company continues its ongoing Phase 3 VISTA Trial for Vicineum for the treatment of high-risk NMIBC and seeks marketing approval from the FDA and the European Medicines Agency. The Company has financed its operations to date primarily through private placements of its common stock, preferred stock, common stock warrants and convertible bridge notes, venture debt borrowings, its initial public offering ("IPO"), follow-on public offerings, sales effected in "at-the-market" ("ATM") offerings, a License Agreement with F. Hoffmann-La Roche Ltd and Hoffman-La Roche Inc. (collectively, "Roche") (the "License Agreement with Roche"), a License Agreement with Qilu Pharmaceuticals Ltd. ("Qilu") (the "License Agreement with Qilu"), and, to a lesser extent, from a collaboration. See "Note 9. Stockholders' Equity" below for information regarding the Company's recently completed equity financings.

Under Accounting Standards Codification ("ASC") Topic 205-40, *Presentation of Financial Statements - Going Concern*, management is required at each reporting period to evaluate whether there are conditions and events, considered in the aggregate, that raise substantial doubt about an entity's ability to continue as a going concern within one year after the date that the financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management's plans that have not been fully implemented as of the date the financial statements are issued. When substantial doubt exists, management evaluates whether the mitigating effect of its plans sufficiently alleviates the substantial doubt about the Company's ability to continue as a going concern. The mitigating effect of management's plans, however, is only considered if both (i) it is probable that the plans will be effectively implemented within one year after the date that the financial statements are issued and (ii) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued. Generally, to be considered probable of being effectively implemented, the plans must have been approved by the Company's board of directors before the date that the financial statements are issued.

The Company's future success is dependent on its ability to develop and commercialize Vicineum for the treatment of high-risk NMIBC, and ultimately upon its ability to attain profitable operations. In order to commercialize its product candidates, including Vicineum for the treatment of high-risk NMIBC, the Company needs to complete clinical development and comply with comprehensive regulatory requirements. The Company is subject to a number of risks similar to other late-stage clinical companies, including, but not limited to, successful discovery and development of its product candidates, raising additional capital, development and commercialization by its competitors of new technological innovations, protection of proprietary technology, market acceptance of its products and dependence on third parties for the development and commercialization of Vicineum in certain markets. The successful discovery and development of product candidates, including Vicineum for the treatment of high-risk NMIBC, requires substantial working capital, and management expects to seek additional funds through equity or debt financings or through additional collaboration or licensing transactions or other sources. The Company may be unable to obtain equity or debt financings or enter into additional collaboration or licensing transactions on favorable terms, or at all. To the extent that the Company raises additional capital through the sale of equity or convertible debt securities, the ownership interests of existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of existing stockholders. Debt financing, if available, may involve agreements that include liens or other restrictive covenants limiting the Company's ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If the Company raises additional funds through government or other third-party funding, strategic collaborations and alliances or licensing arrangements, it may have to relinquish valuable rights to its technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable. If the Company is unable to raise additional funds when needed, it may be required to implement cost reduction strategies and delay, limit, reduce or terminate its product development, regulatory approval or future commercialization efforts or grant rights to develop and market products or product candidates that management would otherwise prefer to develop and market.

The Company's management does not believe that its cash and cash equivalents of \$42.0 million as of September 30, 2020 are sufficient to fund the Company's current operating plan for at least twelve months after the issuance of these condensed consolidated financial statements. Given the history of significant losses, negative cash flows from operations, limited cash resources currently on hand, the ongoing COVID-19 pandemic and dependence by the Company on its ability - about which there can be no certainty - to obtain additional financing to fund its operations after the current cash resources are exhausted, substantial doubt exists about the Company's ability to continue as a going concern. These condensed consolidated financial statements were prepared under the assumption that the Company will continue as a going concern and do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

2. BASIS OF PRESENTATION

The accompanying financial statements have been prepared in accordance with United States generally accepted accounting principles ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the ASC and Accounting Standards Updates ("ASUs"), promulgated by the Financial Accounting Standards Board ("FASB").

Interim Financial Statements

The accompanying unaudited interim condensed consolidated financial statements have been prepared from the books and records of the Company in accordance with GAAP for interim financial information and Rule 10-01 of Regulation S-X promulgated by the United States Securities and Exchange Commission ("SEC"), which permit reduced disclosures for interim periods. All adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the accompanying condensed consolidated balance sheets and statements of operations and comprehensive loss, stockholders' equity (deficit) and cash flows have been made. Although these interim financial statements do not include all of the

information and footnotes required for complete annual financial statements, management believes the disclosures are adequate to make the information presented not misleading. These unaudited interim results of operations and cash flows for the nine months ended September 30, 2020 are not necessarily indicative of the results that may be expected for the full year. These unaudited interim condensed consolidated financial statements and footnotes should be read in conjunction with the Company's audited annual consolidated financial statements and footnotes included in its Annual Report on Form 10-K, as filed with the SEC on March 16, 2020, wherein a more complete discussion of significant accounting policies and certain other information can be found.

Use of Estimates

The preparation of financial statements in accordance with GAAP and the rules and regulations of the SEC requires the use of estimates and assumptions, based on judgments considered reasonable, which affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The Company bases its estimates and assumptions on historical experience, known trends and events and various other factors that management believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Although management believes its estimates and assumptions are reasonable when made, they are based upon information available at the time they are made. Management evaluates the estimates and assumptions on an ongoing basis and, if necessary, makes adjustments. Due to the risks and uncertainties involved in the Company's business and evolving market conditions, and given the subjective element of the estimates and assumptions made, actual results may differ from estimated results. The most significant estimates and judgments impact the fair value of intangible assets, goodwill and contingent consideration; income taxes (including the valuation allowance for deferred tax assets); research and development expenses; revenue recognition and going concern considerations.

Principles of Consolidation

The Company's consolidated financial statements include the accounts of the Company, its wholly owned subsidiary Viventia and its indirect subsidiaries, Viventia Bio USA Inc. and Viventia Biotech (EU) Limited. All intercompany transactions and balances have been eliminated in consolidation.

Foreign Currency Translation

The functional currency of the Company and each of its subsidiaries is the U.S. dollar.

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The Company's complete summary of significant accounting policies can be found in "Item 15. Exhibits and Financial Statement Schedules - Note 3. Summary of Significant Accounting Policies" in the audited annual consolidated financial statements included in its Annual Report on Form 10-K for the year ended December 31, 2019.

4. RECENT ACCOUNTING PRONOUNCEMENTS

Adopted in 2020

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). ASU 2016-13 requires measurement and recognition of expected credit losses for financial assets held. The amendments in ASU 2016-13 eliminate the probable threshold for initial recognition of a credit loss in GAAP and reflect an entity's current estimate of all expected credit losses. ASU 2016-13 is effective for annual and interim periods beginning January 1, 2020 and is to be applied using a modified retrospective transition method. The Company adopted this guidance effective January 1, 2020, and it did not have a material impact on the Company's financial position, results of operations or cash flows.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurements* ("ASU 2018-13"). ASU 2018-13 modifies fair value measurement disclosure requirements. ASU 2018-13 is effective for annual and interim periods beginning after December 15, 2019. The Company adopted this guidance effective January 1, 2020, and although it resulted in some additional footnote disclosures, it did not have a material impact on the Company's disclosures. For the new disclosures regarding our Level 3 instruments, please read Note 5, Fair Value Measurements and Financial Instruments, to these condensed consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-15, Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service

Contract ("ASU 2018-15"). ASU 2018-15 requires a customer in a cloud computing arrangement that is a service contract to follow the internal-use software guidance to determine which implementation costs to defer and recognize as an asset. The effective date for ASU 2018-15 is for annual and interim periods beginning after December 15, 2019. The amendments in this ASU should be applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption. The Company adopted this guidance effective January 1, 2020, and it did not have a material impact on the Company's financial position, results of operations or cash flows.

Pending Adoption

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* ("ASU 2019-12"). ASU 2019-12 simplifies the accounting for income taxes by removing certain exceptions to the general principles in Topic 740. The amendments in ASU 2019-12 also improve consistent application of and simplify GAAP for other areas of Topic 740 by clarifying and amending existing guidance. ASU 2019-12 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. Early adoption is permitted. The method with which the amendments in this ASU are to be applied varies depending on the nature of the tax item impacted by amendment. Because the Company generates losses and pays no income taxes, it does not expect the adoption of ASU 2019-12 to have a material impact on the Company's financial position, results of operations or cash flows.

5. FAIR VALUE MEASUREMENT AND FINANCIAL INSTRUMENTS

The carrying values of cash and cash equivalents, restricted cash, prepaid expenses and other current assets, and accounts payable on the Company's condensed consolidated balance sheets approximated their fair values as of September 30, 2020 and December 31, 2019 due to their short-term nature.

Certain of the Company's financial instruments are measured at fair value using a three-level hierarchy that prioritizes the inputs used to measure fair value. This fair value hierarchy prioritizes the use of observable inputs and minimizes the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

- <u>Level 1</u>: Inputs are quoted prices for identical instruments in active markets.
- <u>Level 2</u>: Inputs are quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; or model-derived valuations whose inputs are observable or whose significant value drivers are observable.
- <u>Level 3</u>: Inputs are unobservable and reflect the Company's own assumptions, based on the best information available, including the Company's own data.

The following tables set forth the carrying amounts and fair values of the Company's financial instruments measured at fair value on a recurring basis as of September 30, 2020 and December 31, 2019 (in thousands):

				September 30, 2020								
	·				Fair V	alue	Measurement 2	Bas	ed on			
		arrying Amount	 Fair Value	(in Active Markets				Significant Unobservable Inputs (Level 3)	
Assets:												
Money market funds (cash equivalents)	\$	16,370	\$ 16,370	\$	16,370	\$	_	\$	_			
Liabilities:												
Contingent consideration	\$	103,200	\$ 103,200	\$	_	\$	_	\$	103,200			

			December 31, 2019								
				Fair V	alue	Measurement l	Base	ased on			
	Carrying Amount	Fair Value	Ç	Ouoted Prices in Active Markets (Level 1)		gnificant other Observable Inputs (Level 2)	τ	Significant Unobservable Inputs (Level 3)			
Assets:											
Money market funds (cash equivalents)	\$ 31,146	\$ 31,146	\$	31,146	\$	_	\$	_			
Liabilities:											
Contingent consideration	\$ 120.020	\$ 120.020	\$	_	\$	_	\$	120,020			

The Company evaluates transfers between fair value levels at the end of each reporting period. There were no transfers of assets or liabilities between fair value levels during the nine months ended September 30, 2020.

Contingent Consideration

On September 20, 2016, the Company acquired Viventia through the issuance of shares of common stock plus contingent consideration, pursuant to the terms of a Share Purchase Agreement. The Company recorded the acquired assets and liabilities based on their estimated fair values as of the acquisition date and finalized its purchase accounting for the Viventia Acquisition during the third quarter of 2017. The contingent consideration relates to amounts potentially payable to the former shareholders of Viventia under the Share Purchase Agreement. Contingent consideration is measured at its estimated fair value at each reporting period, with fluctuations in value resulting in a non-cash charge to earnings (or loss) during the period. The estimated fair value measurement is based on significant inputs, including internally developed financial forecasts, probabilities of success, and the timing of certain milestone events and achievements, which are not observable in the market, representing a Level 3 measurement within the fair value hierarchy. The valuation of contingent consideration requires the use of significant assumptions and judgments, which management believes are consistent with those that would be made by a market participant. Management reviews its assumptions and judgments on an ongoing basis as additional market and other data is obtained, and any future changes in the assumptions and judgments utilized by management may cause the estimated fair value of contingent consideration to fluctuate materially, resulting in earnings volatility.

The following table sets forth a summary of the change in the fair value of the Company's contingent consideration liability, measured on a recurring basis at each reporting period, for the nine months ended September 30, 2020 (in thousands):

Balance at December 31, 2019	\$ 120,020
Change in fair value of contingent consideration	(16,820)
Balance at September 30, 2020	\$ 103,200

The fair value of the Company's contingent consideration was determined using probabilities of successful achievement of regulatory milestones and commercial sales, the period in which these milestones and sales are expected to be achieved ranging from 2021 to 2033, and the level of commercial sales of Vicineum forecasted for the United States, Europe, Japan, China and other potential markets. There have been no changes to the valuation methods utilized during the nine months ended September 30, 2020. Because of the ongoing business environment uncertainty created by the ongoing COVID-19 pandemic, management carefully reviewed as of September 30, 2020 all of the Company's financial forecast assumptions related to probability, timing and anticipated level of commercial sales in both US and OUS markets which were used to determine the estimated fair value of contingent consideration, and updated its forecasts for commercial sales in the third quarter of 2020 as needed. However, given the evolving and uncertain nature of the COVID-19 pandemic, management will continue to closely monitor developments in order to timely determine if any financial forecast changes may be required. As of September 30, 2020, no financial forecast changes due to COVID-19 were currently required. Changes to probabilities of success, timing of certain milestones and achievements, and level of commercial sales could materially affect the valuation of contingent consideration.

The estimated fair value of contingent consideration is also determined by applying appropriate discount rates to future cash outflows related to the contingent payment obligations, and these discount rates have fluctuated significantly in 2020 as a result of the extreme volatility of financial markets as global economies shut down in order to contain the spread of COVID-19. The milestone payments constitute debt-like obligations, and the high-yield debt index rate applied to the milestones in order to determine the estimated fair value moved from 11.8% as of December 31, 2019 to 17.9% as of March 31, 2020, 14.5% as of June 30, 2020 and back to 11.8% as of September 30, 2020. The discount rate applied to the 2% royalty due on forecasted Vicineum revenues is derived from the Company's estimated weighted-average cost of capital ("WACC"), and this WACC-derived discount rate fluctuated from 5.6% as of December 31, 2019 to 14.7% as of March 31, 2020, to 13.2% as of June 30,

2020 and to 9.4% as of September 30, 2020. These changes in the applicable discount rates, plus refinement of timelines in certain OUS markets and changes to the competitive landscape, resulted in an overall \$16.8 million decrease in the estimated fair value of contingent consideration as of September 30, 2020. Changes to the discount rates could materially affect the valuation of the contingent consideration.

6. INTANGIBLE ASSETS AND GOODWILL

Intangible Assets

Intangible assets on the Company's condensed consolidated balance sheet are the result of the Viventia Acquisition in September 2016. The following table sets forth the composition of intangible assets as of September 30, 2020 and December 31, 2019 (in thousands):

	Sep	tember 30, 2020	De	cember 31, 2019
IPR&D intangible assets:				
Vicineum United States rights	\$	31,700	\$	31,700
Vicineum European Union rights		14,700		14,700
Total Intangibles	\$	46,400	\$	46,400

Goodwill

Goodwill on the Company's consolidated balance sheet is the result of the Viventia Acquisition in September 2016. Goodwill had a carrying value of \$13.1 million as of September 30, 2020 and December 31, 2019.

7. LEASES

On January 1, 2019, the Company adopted ASC Topic 842, Leases using the optional transition method. The Company's lease portfolio includes:

- 1. An operating lease for its 31,100 square foot facility in Winnipeg, Manitoba which consists of manufacturing, laboratory, warehouse and office space. In September 2020, the Company entered into an extension of this lease for an additional two years, through September 2022, with a right to extend the lease for one subsequent three-year term. The minimum monthly rent under this lease is \$13,500 per month. In addition to rent expense, the Company expects to incur \$12,300 per month in related operating expenses. Operating lease cost under this lease, including the related operating costs, was \$75,000 and \$223,000 for the three and nine months ended September 30, 2020 and \$76,000 and \$222,000 for the three and nine months ended September 30, 2019, respectively;
- 2. Short-term property leases for modular office space for 1) its corporate headquarters in Cambridge, MA and 2) office space in Philadelphia, PA. The short-term leases renew every four to nine months and currently extend through May 2021. The minimum monthly rent for these office spaces is \$21,400 per month, which is subject to change if and as the Company adds or deducts space to or from the leases. The Company recorded \$64,000 and \$195,000 in rent expense for the three and nine months ended September 30, 2020, respectively, and \$59,000 and \$188,000 in rent expense for the three and nine months ended September 30, 2019, respectively, for these leases.

The asset component of the Company's operating leases is recorded as operating lease right-of-use assets and reported within other assets on the Company's condensed consolidated balance sheets. The short-term liability is recorded in other current liabilities on the Company's condensed consolidated balance sheet. Operating lease cost is recognized on a straight-line basis over the term of the lease.

8. ACCRUED EXPENSES

The following table sets forth the composition of accrued expenses as of September 30, 2020 and December 31, 2019 (in thousands):

	Sep	tember 30, 2020	Decemb	er 31, 2019
Research and development	\$	5,145	\$	3,688
Payroll-related expenses		1,474		1,638
Severance to former Executives and other employees		_		378
Professional fees		1,060		378
Other		24		87
Total Accrued Expenses	\$	7,703	\$	6,169

Management Changes

On August 26, 2019, Richard Fitzgerald departed as the Company's Chief Financial Officer. In connection with his separation from the Company, Mr. Fitzgerald and the Company entered into a Separation Agreement and General Release dated as of September 9, 2019 (the "Fitzgerald Separation Agreement), pursuant to which the Company provided Mr. Fitzgerald with twelve months of separation payments and benefits. The Company recorded \$0.3 million of expense related to this agreement in 2019. The separation payments were paid through the normal payroll cycle through August 2020, when the Company concluded its obligations under the Fitzgerald Separation Agreement.

On August 2, 2019, Dennis Kim, M.D., MPH departed as the Company's Chief Medical Officer. In connection with his separation from the Company, Dr. Kim and the Company entered into a Separation Agreement and General Release dated as of August 2, 2019 (the "Kim Separation Agreement"), pursuant to which the Company provided Dr. Kim with six months of separation payments in the amount of \$0.2 million. In addition, Dr. Kim and the Company entered into a Consulting Agreement dated as of August 3, 2019 (the "Kim Consulting Agreement"), pursuant to which the Company agreed to pay Dr. Kim \$0.1 million in consulting fees and transition expenses over the three months ended November 2, 2019. The Company recorded \$0.3 million of expenses related to these agreements in 2019. The Kim Consulting Agreement payments were made in a lump sum when the agreement concluded in November 2019. The separation payments were paid through the normal payroll cycle through January 2020, when the Company concluded its obligations under the Kim Separation Agreement.

9. STOCKHOLDERS' EQUITY (DEFICIT)

Equity Financings

ATM Offering

In November 2019, the Company entered into an Open Market Sale Agreement SM (the "Sale Agreement") with Jefferies LLC ("Jefferies"), under which the Company may issue and sell shares of its common stock from time to time for an aggregate sales price of up to \$35.0 million through Jefferies (the "ATM Offering"). Sales of common stock under the Sale Agreement are made by any method that is deemed to be an ATM offering as defined in Rule 415(a)(4) of the Securities Act of 1933, as amended, including but not limited to sales made directly on or through the Nasdaq Global Market or any other existing trading market for the common stock. The Company has no obligation to sell any of its common stock and may at any time suspend offers under the Sale Agreement or terminate the Sale Agreement. Subject to the terms and conditions of the Sale Agreement, Jefferies will use its commercially reasonable efforts to sell common stock from time to time, as the sales agent, based upon the Company's instructions, which include a prohibition on sales below a minimum price set by the Company from time to time. The Company has provided Jefferies with customary indemnification rights, and Jefferies is entitled to a commission at a fixed rate equal to 3.0% of the gross proceeds for each sale of common stock under the Sale Agreement. The Company incurred \$0.2 million in legal, accounting and printing costs related to the commencement of the ATM Offering. For the nine months ended September 30, 2020, the Company raised \$16.2 million of net proceeds from the sale of 16.8 million shares of common stock at a weighted-average price of \$0.99 per share under the ATM Offering, including \$8.2 million of net proceeds from the sale of 7.0 million shares of common stock at a weighted-average price of \$1.21 per share during the three months ended September 30, 2020. Share issue costs, including sales agent commissions, related to the ATM Offering totaled \$0.3 million and \$0.5 million during the three and nine months ended September 30, 2020, respect

June 2019 Financina

In June 2019, the Company raised \$27.8 million of net proceeds from the sale of 20.4 million shares of common stock and accompanying warrants to purchase an additional 20.4 million shares of common stock in an underwritten public offering (the "June 2019 Financing"). The combined purchase price for each share of common stock and accompanying warrant was \$1.47. Subject to certain ownership limitations, the warrants issued in the June 2019 Financing were exercisable immediately upon issuance at an exercise price of \$1.47 per share, subject to adjustments as provided under the terms of such warrants, and had a

one-year term expiring on June 21, 2020. As of September 30, 2020, all warrants issued in connection with the June 2019 financing have expired.

Preferred Stock

Pursuant to its Amended and Restated Certificate of Incorporation (the "Certificate of Incorporation"), the Company is authorized to issue 5.0 million shares of "blank check" preferred stock, \$0.001 par value per share, which enables its board of directors, from time to time, to create one or more series of preferred stock. Each series of preferred stock issued shall have the rights, preferences, privileges and restrictions as designated by the board of directors. The issuance of any series of preferred stock could affect, among other things, the dividend, voting and liquidation rights of the common stock. The Company had no preferred stock issued and outstanding as of September 30, 2020 and December 31, 2019.

Common Stock

Pursuant to its Certificate of Incorporation, the Company is authorized to issue 200.0 million shares of common stock, \$0.001 par value per share, of which 123.6 million and 106.8 million shares were issued and outstanding as of September 30, 2020 and December 31, 2019, respectively. In addition, the Company had reserved for issuance the following amounts of shares of its common stock for the purposes described below as of September 30, 2020 and December 31, 2019 (in thousands):

	September 30, 2020	December 31, 2019
Shares of common stock issued	123,645	106,801
Shares of common stock reserved for issuance for:		
Warrants	2,485	22,895
Stock options	10,227	6,236
Shares available for grant under 2014 Stock Incentive Plan	4,795	8,753
Shares available for sale under 2014 Employee Stock Purchase Plan		28
Total shares of common stock issued and reserved for issuance	141,152	144,713

The voting, dividend and liquidation rights of holders of shares of common stock are subject to and qualified by the rights, powers and preferences of holders of shares of preferred stock. Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders; provided, however, that, except as otherwise required by law, holders of common stock shall not be entitled to vote on any amendment to the Company's Certificate of Incorporation that relates solely to the terms of one or more outstanding series of preferred stock if the holders of such affected series are entitled, either separately or together as a class with the holders of one or more such series, to vote thereon. There shall be no cumulative voting.

Dividends may be declared and paid on the common stock from funds lawfully available thereof as and when determined by the board of directors and subject to any preferential dividend or other rights of any then-outstanding preferred stock. The Company has never declared or paid, and for the foreseeable future does not expect to declare or pay, dividends on its common stock.

Upon the dissolution or liquidation of the Company, whether voluntary or involuntary, holders of common stock will be entitled to receive all assets of the Company available for distribution to its stockholders, subject to any preferential or other rights of any then-outstanding preferred stock.

Warrants

All of the Company's outstanding warrants are non-tradeable and permanently classified as equity because they meet the derivative scope exception under ASC Topic 815-40, *Derivatives and Hedging - Contracts in Entity's Own Equity* ("ASC 815-40"). The following table sets forth the Company's warrant activity for the nine months ended September 30, 2020 (in thousands):

Year-to-Date	Warrant	Activity
Icai-w-Dau	. warrani	ACHIVILY

Issued	Exercise Price (1)	Expiration	December 31, 2019	Issued	(Exercised)	(Expired)	September 30, 2020
Jun-2019	\$1.47	Jun-2020	20,410		_	(20,410)	_
Mar-2018	\$0.55*	Mar-2023	1,943	_	_	_	1,943
Nov-2017	\$0.55*	Nov-2022	487	_	_	_	487
May-2015	\$11.83	Nov-2024	28	_	_	_	28
Nov-2014	\$11.04	Nov-2024	27	_	_	_	27
			22,895			(20,410)	2,485

⁽¹⁾ As of September 30, 2020.

In March 2018, the Company raised \$9.0 million of net proceeds from the sale of common stock in a registered direct public offering and the sale of warrants to purchase shares of common stock with an exercise price of \$1.20 per share (the "2018 Warrants") in a concurrent private placement. On October 28, 2019, the Company entered into transactions with certain holders of its then outstanding 2018 Warrants to amend their warrants pursuant to a Warrant Amendment Agreement (the "2018 Warrant Amendment Agreements"). The 2018 Warrant Amendment Agreements reduced the exercise price of the warrants from \$1.20 to the lesser of (a) \$0.95 per share of common stock and (b) the exercise price as determined from time to time, pursuant to the anti-dilution provisions in the 2018 Warrant Amendment Agreements. During the second quarter of 2020, the anti-dilution provision was triggered; as such, the Company recognized a deemed dividend of approximately \$0.1 million which reduced the income available to common stockholders. As the Company has an accumulated deficit balance, there is no overall impact to additional paid-in capital, as the deemed dividend is recorded as offsetting debit and credit entries to additional paid-in capital. Therefore the amounts were not presented on the Statement of Stockholders' Equity (Deficit). There were no adjustments to the exercise price of any warrants for the three month period ended September 30, 2020.

10. LOSS PER SHARE

A net loss cannot be diluted. Therefore, when the Company is in a net loss position, basic and diluted loss per common share are the same. If the Company achieves profitability, the denominator of a diluted earnings per common share calculation includes both the weighted-average number of shares outstanding and the number of common stock equivalents, if the inclusion of such common stock equivalents would be dilutive. Dilutive common stock equivalents potentially include warrants, stock options and non-vested restricted stock awards and units using the treasury stock method, along with the effect, if any, from outstanding convertible securities. The majority of the Company's outstanding warrants to purchase common stock have participation rights to any dividends that may be declared in the future and are therefore considered to be participating securities. Participating securities have the effect of diluting both basic and diluted earnings per share during periods of income. During periods of loss, no loss is allocated to the participating securities since the holders have no contractual obligation to share in the losses of the Company.

The following potentially dilutive securities outstanding as of September 30, 2020 and 2019 have been excluded from the denominator of the diluted loss per share of common stock outstanding calculation as their effect is anti-dilutive (in thousands):

	Three Month Septembe		Nine Months Ended September 30,		
	2020	2019	2020	2019	
Warrants	2,485	6,450	2,485	6,450	
Stock options	10,227	26,307	10,227	26,307	
	12,712	32,757	12,712	32,757	

11. SHARE-BASED COMPENSATION

The following table sets forth the amount of share-based compensation expense recognized by the Company by line item on its consolidated statements of operations for the three and nine months ended September 30, 2020 and 2019 (in thousands):

^{*} Exercise price shown subject to further adjustment based on down round provision added by amendment.

	Th	Three Months ended September 30,			Nine Months ende September 30,		
		2020		2019	2020		2019
Research and development	\$	95	\$	(20) \$	266	\$	119
General and administrative		358		249	1,085		792
	\$	453	\$	229 \$	1,351	\$	911

2014 Stock Incentive Plan

The Company's 2014 Stock Incentive Plan, as amended ("2014 Plan"), was adopted by its board of directors in December 2013 and subsequently approved by its stockholders in January 2014. The 2014 Plan became effective immediately prior to the closing of the Company's IPO in February 2014 and provides for the grant of incentive and non-qualified stock options, restricted stock awards and units, stock appreciation rights and other stock-based awards, with amounts and terms of grants determined by the Company's board of directors at the time of grant, to the Company's employees, officers, directors, consultants and advisors. Currently there are only stock options outstanding under the 2014 Plan, which generally vest over a four-year period at the rate of 25% of the grant vesting on the first anniversary of the date of grant and 6.25% of the grant vesting at the end of each successive three-month period thereafter. Stock options granted under the 2014 Plan are exercisable for a period of ten years from the date of grant. There were 8.0 million stock options outstanding under the 2014 Plan as of September 30, 2020. There were 4.8 million shares of common stock available for issuance under the 2014 Plan as of September 30, 2020.

2009 Stock Incentive Plan

The Company maintains a 2009 Stock Incentive Plan, as amended and restated ("2009 Plan"), which provided for the grant of incentive and non-qualified stock options and restricted stock awards and units, with amounts and terms of grants determined by the Company's board of directors at the time of grant, to its employees, officers, directors, consultants and advisors. Upon the closing of its IPO in February 2014, the Company ceased granting awards under the 2009 Plan and all shares (i) available for issuance under the 2009 Plan at such time and (ii) subject to outstanding awards under the 2009 Plan that expire, terminate or are otherwise surrendered, canceled, forfeited or repurchased without having been fully exercised or resulting in any common stock being issued were carried over to the 2014 Plan. Stock options granted under the 2009 Plan are exercisable for a period of ten years from the date of grant. There were 0.1 million fully vested stock options outstanding under the 2009 Plan as of September 30, 2020.

Out-of-Plan Inducement Grants

From time to time, the Company has granted equity awards to its newly hired executives in accordance with the Nasdaq Stock Market LLC ("Nasdaq") employment inducement grant exemption (Nasdaq Listing Rule 5635(c)(4)). Such grants are made outside of the 2014 Plan and act as an inducement material to the executive's acceptance of employment with the Company. There were 2.1 million stock options outstanding which were granted as employment inducement awards outside of the 2014 Plan as of September 30, 2020.

Stock Options

The following table sets forth a summary of the Company's total stock option activity, including awards granted under the 2014 Plan and 2009 Plan and inducement grants made outside of stockholder approved plans, for the nine months ended September 30, 2020:

	Number of Shares under Option (in thousands)	Weighted- average Exercise Price per Option	Weighted- average Remaining Contractual Life (in years)	gregate ssic Value lousands)
Outstanding at December 31, 2019	6,236	\$1.52	8.8	\$ 358
Granted	4,044	\$0.87		
Exercised	_	\$0.00		
Canceled or forfeited	(53)	\$0.84		
Outstanding at September 30, 2020	10,227	\$1.26	8.6	\$ 3,541
Exercisable at September 30, 2020	3,637	\$1.73	8.0	\$ 786

The Company recognized share-based compensation expense related to stock options of \$0.5 million and \$1.4 million for the three and nine months ended September 30, 2020, respectively, and \$0.2 million and \$0.9 million for the three and nine months ended September 30, 2019, respectively. As of September 30, 2020, there was \$4.1 million of total unrecognized compensation cost related to non-vested stock options which the Company expects to recognize over a weighted-average period of 2.6 years. The weighted-average grant-date fair value of stock options granted during the nine months ended September 30, 2020 was \$0.56 per option. The total intrinsic value of stock options exercised during the nine months ended September 30, 2020 was de minimus.

For the nine months ended September 30, 2020 and 2019, the grant-date fair value of stock options was determined using the following weighted-average inputs and assumptions in the Black-Scholes option pricing model:

	September 30 2020	, September 30, 2019
Fair value of common stock	\$0.56	\$0.69
Exercise price	\$0.87	\$1.02
Expected term (in years)	6.10	5.98
Risk-free interest rate	1.3	2.1
Expected volatility	71.5	78.1
Dividend vield	<u> </u>	%

12. EMPLOYEE BENEFIT PLANS

2014 Employee Stock Purchase Plan

The Company's 2014 Employee Stock Purchase Plan ("2014 ESPP") was adopted by its board of directors in December 2013 and subsequently approved by its stockholders in January 2014. The 2014 ESPP became effective immediately prior to the closing of the Company's IPO in February 2014 and established an initial reserve of 0.2 million shares of the Company's common stock for issuance to participating employees. The purpose of the 2014 ESPP is to enhance employee interest in the success and progress of the Company by encouraging employee ownership of common stock of the Company. The 2014 ESPP provides employees with the opportunity to purchase shares of common stock at a 15% discount to the market price through payroll deductions or lump sum cash investments. The Company estimates the number of shares to be issued at the end of an offering period and recognizes expense over the requisite service period. Shares of the common stock issued and sold pursuant to the 2014 ESPP are shown on the consolidated statements of changes in stockholders' equity (deficit). The most recent offering of the 2014 ESPP, which closed in September 2020, exhausted the remaining shares available for sale under the 2014 ESPP. As such, as of September 30, 2020, there were no further shares of common stock available for sale under the 2014 ESPP.

Defined Contribution Plans

United States - 401(k) Plan

The Company maintains a 401(k) defined contribution retirement plan which covers all of its U.S. employees. Employees are eligible to participate immediately upon their date of hire. Under the 401(k) plan, participating employees may defer up to 75% of their pre-tax salary, subject to certain statutory limitations. Employee contributions vest immediately. The plan allows for a

discretionary match per participating employee up to a maximum \$4,000 per year. The expenses incurred for the periods presented were de minimis.

Canada - Defined Contribution Plan

The Company maintains a defined contribution plan for its Canadian employees. Participants may contribute a percentage of their annual compensation to this plan, subject to statutory limitations. The Company contributes up to the first 4% of eligible compensation for its Canadian-based employees to the retirement plan. The expenses incurred for the periods presented were de minimis.

13. LICENSE AGREEMENTS

In-License Agreements

License Agreement with Zurich

The Company has a License Agreement with the University of Zurich ("Zurich") which grants the Company exclusive license rights, with the right to sublicense, to make, have made, use and sell under certain patents primarily directed to the Company's targeting agent, including an EpCAM chimera and related immunoconjugates and methods of use and manufacture of the same. These patents cover some key aspects of Vicineum. The Company may be obligated to pay \$0.75 million in milestone payments for the first product candidate that achieves applicable clinical development milestones. Based on current status, the Company anticipates that these milestones may be triggered by Vicineum's clinical development pathway. As part of the consideration, the Company is also obligated to pay up to a 4% royalty on the net product sales for products covered by or manufactured using a method covered by a valid claim in the Zurich patent rights. Royalties owed to Zurich will be reduced if the total royalty rate owed by the Company to Zurich and any other third party is 10% or greater, provided that the royalty rate to Zurich may not be less than 2% of net sales. The obligation to pay royalties in a particular country expires upon the expiration or termination of the last of the Zurich patent rights that covers the manufacture, use or sale of a product. There is no obligation to pay royalties in a country if there is no valid claim that covers the product or a method of manufacturing the product.

License Agreement with Micromet

The Company has a License Agreement with Micromet AG ("Micromet"), now part of Amgen, Inc., which grants it nonexclusive rights, with certain sublicense rights, for know-how and patents allowing exploitation of certain single chain antibody products. These patents cover some key aspects of Vicineum. Under the terms of the License Agreement with Micromet, the Company may be obligated to pay up to €3.6 million in milestone payments for the first product candidate that achieves applicable clinical development milestones. The Company anticipates that certain of these milestones may be triggered by Vicineum's clinical development pathway. The Company is also required to pay up to a 3.5% royalty on the net sales for products covered by the agreement, which includes Vicineum. The royalty rate owed to Micromet in a particular country will be reduced to 1.5% if there are no valid claims covering the product in that country. The obligation to pay royalties in a particular country expires upon the later of the expiration date of the last valid claim covering the product and the tenth anniversary of the first commercial sale of the product in such country. Finally, the Company is required to pay to Micromet an annual license maintenance fee of €50,000, which can be credited towards any royalty payment the Company owes to Micromet.

License Agreement with XOMA

The Company has a License Agreement with XOMA Ireland Limited ("XOMA") which grants it non-exclusive rights to certain XOMA patent rights and know-how related to certain expression technology, including plasmids, expression strains, plasmid maps and production systems. These patents and related know-how cover some key aspects of Vicineum. Under the terms of the License Agreement with XOMA, the Company is required to pay up to \$0.25 million in milestone payments for a product candidate that incorporates know-how under the license and achieves applicable clinical development milestones. Based on current clinical status, the Company anticipates that these milestones may be triggered by Vicineum's clinical development pathway. The Company is also required to pay a 2.5% royalty on the net sales for products incorporating XOMA's technology, which includes Vicineum. The Company has the right to reduce the amount of royalties owed to XOMA on a country-by-country basis by the amount of royalties paid to other third parties, provided that the royalty rate to XOMA may not be less than 1.75% of net sales. In addition, the foregoing royalty rates are reduced by 50% with respect to products that are not covered by a valid patent claim in the country of sale. The obligation to pay royalties in a particular country expires upon the later of the expiration date of the last valid claim covering the product and the tenth anniversary of the first commercial sale of the product in such country.

Out-License Agreements

License Agreement with Roche

In June 2016, the Company entered into the License Agreement with Roche, pursuant to which the Company granted Roche an exclusive, worldwide license, including the right to sublicense, to its patent rights and know-how related to the Company's monoclonal antibody EBI-031 and all other IL-6 anti-IL-6 antagonist monoclonal antibody technology owned by the Company (collectively, the "Roche Licensed Intellectual Property"). Under the License Agreement with Roche, Roche is required to continue developing, at its cost, EBI-031 and any other product made from the Licensed Intellectual Property that contains an IL-6 antagonist anti-IL monoclonal antibody ("Roche Licensed Product") and pursue ongoing patent prosecution, at its cost.

Financial Terms

The Company received from Roche an upfront license fee of \$7.5 million in August 2016 upon the effectiveness of the License Agreement with Roche following approval by the Company's stockholders, and Roche agreed to pay up to an additional \$262.5 million upon the achievement of specified regulatory, development and commercialization milestones with respect to up to two unrelated indications. Specifically, an aggregate amount of up to \$197.5 million is payable to the Company for the achievement of specified milestones with respect to the first indication, consisting of \$72.5 million in development milestones, \$50.0 million in regulatory milestones and \$75.0 million in commercialization milestones. In September 2016, Roche paid the Company the first development milestone of \$22.5 million as a result of the Investigational New Drug application for EBI-031 becoming effective on or before September 15, 2016. Additional amounts of up to \$65.0 million are payable upon the achievement of specified development and regulatory milestones in a second indication.

In addition, the Company is entitled to receive royalty payments in accordance with a tiered royalty rate scale, with rates ranging from 7.5% to 15% of net sales of potential future products containing EBI-031 and up to 50% of these rates for net sales of potential future products containing other IL-6 compounds, with each of the royalties subject to reduction under certain circumstances and to the buy-out options of Roche.

Buy-Out Options

The License Agreement with Roche provides for two "option periods" during which Roche may elect to make a one-time payment to the Company and, in turn, terminate its diligence, milestone and royalty payment obligations under the License Agreement with Roche. Specifically, (i) Roche may exercise a buy-out option following the first dosing ("Initiation") in the first Phase 2 study for a Licensed Product until the day before Initiation of the first Phase 3 study for a Licensed Product, in which case Roche is required to pay the Company \$135.0 million within 30 days after Roche's exercise of such buy-out option and receipt of an invoice from the Company, or (ii) Roche may exercise a buy-out option following the day after Initiation of the first Phase 3 study for a Licensed Product until the day before the acceptance for review by the FDA or other regulatory authority of a BLA or similar application for marketing approval for a Licensed Product in either the United States or in the E.U., in which case Roche is required to pay the Company, within 30 days after Roche's exercise of such buy-out option and receipt of an invoice from the Company, \$265.0 million, which amount would be reduced to \$220.0 million if none of the Company's patent rights containing a composition of matter claim covering any compound or Roche Licensed Product has issued in the E.U.

Termination

Either the Company or Roche may each terminate the License Agreement with Roche if the other party breaches any of its material obligations under the agreement and does not cure such breach within a specified cure period. Roche may terminate the License Agreement with Roche following effectiveness by providing advance written notice to the Company or by providing written notice if the Company is debarred, disqualified, suspended, excluded, or otherwise declared ineligible from certain federal or state agencies or programs. The Company may terminate the License Agreement with Roche if, prior to the first filing of a BLA for a Roche Licensed Product, there is a period of 12 months where Roche is not conducting sufficient development activities with respect to the products made from the Roche Licensed Intellectual Property.

License Agreement with Qilu

On July 30, 2020, the Company and its a wholly-owned subsidiary, Viventia Bio, Inc., entered into the License Agreement with Qilu pursuant to which the Company granted Qilu an exclusive, sublicensable, royalty-bearing license, under certain intellectual property owned or exclusively licensed by the Company, to develop, manufacture and commercialize VicineumTM (the "Licensed Product") for the treatment of NMIBC and other types of cancer (the "Field") in China, Hong Kong, Macau and Taiwan (the "Territory"). The Company also granted Qilu a non-exclusive, sublicensable, royalty-bearing sublicense, under certain other intellectual property licensed by the Company to develop, manufacture and commercialize the Licensed Product in the Territory. The Company retains development, manufacturing and commercialization rights with respect to Vicineum in the rest of the world.

In consideration for the rights granted by the Company, Qilu agreed to pay to the Company (i) a one-time upfront cash payment of \$12 million, subject to certain tax withholdings such as income taxes and value added taxes ("VAT"), payable within 45 business days of the execution date, subject to delivery by the Company of certain know-how and other documentation related

to the Licensed Product to Qilu, and (ii) milestone payments totaling up to \$23 million upon the achievement of certain technology transfer, development and regulatory milestones. All payments are inclusive of VAT, which are withheld by Qilu upon payment, and for which future recovery of such taxes may be available. In September 2020, the Company received \$10.0 million in net proceeds associated with the \$12 million upfront payment due under the License Agreement with Qilu.

Qilu also agreed to pay the Company a 12% royalty based upon annual net sales of Licensed Products in the Territory. The royalties are payable on a Licensed Product-by-Licensed Product and region-by-region basis commencing on the first commercial sale of a Licensed Product in a region and continuing until the latest of (i) twelve years after the first commercial sale of such Licensed Product in such region, (ii) the expiration of the last valid patent claim covering or claiming the composition of matter, method of treatment, or method of manufacture of such Licensed Product in such region, and (iii) the expiration of regulatory or data exclusivity for such Licensed Product in such region (collectively, the "Royalty Term"). The royalty rate is subject to reduction under certain circumstances, including when there is no valid claim of a licensed patent that covers a Licensed Product in a particular region or no data or regulatory exclusivity of a Licensed Product in a particular region.

Qilu is responsible for all costs related to developing, obtaining regulatory approval of and commercializing the Licensed Products in the Field in the Territory. Qilu is required to use commercially reasonable efforts to develop, seek regulatory approval for, and commercialize at least one Licensed Product in the Field in the Territory. A joint development committee will be established between the Company and Qilu to coordinate and review the development, manufacturing and commercialization plans with respect to the Licensed Products in the Territory. The Company and Qilu also agreed to negotiate in good faith the terms and conditions of a supply agreement and related quality agreement pursuant to which the Company will manufacture or have manufactured and supply Qilu with all quantities of the Licensed Product necessary for Qilu to develop and commercialize the Licensed Product in the Field in the Territory until the Company has completed manufacturing technology transfer to Qilu and approval of a Qilu manufactured product by the National Medical Products Administration in China for the Licensed Product.

The License Agreement with Qilu will expire on a Licensed Product-by-Licensed Product and region-by-region basis on the date of the expiration of all applicable Royalty Terms. Either party may terminate the License Agreement with Qilu for the other party's material breach following a cure period or upon certain insolvency events. Qilu has the right to receive a refund of all amounts paid to the Company in the event the License Agreement with Qilu is terminated under certain circumstances. The License Agreement with Qilu includes customary representations and warranties, covenants and indemnification obligations for a transaction of this nature.

The License Agreement with Qilu is subject to the provisions of Accounting Standards Codification 606, Revenue from Contracts with Customers ("ASC 606"), which was adopted effective January 1, 2018. The initial transaction price was estimated to be \$11.2 million and was based on the up-front fixed consideration of \$12 million less amounts withheld for VAT. The Company concluded that its promises under the License Agreement with Qilu represented one bundled performance obligation that had been achieved as of September 30, 2020. As such, \$11.2 million of the total \$11.2 million transaction price was considered earned and the Company recorded \$11.2 million of revenue during the three-month period ended September 30, 2020. The Company is reasonably certain that no refund of the upfront payment will be due to Qilu. As of September 30, 2020, \$0.2 million of the up-front fixed consideration remains payable to the Company. Additional consideration to be paid to the Company upon the achievement of certain milestones, as well as recoverability of VAT, will be included if it is expected that the amounts will be received and the amounts would not be subject to a constraint. As of September 30, 2020, none of these amounts were reasonably certain to be achieved due to the nature and timing of the underlying activities.

For the three and nine months ended September 30, 2020, the Company recorded \$1.1 million of income tax expense pursuant to the License Agreement with Qilu. The income tax expense relates to withholding taxes paid in foreign jurisdictions and is reported as provision for income taxes on the condensed consolidated statement of operations and comprehensive loss for each period.

14. RELATED PARTY TRANSACTIONS

The Company leases its facility in Winnipeg, Manitoba from an affiliate of Leslie L. Dan, a director of the Company until his retirement in July 2019. The Company paid \$0.1 million and \$0.2 million of rent for the three and nine months ended September 30, 2020, respectively, and \$0.1 million and \$0.2 million of rent for the three and nine months ended September 30, 2019, respectively. All payments include related operating expenses. In September 2020, the Company entered into an extension of this lease for an additional two years, through September 2022, with a right to extend the lease for one subsequent three-year term.

The Company pays fees under an intellectual property license agreement to Protoden Technologies Inc. ("Protoden"), a company owned by Clairmark, an affiliate of Mr. Dan. Pursuant to the agreement, the Company has an exclusive, perpetual, irrevocable and non-royalty bearing license, with the right to sublicense, to certain patents and technology to make, use and sell

products that utilize such patents and technology. The annual fee is \$0.1 million. Upon expiration of the term on December 31, 2024, the licenses granted to the Company will require no further payments to Protoden. For each of the nine months ended September 30, 2020 and 2019, the Company paid \$0.1 million under this agreement. The Company did not make payments under this agreement during the three months ended September 30, 2020 and 2019.

Mr. Dan was not deemed a related party during the three and nine months ended September 30, 2020; as such, only payments made during the three and nine months ended September 30, 2019 are considered payments to a related party.

15. SUBSEQUENT EVENTS

On October 30, 2020, the Company entered into an amendment to the Sale Agreement pursuant to which it may issue and sell an additional \$50 million of shares of common stock through Jefferies.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations, as well as other sections in this Quarterly Report on Form 10-Q, should be read in conjunction with our unaudited interim condensed consolidated financial statements and related notes thereto appearing elsewhere herein and our audited annual consolidated financial statements and related notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations" for the year ended December 31, 2019, included in our Annual Report on Form 10-K filed with the United States Securities and Exchange Commission ("SEC") on March 16, 2020. In addition to historical financial information, some of the information contained in the following discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended ("Exchange Act"). All statements other than statements of historical facts, including statements regarding our future results of operations and financial position, the impact of the COVID-19 pandemic, business strategy, current and prospective products, product approvals, research and development costs, current and prospective collaborations, timing and likelihood of success, plans and objectives of management for future operations and future results of current and anticipated products, are forward-looking statements. These statements involve known and unknown risks, uncertainties, assumptions and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this Quarterly Report on Form 10-Q are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to a number of risks, uncertainties and assumptions described in "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for us to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Unless the context otherwise requires, all references in this Quarterly Report on Form 10-Q to the "Company," "Sesen," "we," "us," and "our" include Sesen Bio, Inc. and its subsidiaries.

Overview

We are a late-stage clinical company advancing targeted fusion protein therapeutics ("TFPTs") for the treatment of patients with cancer. We genetically fuse the targeting antibody fragment and the cytotoxic protein payload into a single molecule which is produced through our proprietary one-step, microbial manufacturing process. We target tumor cell surface antigens with limited expression on normal cells. Binding of the target antigen by the TFPT allows for rapid internalization into the targeted cancer cell. We have designed our targeted proteins to overcome the fundamental efficacy and safety challenges inherent in existing antibody-drug conjugates ("ADCs") where a payload is chemically attached to a targeting antibody.

Our most advanced product candidate, Vicineum, also known as VB4-845, is a locally-administered targeted fusion protein composed of an anti-epithelial cell adhesion molecule ("EpCAM") antibody fragment tethered to a truncated form of *Pseudomonas exotoxin A* for the treatment of high-risk non-muscle invasive bladder cancer ("NMIBC"). On December 6, 2019, we initiated our Biologics License Application ("BLA") submission for Vicineum to the United States Food and Drug Administration ("FDA") under Rolling Review. "Rolling Review" of the BLA enables individual modules to be submitted and reviewed on an ongoing basis, rather than waiting for all sections to be completed before submission. The submission consisted of Modules 1, 2, 4 and 5, with information amendments to be submitted to these modules throughout 2020. We anticipate completing Module 3 (Chemistry, Manufacturing and Controls ("CMC")) to finalize the BLA submission by the end of 2020. We may experience disruptions as a result of the COVID-19 pandemic that may impact our expected timeline to finalize the BLA submission, including manufacturing activities of our contract manufacturers due to limitations on work and travel imposed or recommended by federal or state governments, employers and others.

In August 2019, we reported updated preliminary efficacy data from our ongoing single-arm, multi-center, open-label Phase 3 clinical trial of Vicineum as a monotherapy in patients with high-risk, bacillus Calmette-Guérin ("BCG")-unresponsive NMIBC (the "VISTA Trial"). As of the May 29, 2019 data cutoff date, we reported the preliminary complete response rates ("CRRs") in evaluable carcinoma *in situ* ("CIS") patients following three, six, nine and 12 months of treatment in the clinical trial. The results were consistent with the results observed in the previously completed Phase 1 and Phase 2 clinical trials of Vicineum for the treatment of high-risk NMIBC. The VISTA Trial completed enrollment in April 2018 with a total of 133 patients across three cohorts based on histology and time to disease recurrence after adequate BCG treatment (under 2018 FDA guidance on treatment of NMIBC, adequate BCG is defined as at least two courses of BCG with at least five doses in an initial induction course of treatment, plus at least two doses in a second course of treatment):

- Cohort 1 (n=86): Patients with CIS with or without papillary disease that were determined to be refractory or recurred within six months of their last course of adequate BCG;
- Cohort 2 (n=7): Patients with CIS with or without papillary disease that recurred after six months, but less than 11 months, after their last course of adequate BCG; and
- Cohort 3 (n=40): Patients with high-risk (Ta or T1) papillary disease without CIS that was determined to be refractory or recurred within six months of their last course of adequate BCG.

As of the end of April 2020, all patients have completed treatment in the VISTA Trial. The primary endpoints of the VISTA Trial are CRR at 3 months in patients with CIS (with or without papillary disease) whose disease is BCG-unresponsive and duration of response ("DoR") for BCG-unresponsive CIS patients who experience a complete response ("CR").

As of the May 29, 2019 data cutoff date, preliminary primary and secondary endpoint data for each of the trial cohorts were as follows:

Cohort 1 (n=86) Evaluable Population (n=82) Complete Response Rate, for CIS:

Time Point	Evaluable Patients*	Complete Response Rate (95% Confidence Interval)
3-months	n=82	39% (28%-50%)
6-months	n=82	26% (17%-36%)
9-months	n=82	20% (12%-30%)
12-months	n=82	17% (10%-27%)

 $^{* \} Response-evaluable \ population \ includes \ any \ modified \ intention-to-treat \ ("mITT") \ subject \ who \ completed \ the \ induction \ phase.$

Cohort 2 (n=7) Evaluable Population (n=7) Complete Response Rate, for CIS:

Time Point	Evaluable Patients*	Complete Response Rate (95% Confidence Interval)
3-months	n=7	57% (18%-90%)
6-months	n=7	57% (18%-90%)
9-months	n=7	43% (10%-82%)
12-months	n=7	14% (0%-58%)

^{*} Response-evaluable population includes any mITT subject who completed the induction phase.

Pooled Cohorts 1 and 2 Evaluable Population (n=89) Complete Response Rate, for CIS:

Time Point	Evaluable Patients*	Complete Response Rate (95% Confidence Interval)
3-months	n=89	40% (30%-51%)
6-months	n=89	28% (19%-39%)
9-months	n=89	21% (13%-31%)
12-months	n=89	17% (10%-26%)

^{*} Response-evaluable population includes any mITT subject who completed the induction phase.

Phase 3 Pooled Complete Response Rate vs. Phase 2 Pooled Complete Response Rate:

Time Point	Preliminary Phase 3 Pooled CRR (95% Confidence Interval)	Phase 2 Pooled CRR (95% Confidence Interval)
3-months	40% (30%-51%)	40% (26%-56%)
6-months	28% (19%-39%)	27% (15%-42%)
9-months	21% (13%-31%)	18% (8%-32%)
12-months	17% (10%-26%)	16% (7%-30%)

Cohort 3 (n=40) Evaluable Population (n=38) Recurrence-Free Rate†:

Time Point	Evaluable Patients*	Recurrence-Free Rate (95% Confidence Interval)
3-months	n=38	71% (54%-85%)
6-months	n=38	58% (41%-74%)
9-months	n=38	45% (29%-62%)
12-months	n=38	42% (26%-59%)

 $[\]dagger$ Recurrence-free rate is defined as the percentage of patients that are recurrence-free at the given assessment time point.

Duration of Response: The median DoR for patients in Cohort 1 and Cohort 2 combined (n=93) is 287 days (lower 95% confidence interval ("CI") = 154 days, upper 95% confidence interval is not estimable ("NE") due to the limited number of events occurring beyond the median), using the Kaplan-Meier method. The Kaplan-Meier method is a non-parametric statistical analysis used to estimate survival times and times to event when incomplete observations in data exist. Additional *ad hoc* analysis of pooled data for all patients with CIS (Cohorts 1 and 2, n=93) shows that among patients who achieved a complete response at 3 months, 52% remained disease-free for a total of 12 months or longer after starting treatment, using the Kaplan-Meier method. DoR is defined as the time from first occurrence of complete response to documentation of treatment failure or death.

^{*} Response-evaluable population includes any mITT subject who completed the induction phase.

We have conducted additional analyses for secondary endpoints based on the May 29, 2019 data cutoff date. These additional preliminary data include the following:

- *Time to Cystectomy:* Across all 133 patients treated with Vicineum in the VISTA Trial, greater than 75% of all patients are estimated to remain cystectomy-free at 3 years, using the Kaplan-Meier method. Additional *ad hoc* analysis shows that approximately 88% of responders are estimated to remain cystectomy-free at 3 years. Time to cystectomy is defined as the time from the date of first dose of study treatment to surgical bladder removal. The first 2018 FDA guidance on treatment of BCG-unresponsive NMIBC patients states that the goal of therapy in such patients is to avoid cystectomy. Therefore, time to cystectomy is a key secondary endpoint in the VISTA Trial.
- *Time to Disease Recurrence:* High-grade papillary (Ta or T1) NMIBC is associated with higher rates of progression and recurrence. The median time to disease recurrence for patients in Cohort 3 (n=40) is 402 days (95% CI, 170-NE), using the Kaplan-Meier method. Time to disease recurrence is defined as the time from the date of the first dose of study treatment to the first occurrence of treatment failure or death on or prior to treatment discontinuation.
- *Progression-Free Survival ("PFS"):* 90% of all 133 patients treated with Vicineum in the VISTA Trial are estimated to remain progression-free for 2 years or greater, using the Kaplan-Meier method. PFS is defined as the time from the date of first dose of study treatment to the first occurrence of disease progression (e.g. T2 or more advanced disease) or death on or prior to treatment discontinuation.
- *Event-Free Survival:* 29% of all 133 patients treated with Vicineum in the VISTA Trial are estimated to remain event-free at 12 months, using the Kaplan-Meier method. Event-free survival is defined as the time from the date of first dose of study treatment to the first occurrence of disease recurrence, progression or death on or prior to treatment discontinuation.
- Overall Survival ("OS"): 96% of all 133 patients treated with Vicineum in the VISTA Trial are estimated to have an overall survival of 2 years or greater, using the Kaplan-Meier method. OS is defined as the time from the date of first dose of study treatment to death from any

Preliminary Safety Results

As of the May 29, 2019 data cutoff date, in patients across all cohorts (n=133) of our Phase 3 VISTA Trial of Vicineum for the treatment of high-risk NMIBC, 88% experienced at least one adverse event, with 95% of adverse events being Grade 1 or 2. The most commonly reported treatment-related adverse events were dysuria (14%), hematuria (13%) and urinary tract infection (12%) - all of which are consistent with the profile of bladder cancer patients and the use of catheterization for treatment delivery. These adverse events were determined by the clinical investigators to be manageable and reversible, and only four patients (3%) discontinued treatment due to an adverse event. Serious adverse events, regardless of treatment attribution, were reported in 14% of patients. There were four treatment-related serious adverse events reported in three patients including acute kidney injury (Grade 3), pyrexia (Grade 2), cholestatic hepatitis (Grade 4) and renal failure (Grade 5). There were no age-related increases in adverse events observed in the VISTA Trial.

Other Vicineum Activity

In August 2018, we received Fast Track designation from the FDA for Vicineum for the treatment of high-risk NMIBC.

In May 2019, we met with the FDA for a Type C meeting for CMC and reached agreement with the FDA on the analytical comparability plan to be used to assess comparability between the drug supply used in clinical trials and the potential commercial drug supply to be produced by Fujifilm. We also confirmed with the FDA that, subject to final comparability data to be provided in the BLA submission, no additional clinical trials were deemed necessary to establish comparability.

In June 2019, we met with the FDA for a Type B Pre-BLA meeting regarding the approval pathway for Vicineum for the treatment of patients with high-risk, BCG-unresponsive NMIBC. At the meeting, we reached alignment with the FDA on an accelerated approval pathway for Vicineum along with Rolling Review. The FDA also indicated that the clinical data, nonclinical data, clinical pharmacology data, and the safety database were sufficient to support a BLA submission, and that no additional clinical trials were necessary for a BLA submission. Per the official FDA minutes received post-meeting, the FDA stated that the pre-licensing inspection may be completed at the time of process performance qualification manufacturing, which we believe will benefit the overall review timeline for the BLA. In addition, the FDA communicated that they expect that a meeting with the FDA's Oncologic Drugs Advisory Committee ("ODAC") will be required as part of the accelerated approval pathway. If Vicineum receives marketing approval for treatment of NMIBC, a post-marketing confirmatory trial will also be required.

In November 2019, we met with the FDA for a Type C meeting to discuss the details of a post-marketing confirmatory trial for Vicineum for the treatment of high-risk NMIBC. At that meeting, we reached agreement with the FDA that the post-marketing confirmatory trial for Vicineum will enroll BCG-refractory patients who have received less-than-adequate BCG, which is especially important in light of the ongoing BCG shortage. This represents a broader patient population than the BCG-intolerant population originally proposed. We anticipate that, if Vicineum is approved by the FDA, the initial indication will be for BCG-unresponsive patients who have received adequate BCG. If the post-marketing confirmatory trial is successful, it could result in an expanded label to include this additional population of patients who have received less-than-adequate BCG.

On December 4, 2019, we met with the FDA for a Type B pre-BLA meeting for CMC. At that meeting, we reached agreement with the FDA on the final content for Module 3 (CMC) of the BLA.

On December 6, 2019, we initiated our BLA submission for Vicineum to the FDA under Rolling Review. The submission consisted of Modules 1, 2, 4 and 5, with information amendments to be submitted to these modules throughout 2020. We anticipate completing Module 3 (CMC) to finalize the BLA submission in December 2020.

On May 7, 2020, we received clinical Scientific Advice from the Committee for Medicinal Products for Human Use ("CHMP") of the European Medicines Agency ("EMA") stating that the Committee agreed that our nonclinical, clinical pharmacology and safety database are all sufficient to support a marketing authorization application ("MAA"). Furthermore, additional clinical trials were not requested by the CHMP in support of the MAA submission for Vicineum for the treatment of high-risk NMIBC. Based on the guidance received, we expect to submit the MAA for Vicineum for the treatment of high-risk NMIBC to the EMA in early 2021, with potential approval anticipated in early 2022.

On May 29, 2020, we received CMC Scientific Advice from the CHMP of the EMA, stating that the committee agreed that our comparability plan provides a strong analytical package, and no additional clinical trials to establish comparability are deemed necessary at this time. Furthermore, the CHMP agreed to accept the Good

Manufacturing Practice ("GMP") inspections conducted by the FDA and will therefore not conduct an independent inspection of the manufacturing facilities.

On June 17, 2020, we were informed that the FDA has conditionally accepted the proprietary brand name VICINEUM™ for our product candidate, oportuzumab monatox. The name VICINEUM was developed in compliance with the FDA's final Guidance for Industry, Contents of a Complete Submission for the Evaluation of Proprietary Names and the FDA's draft Guidance for Industry, Best Practices in Developing Proprietary Name for Drugs. We believe VICINEUM is a proprietary name with strong marketing potential that is also consistent with FDA's goal of preventing medication errors and potential harm to the public by ensuring that only appropriate proprietary names are approved for use. Final approval of the VICINEUM brand name is conditional on FDA approval of our product candidate, oportuzumab monatox. Based upon FDA feedback, we withdrew our previously submitted proposed brand name, VICINIUM®, from consideration due to potential for confusion with ammonium derivatives products with the "-ium" suffix as established by the United States Adopted Names Council.

On July 28, 2020, we received notice from the EMA that it has approved our request to review Vicineum under the EMA's centralized authorization procedure drug review process and on September 29, 2020, we received notice from the EMA that it has appointed the Rapporteur and Co-Rapporteur for our planned MAA. The Rapporteur and Co-Rapporteur are members of EMA's CHMP and will jointly coordinate CHMP's evaluation of our planned MAA for Vicineum.

On October 23, 2020, we completed a successful pre-submission meeting with the EMA which addressed product-specific, legal, regulatory and scientific topics related to Vicineum. The information and insights gained from the meeting will help to facilitate the validation of the MAA and support a smooth evaluation. The agency also provided guidance on various administrative topics which helps to clarify the regulatory path forward. The success of this meeting, in addition to the receipt of centralized procedure eligibility confirmation from the EMA, are significant milestones toward our regulatory path forward in Europe and reaffirms our intent to complete all necessary pre-submission activities with the EMA by the end of 2020 and submit the MAA in early 2021.

Manufacturing

In October 2018, we entered into a Master Bioprocessing Services Agreement with Fujifilm (the "Fujifilm MSA") for the manufacturing process and technology transfer of Vicineum drug substance production. In April 2019, the first full, commercial-scale current GMP ("cGMP") run was completed at Fujifilm and all quality acceptance criteria were met. This supports Fujifilm's ability to produce the bulk drug substance form of Vicineum for commercial purposes if we receive regulatory approval to market Vicineum for the treatment of high-risk NMIBC. In February 2020, manufacturing of the pre-process performance qualification ("pre-PPQ") cGMP batch was completed at Fujifilm. Full quality release testing of the drug substance has been completed and all quality acceptance criteria were met. On August 4, 2020, we completed manufacturing of the drug substance PPQ batches. In September, 2020, we successfully completed the final of three drug product PPQ batches. All of the completed drug substance PPQ batches and the first and second of three drug product PPQ batches met all quality acceptance criteria. We believe these results are a strong indicator for meeting the quality testing acceptance criteria for the third drug product PPQ batch. Testing of this batch is currently underway and is expected to be completed in November 2020.

Joint Development

In June 2017, we entered into a Cooperative Research and Development Agreement ("CRADA") with the National Cancer Institute ("NCI") for the development of Vicineum in combination with AstraZeneca's immune checkpoint inhibitor durvalumab for the treatment of NMIBC. Under the terms of the CRADA, the NCI will conduct a Phase 1 clinical trial in patients with high-risk NMIBC to evaluate the safety, efficacy and biological correlates of Vicineum in combination with durvalumab. This Phase 1 clinical trial is open and is actively recruiting patients.

Vicineum has also been evaluated for the treatment of squamous cell carcinoma of the head and neck ("SCCHN"). Vicineum for the treatment of SCCHN had previously been designated as ProxiniumTM to indicate its different fill volume and vial size as well as its different route for local administration via intratumoral injection. In addition to our locally-administered TFPTs, our pipeline also includes systemically-administered TFPTs that are built around our proprietary de-immunized variant of the plant-derived cytotoxin bouganin ("deBouganin"). One of these product candidates, VB6-845d, is a TFPT consisting of an EpCAM-targeting fragment antigen binding domain ("Fab") genetically linked to deBouganin, a novel plant derived cytotoxic payload that we have optimized for minimal immunogenic potential and is administered by intravenous infusion. We have deferred further development of Vicineum for the treatment of SCCHN and of VB6-845d in order to focus our efforts and our

resources on our ongoing development of Vicineum for the treatment of high-risk NMIBC. We are also exploring collaborations for Vicineum for the treatment of SCCHN and for VB6-845d.

We maintain global development, marketing and commercialization rights for all of our TFPT-based product candidates. We intend to explore various commercialization strategies to market our approved products. If we obtain regulatory approval for Vicineum for the treatment of high-risk NMIBC, we intend to build a specialty urology sales force to market the product in the United States. Outside the United States, we will seek commercialization partners with urology expertise. We also own or exclusively license worldwide intellectual property rights for all of our TFPT-based product candidates, covering our key patents with protection into 2036.

License Agreement with Roche

In June 2016, we entered into a License Agreement with F. Hoffman-La Roche Ltd. and Hoffman-La Roche Inc. (collectively, "Roche") (the "License Agreement with Roche"), pursuant to which we granted Roche an exclusive, worldwide license, including the right to sublicense, to our patent rights and know-how related to our monoclonal antibody EBI-031 and all other IL-6 anti-IL antagonist monoclonal antibody technology owned by us (collectively, the "Licensed Intellectual Property"). Under the License Agreement with Roche, Roche is required to continue developing, at its cost, EBI-031 and any other product made from the Licensed Intellectual Property that contains an IL-6 antagonist anti-IL monoclonal antibody ("Licensed Product") and pursue ongoing patent prosecution, at its cost. At the time of the License Agreement with Roche, EBI-031, which was derived using our previous AMP-Rx platform, was in pre-clinical development as an intravitreal injection for diabetic macular edema and uveitis.

Through September 30, 2020, we have received a total of \$30.0 million in payments pursuant to the License Agreement with Roche, including a \$7.5 million upfront payment in August 2016 and a \$22.5 million milestone payment in September 2016 as a result of the investigational new drug ("IND") application for EBI-031 becoming effective. We are also entitled to receive up to an additional \$240.0 million upon the achievement of other specified regulatory, development and commercial milestones, as well as royalty payments in accordance with a tiered royalty rate scale, with rates ranging from 7.5% to 15% of net sales of potential future products containing EBI-031 and up to 50% of these rates for net sales of potential future products containing other IL-6 compounds, with each of the royalties subject to reduction under certain circumstances and to the buy-out options of Roche.

License Agreement with Qilu

On July 30, 2020, we and our wholly-owned subsidiary, Viventia Bio, Inc., entered into an exclusive license agreement with Qilu Pharmaceuticals, Ltd. ("Qilu") ("License Agreement with Qilu") pursuant to which we granted Qilu an exclusive, sublicensable, royalty-bearing license, under certain intellectual property owned or exclusively licensed by us, to develop, manufacture and commercialize Vicineum for the treatment of NMIBC and other types of cancer in China, Hong Kong, Macau and Taiwan ("the Territory"). We also granted Qilu a non-exclusive, sublicensable, royalty-bearing sublicense, under certain other intellectual property licensed by us to develop, manufacture and commercialize VicineumTM in the Territory. We retained development, manufacturing and commercialization rights with respect to Vicineum in the rest of the world.

Through September 30, 2020, we have received a total of \$10 million in net proceeds associated with the \$12 upfront payment due pursuant to the License Agreement with Qilu. We are also entitled to receive up to an additional \$23 million upon the achievement of certain technology transfer, development and regulatory milestones, as well as a 12% royalty based upon annual net sales of Vicineum in the Territory. The royalties are payable upon the first commercial sale of Vicineum in a region and continuing until the latest of (i) twelve years after the first commercial sale of Vicineum in such region, (ii) the expiration of the last valid patent claim covering or claiming the composition of matter, method of treatment, or method of manufacture of such Vicineum in such region, and (iii) the expiration of regulatory or data exclusivity for such Vicineum in such region. The royalty rate is subject to reduction under certain circumstances, including when there is no valid claim of a licensed patent that covers Vicineum in a particular region or no data or regulatory exclusivity of Vicineum in a particular region.

Liquidity and Going Concern

As of September 30, 2020, we had cash and cash equivalents of \$42.0 million, net working capital (current assets less current liabilities) of \$39.3 million and an accumulated deficit of \$300.9 million. We incurred negative cash flows from operating activities of \$37.5 million for the year ended December 31, 2019 and \$22.3 million for the nine months ended September 30, 2020. Since our inception, we have received no revenue from sales of our products, and we anticipate that operating losses will continue for the foreseeable future as we continue our ongoing Phase 3 VISTA Trial of Vicineum for the treatment of high-risk NMIBC and seek marketing approval from the FDA and EMA. We have financed our operations to date primarily through private placements of our common stock, preferred stock, common stock warrants and convertible bridge notes, venture debt borrowings, our

initial public offering ("IPO"), follow-on public offerings, sales effected in "at-the-market" ("ATM") offerings, our License Agreement with Roche, our License Agreement with Qilu and, to a lesser extent, from a collaboration.

Under Accounting Standards Codification Topic 205-40, *Presentation of Financial Statements - Going Concern*, we are required at each reporting period to evaluate whether there are conditions and 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. This evaluation initially does not take into consideration the potential mitigating effect of our plans that have not been fully implemented as of the date the financial statements are issued. When substantial doubt exists, we evaluate whether the mitigating effect of our plans sufficiently alleviates the substantial doubt about our ability to continue as a going concern. The mitigating effect of our plans, however, is only considered if both (i) it is probable that our plans will be effectively implemented within one year after the date that our financial statements are issued and (ii) it is probable that our plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about our ability to continue as a going concern within one year after the date that our financial statements are issued. Generally, to be considered probable of being effectively implemented, our plans must have been approved by our board of directors before the date that our financial statements are issued.

Our future success is dependent on our ability to develop our product candidates, including Vicineum for the treatment of high-risk NMIBC, and ultimately upon our ability to attain profitable operations. In order to commercialize our product candidates, including Vicineum for the treatment of high-risk NMIBC, we need to complete clinical development and comply with comprehensive regulatory requirements. We are subject to a number of risks similar to other late-stage clinical companies, including, but not limited to, successful discovery and development of our product candidates, raising additional capital, development and commercialization by our competitors of new technological innovations, protection of proprietary technology and market acceptance of our products. The successful discovery and development of product candidates, including Vicineum for the treatment of high-risk NMIBC. requires substantial working capital, and we expect to seek additional funds through equity or debt financings or through additional collaboration, licensing transactions or other sources. We may be unable to obtain equity or debt financings or enter into additional collaboration or licensing transactions at favorable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of existing stockholders. Debt financing, if available, may involve agreements that include liens or other restrictive covenants limiting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through government or other third-party funding, strategic collaborations and alliances or licensing arrangements, we may have to relinquish valuable rights to our technologies. future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable. If we are unable to raise additional funds when needed, we may be required to implement cost reduction strategies and delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market.

We continue to monitor the effect of the outbreak of a novel strain of coronavirus ("COVID-19"). This virus continues to spread globally, has been declared a pandemic by the World Health Organization and has spread to over 200 countries and territories, including the United States disproportionately. The impact of this pandemic has been and will likely continue to be extensive in many aspects of society, which has resulted in and will likely continue to result in significant disruptions to businesses and capital markets around the world. We are proactively executing risk mitigation strategies to attenuate the impact of COVID-19 on us, and at this time, we have not yet experienced any business disruptions as a result of the pandemic. We are continually assessing the effect of the COVID-19 pandemic on our operations and we are monitoring the spread of COVID-19 and the actions implemented to combat the virus throughout the world.

We do not believe that our cash and cash equivalents of \$42.0 million as of September 30, 2020 is sufficient to fund our current operating plan for at least twelve months after the issuance of our condensed consolidated financial statements. Based on our current operating plan, we anticipate having sufficient cash and cash equivalents to fund our operations into the second quarter of 2021; however, we have based this estimate on assumptions that may prove to be wrong, and our capital resources may be utilized faster than we currently expect. Given our history of significant losses, negative cash flows from operations, limited cash resources currently on hand, the ongoing COVID-19 pandemic and dependence on our ability - about which there can be no certainty - to obtain additional financing to fund our operations after the current cash resources are exhausted, substantial doubt exists about our ability to continue as a going concern. The condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q were prepared under the assumption that we will continue as a going concern and

do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

Components of Our Results of Operations

License Revenue

License revenue consists of revenue recognized pursuant to our License Agreement with Qilu and for which is assessed under ASC 606. In the future, we may generate revenue from a combination of reimbursements, up-front payments, milestone payments and royalties in connection with the License Agreement with Qilu.

Research and Development

Research and development expenses consist primarily of costs incurred for the development of Vicineum for the treatment of high-risk NMIBC, which include:

- employee-related expenses, including salaries, benefits, travel and share-based compensation expense;
- · expenses incurred under agreements with contract research organizations ("CROs") and investigative sites that conduct our clinical trials;
- expenses associated with developing manufacturing capabilities;
- expenses associated with transferring manufacturing capabilities to contract manufacturing organizations ("CMOs") for commercial-scale production;
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies; and
- expenses associated with regulatory activities.

We expense research and development costs as incurred. We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and our clinical sites.

The successful development and commercialization of Vicineum for the treatment of high-risk NMIBC is highly uncertain. This is due to the numerous risks and uncertainties associated with product development and commercialization, including the uncertainty of:

- the scope, progress, outcome and costs of our clinical trials and other research and development activities;
- the efficacy and potential advantages of Vicineum for the treatment of high-risk NMIBC compared to alternative treatments, including any standard of care:
- the market acceptance of Vicineum for the treatment of high-risk NMIBC;
- the cost and timing of the implementation of commercial-scale manufacturing of Vicineum;
- · obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- significant and changing government regulation;
- the impact of the COVID-19 pandemic; and
- the timing, receipt and terms of any marketing approvals.

A change in the outcome of any of these variables with respect to the development of Vicineum for the treatment of high-risk NMIBC could mean a significant change in the costs and timing associated with the development of Vicineum for the treatment of high-risk NMIBC. For example, if the FDA, EMA or another regulatory authority were to require us to conduct clinical trials or other testing beyond those that we currently contemplate will be required for the completion of clinical development of Vicineum for the treatment of high-risk NMIBC, we could be required to expend significant additional financial resources and time on the completion of clinical development of Vicineum for the treatment of high-risk NMIBC.

We allocate direct research and development expenses, consisting principally of external costs, such as fees paid to investigators, consultants, central laboratories and CROs in connection with our clinical trials, and costs related to manufacturing or purchasing clinical trial materials and technology transfer, to specific product programs. We do not allocate employee and contractor-related costs, costs associated with our platform and facility expenses, including depreciation or other indirect costs, to specific product programs because these costs may be deployed across multiple product programs under research and development and, as such, are separately classified. The table below provides research and development expenses incurred for Vicineum for the treatment of high-risk NMIBC and other expenses by category. We have deferred further development of Vicineum for the treatment of SCCHN and VB6-845d in order to focus our efforts and our resources on our ongoing development of Vicineum for the treatment of high-risk NMIBC.

We did not allocate research and development expenses to any other specific product program during the periods presented (in thousands):

	Three Months ended September 30,					nths ended aber 30,	
		2020	2019		2020		2019
Programs:					_		
Vicineum for the treatment of high-risk NMIBC	\$	8,506	\$	4,248 \$	19,005	\$	12,620
Total direct program expenses		8,506		4,248	19,005		12,620
Personnel and other expenses:							
Employee and contractor-related expenses		1,314		1,916	3,688		4,973
Platform-related lab expenses		184		51	264		464
Facility expenses		109		94	322		319
Other expenses		83		304	346		867
Total personnel and other expenses		1,690		2,365	4,620		6,623
Total Research and Development	\$	10,196	\$	6,613 \$	23,625	\$	19,243

General and Administrative

General and administrative expenses consist primarily of salaries and related costs for personnel, including share-based compensation, in executive, operational, finance, business development and human resource functions. Other general and administrative expenses include facility-related costs, professional fees for legal, insurance, patent, consulting and accounting services, commercial market research and United States pre-launch market readiness.

Change in Fair Value of Contingent Consideration

In connection with the acquisition of Viventia Bio, Inc. ("Viventia") in September 2016, we recorded contingent consideration pertaining to the amounts potentially payable to the former shareholders of Viventia pursuant to the terms of the Share Purchase Agreement among us, Viventia and the other signatories thereto (the "Share Purchase Agreement") and are based on regulatory approval in certain markets and future revenue levels. The fair value of contingent consideration is assessed at each balance sheet date and changes, if any, to the fair value are recognized in earnings (or loss) for the period.

Other Income (Expense), Net

Other income (expense), net consists primarily of interest income earned on cash and cash equivalents and, to a lessor extent, any gains or losses on foreign exchange.

Provision for Income Taxes

Provision for income taxes consists of income taxes paid to foreign jurisdictions pursuant to our License Agreement with Qilu.

Our Results of Operations

Comparison of the Three Months ended September 30, 2020 and 2019

	Three Months ended September 30,					Increase/(Decrease)			
		2020		2019		Dollars	Percentage		
License revenue	\$	11,236	\$	_	\$	11,236	_		
Operating expenses:									
Research and development	\$	10,196	\$	6,613	\$	3,583	54 %		
General and administrative		4,115		3,238		877	27 %		
Change in fair value of contingent consideration		18,400		3,600		14,800	411 %		
Total operating expenses		32,711		13,451		19,260	143 %		
Loss from operations		(21,475)		(13,451)		(8,024)	60 %		
Other income (expense), net:									
Other income (expense), net		(1)		319		(320)	(100) %		
Net Loss and Comprehensive Loss Before Taxes	\$	(21,476)	\$	(13,132)	\$	(8,344)	64 %		
Provision for income taxes	\$	(1,132)	\$	_	\$	(1,132)	_		
Net Loss and Comprehensive Loss After Taxes	\$	(22,608)	\$	(13,132)	\$	(9,476)	72 %		
	_								

Revenue

Revenue for the three months ended September 30, 2020 was \$11.2 million, which was due to the recognition of revenue pursuant to the License Agreement with Qilu. The Company did not record any revenue for the three months ended September 30, 2019.

Research and Development

Research and development expenses were \$10.2 million for the three months ended September 30, 2020 compared to \$6.6 million for the three months ended September 30, 2019. The increase of \$3.6 million was due primarily to increased costs associated with technology transfer and manufacturing scale-up for commercial supply and timing of procurement of manufacturing consumables, offset by lower clinical trial expenses as a result of our Phase 3 VISTA Trial winding down and lower regulatory consulting fees.

General and Administrative

General and administrative expenses were \$4.1 million for the three months ended September 30, 2020 compared to \$3.2 million for the three months ended September 30, 2019. The increase of \$0.9 million was due primarily to increases in investment banking and legal fees related to our License Agreement with Qilu.

Change in Fair Value of Contingent Consideration

The non-cash change in fair value of contingent consideration was an \$18.4 million loss for the three months ended September 30, 2020 compared to a \$3.6 million loss for the three months ended September 30, 2019. The increase in the fair value of contingent consideration of \$18.4 million for the three months ended September 30, 2020 was attributable primarily to lower discount rates, based on prevailing market conditions as of September 30, 2020, and to a lessor extent by refinement of timelines in certain OUS markets. The estimated fair value of contingent consideration is determined by applying appropriate discount rates to future cash outflows related to the contingent payment obligations, and these discount rates continue to remain volatile as global economies shut down in order to contain the spread of COVID-19. The milestone payments constitute debt-like obligations, and the high-yield debt index rate applied to the milestones in order to determine the estimated fair value fluctuated from 11.8% as of December 31, 2019, to 17.9% of March 31, 2020, to 14.5% as of June 30, 2020 and to 11.8% as of September 30, 2020. The discount rate applied to the 2% royalty due on forecasted Vicineum revenues is derived from our estimated weighted-average cost of capital ("WACC"), and this WACC-derived discount rate fluctuated from 5.6% as of December 31, 2019, 14.7% as of March 31, 2020, 13.2% as of June 30, 2020 and 9.4% as of September 30, 2020.

The change in the fair value of contingent consideration was a \$3.6 million loss for the three months ended September 30, 2019 and was primarily attributable to a slightly lower discount rate, based on prevailing market conditions as of September 30,

2019, applicable to the earnout royalty payments potentially payable to Viventia's shareholders under the Share Purchase Agreement.

Changes in forecast assumptions, including the probability of regulatory approvals and Vicineum pricing and sales volumes, as well as changes in the discount rates utilized based on prevailing market conditions, could result in materially different fair value estimates.

Other Income (Expense), Net

Other income (expense), net was de minimus for the three months ended September 30, 2020 compared to \$0.3 million of income for the three months ended September 30, 2019. The change of \$0.3 million was due primarily to lower interest income earned on cash balances.

Provision for Income Taxes

Provision for income taxes was \$1.1 million of expense for the three months ended September 30, 2020 compared to no provision for income taxes for the three months ended September 30, 2019. The increase of \$1.1 million was due to income taxes paid to a foreign jurisdiction pursuant to our License Agreement with Qilu.

Comparison of the Nine Months ended September 30, 2020 and 2019

	Nine Months ended September 30,				Increase/(Decrease)		
	 2020		2019		Dollars	Percentage	
License revenue	\$ 11,236	\$	_	\$	11,236	— %	
Operating expenses:							
Research and development	\$ 23,625	\$	19,243	\$	4,382	23 %	
General and administrative	10,882		8,910		1,972	22 %	
Change in fair value of contingent consideration	(16,820)		46,600		(63,420)	(136) %	
Total operating expenses	17,687		74,753		(57,066)	(76) %	
Loss from operations	 (6,451)		(74,753)		68,302	(91) %	
Other income (expense), net:							
Other income (expense), net	195		806		(611)	(76) %	
Net Loss and Comprehensive Loss	\$ (6,256)	\$	(73,947)	\$	67,691	(92) %	
Provision for income taxes	\$ (1,132)	\$			(1,132)	— %	
Net Loss and Comprehensive Loss	\$ (7,388)	\$	(73,947)	\$	66,559	(90)%	

Revenue

Revenue for the nine months ended September 30, 2020 was \$11.2 million, which was due to the recognition of revenue pursuant to the License Agreement with Qilu. The Company did not record any revenue for the nine months ended September 30, 2019.

Research and Development

Research and development expenses were \$23.6 million for the nine months ended September 30, 2020 compared to \$19.2 million for the nine months ended September 30, 2019. The increase of \$4.4 million was due primarily to increased costs associated with technology transfer and manufacturing scale-up for commercial supply, timing of procurement of manufacturing consumables and professional fees in support of regulatory activities, partially offset by lower employee compensation and lower clinical trial expenses as a result of our Phase 3 VISTA Trial winding down.

General and Administrative

General and administrative expenses were \$10.9 million for the nine months ended September 30, 2020 compared to \$8.9 million for the nine months ended September 30, 2019. The increase of \$2.0 million was due primarily to increases in employee compensation, legal, insurance and investment banking fees, which were partially offset by reduced market research.

Change in Fair Value of Contingent Consideration

The non-cash change in fair value of contingent consideration was income of \$16.8 million for the nine months ended September 30, 2020 compared to a \$46.6 million loss for the nine months ended September 30, 2019. The decrease in the fair value of contingent consideration of \$16.8 million for the nine months ended September 30, 2020 was attributable primarily to significantly higher discount rates as a result of financial market conditions as of September 30, 2020, offset by changes to the current competitive landscape. The estimated fair value of contingent consideration is determined by applying appropriate discount rates to future cash outflows related to the contingent payment obligations, and these discount rates have increased significantly as a result of the extreme volatility of financial markets as global economies shut down in order to contain the spread of COVID-19. The milestone payments constitute debt-like obligations, and the high-yield debt index rate applied to the milestones in order to determine the estimated fair value remained unchanged at 11.8% as of both December 31, 2019 and September 30, 2020. However, the discount rate applied to the 2% royalty due on forecasted Vicineum revenues is derived from our estimated WACC, and this WACC-derived discount rate increased from 5.6% as of December 31, 2019 to 9.4% as of September 30, 2020.

The change in fair value of contingent consideration was \$46.6 million for the nine months ended September 30, 2019. During the quarter ended June 30, 2019, we reassessed the total addressable global market for NMIBC and determined that both the global market size and estimated potential Vicineum commercial net sales within the global NMIBC market were likely higher than the Company's previous estimates. Specific drivers of the increased revenue estimates include the expectation that Vicineum could achieve peak market penetration earlier than previously estimated and the expectation that Vicineum sales outside the United States could be two to three times the expected sales volumes in the United States. As contingent consideration incorporates a royalty rate of 2% on all commercial net sales reported through December 2033, an increase in expected future net sales correlates to an increase in the fair value of our potential contingent consideration. Accordingly, our contingent consideration at September 30, 2019 was adjusted to reflect our updated view of the NMIBC market and the potential sales volumes of Vicineum in that market. The change in the nine months ended September 30, 2019 was therefore due to changes in assumptions related to forecasted Vicineum pricing and sales volumes in the U.S. and outside the U.S. ("OUS") compared to prior assumptions utilized as of December 31, 2018.

Changes in forecast assumptions, including the probability of regulatory approvals and Vicineum pricing and sales volumes, as well as changes in the discount rates utilized based on prevailing market conditions, could result in materially different fair value estimates.

Other Income (Expense), Net

Other income (expense), net was \$0.2 million of income for the nine months ended September 30, 2020 compared to \$0.8 million of income for the nine months ended September 30, 2019. The overall decrease of \$0.6 million was due primarily to lower interest income earned on cash balances.

Provision for Income Taxes

Provision for income taxes was \$1.1 million of expense for the nine months ended September 30, 2020 compared to no provision for income taxes for the nine months ended September 30, 2019. The increase of \$1.1 million was due to income taxes paid to a foreign jurisdiction pursuant to our License Agreement with Qilu.

Liquidity and Capital Resources

Overview

As of September 30, 2020, we had cash and cash equivalents of \$42.0 million, net working capital of \$39.3 million and an accumulated deficit of \$300.9 million. We incurred negative cash flows from operating activities of \$37.5 million for the year ended December 31, 2019 and \$22.3 million for the nine months ended September 30, 2020. Since our inception, we have received no revenue from sales of our products, and we anticipate that operating losses will continue for the foreseeable future as we continue our ongoing Phase 3 VISTA Trial of Vicineum for the treatment of high-risk NMIBC and seek marketing approval from the FDA and the EMA. We have financed our operations to date primarily through private placements of our common stock, preferred stock, common stock warrants and convertible bridge notes, venture debt borrowings, our IPO, follow-on public offerings, sales effected in ATM offerings, our License Agreement with Roche, our License Agreement with Qilu and, to a lesser extent, from a collaboration.

In November 2019, we entered into an Open Market Sale Agreement SM (the "Sale Agreement") with Jefferies LLC ("Jefferies"), under which we may issue and sell shares of our common stock from time to time for an aggregate sales price of up to \$35.0 million through Jefferies (the "ATM Offering"). Sales of common stock under the Sale Agreement are made by any method that is deemed to be an ATM offering as defined in Rule 415(a)(4) of the Securities Act of 1933, as amended, including but not limited to sales made directly on or through the Nasdaq Global Market or any other existing trading market for our

common stock. We have no obligation to sell any of our common stock and may at any time suspend offers under the Sale Agreement or terminate the Sale Agreement. Subject to the terms and conditions of the Sale Agreement, Jefferies will use its commercially reasonable efforts to sell common stock from time to time, as the sales agent, based upon our instructions, which include a prohibition on sales below a minimum price set by us from time to time. We have provided Jefferies with customary indemnification rights, and Jefferies is entitled to a commission at a fixed rate equal to 3.0% of the gross proceeds for each sale of common stock under the Sale Agreement. We incurred \$0.2 million in legal, accounting and printing costs related to the commencement of the ATM Offering. For the nine months ended September 30, 2020, we raised \$16.2 million of net proceeds from the sale of 16.8 million shares of common stock at a weighted-average price of \$0.99 per share under the ATM Offering, including \$8.2 million of net proceeds from the sale of 7.0 million shares of common stock at a weighted-average price of \$1.21 per share during the three months ended September 30, 2020. Share issue costs, including sales agent commissions, related to the ATM Offering totaled \$0.3 million and \$0.5 million during the three and nine months ended September 30, 2020, respectively.

On October 30, 2020, we entered into an amendment to the Sale Agreement pursuant to which we may issue and sell an additional \$50.0 million of shares of our common stock through Jefferies.

We continue to monitor the effect of the outbreak of COVID-19. This virus continues to spread globally, has been declared a pandemic by the World Health Organization and has spread to over 200 countries and territories, including the United States disproportionately. The impact of this pandemic has been and will likely continue to be extensive in many aspects of society, which has resulted in and will likely continue to result in significant disruptions to businesses and capital markets around the world. We are proactively executing risk mitigation strategies to attenuate the impact of COVID-19 on us, and at this time, we have not yet experienced any business disruptions as a result of the pandemic. We are continually assessing the effect of the COVID-19 pandemic on our operations and we are monitoring the spread of COVID-19 and the actions implemented to combat the virus throughout the world.

We do not believe that our cash and cash equivalents of \$42.0 million as of September 30, 2020 is sufficient to fund our current operating plan for at least twelve months after the issuance of our condensed consolidated financial statements. Based on our current operating plan, we anticipate having sufficient cash and cash equivalents to fund our operations into the second quarter of 2021; however, we have based this estimate on assumptions that may prove to be wrong, and our capital resources may be utilized faster than we currently expect. Given our history of significant losses, negative cash flows from operations, limited cash resources currently on hand, the impact of the ongoing COVID-19 pandemic on the capital markets and dependence on our ability - about which there can be no certainty - to obtain additional financing to fund our operations after the current cash resources are exhausted, substantial doubt exists about our ability to continue as a going concern. The condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q were prepared under the assumption that we will continue as a going concern and do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

Nasdaq Notice

On March 2, 2020, we received written notice (the "Notice") from The Nasdaq Stock Market, LLC ("Nasdaq") indicating that we are not in compliance with the \$1.00 minimum bid price requirement for continued listing on The Nasdaq Global Market, as set forth in Nasdaq Listing Rule 5450(a)(1).

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we had a period of 180 calendar days, or until August 31, 2020, to regain compliance with the minimum bid price requirement. To regain compliance, the closing bid price of our common stock must meet or exceed \$1.00 per share for a minimum of ten consecutive business days during this 180-day period.

On April 17, 2020, we received written notice from Nasdaq that the 180-day grace period to regain compliance with the \$1.00 minimum bid price requirement had been extended in response to the COVID-19 pandemic and related extraordinary market conditions.

On August 21, 2020, we received notice from Nasdaq confirming that for the last 10 consecutive business days, the closing bid price of our common stock has been equal to or in excess of the \$1.00 per share minimum bid price requirement for continued listing, as set forth in Nasdaq Listing Rule 5450(a)(1). Accordingly, Nasdaq has determined that we had regained compliance with Nasdaq Listing Rule 5450(a)(1) and indicated to us that this matter is now closed.

Funding Requirements

Our future success is dependent on our ability to develop our product candidates, including Vicineum for the treatment of high-risk NMIBC, and ultimately upon our ability to attain profitable operations. In order to commercialize our product candidates, including Vicineum for the treatment of high-risk NMIBC, we need to complete clinical development and comply with

comprehensive regulatory requirements. We are subject to a number of risks similar to other late-stage clinical companies, including, but not limited to, successful discovery and development of our product candidates, raising additional capital, development and commercialization by our competitors of new technological innovations, protection of proprietary technology and market acceptance of our products. The successful discovery and development of product candidates, including Vicineum for the treatment of high-risk NMIBC, requires substantial working capital, and we expect to seek additional funds through equity or debt financings or through additional collaboration, licensing transactions or other sources. We may be unable to obtain equity or debt financings or enter into additional collaboration or licensing transactions at favorable terms, or at all, and, if necessary, we may be required to implement cost reduction strategies.

We will incur substantial expenses if and as we:

- continue our Phase 3 VISTA Trial for Vicineum for the treatment of high-risk NMIBC;
- seek marketing approvals for Vicineum for the treatment of high-risk NMIBC;
- establish sales, marketing and distribution capabilities and scale up and validate external manufacturing capabilities (including completing the
 manufacturing process and technology transfer to any third-party manufacturers) to commercialize Vicineum for the treatment of high-risk
 NMIBC, if approved;
- maintain, expand and protect our intellectual property portfolio;
- add equipment and physical infrastructure to support our research and development;
- hire additional clinical, regulatory, quality control, scientific and management personnel;
- expand our operational, financial and management systems and personnel;
- · conduct research and pre-clinical and clinical development of Vicineum for the treatment of high-risk NMIBC and our other product candidates;
- seek to discover and develop additional product candidates; and
- in-license or acquire the rights to other products, product candidates or technologies.

Our future capital requirements will depend on many factors, including:

- the scope, initiation, progress, timing, costs and results of pre-clinical development and laboratory testing and clinical trials for Vicineum for the treatment of high-risk NMIBC and our other product candidates;
- the cost and timing of any new clinical trials or studies of Vicineum for the treatment of high-risk NMIBC;
- · the ongoing COVID-19 pandemic and its impact on our business;
- our ability to establish collaborations or licensing arrangements on favorable terms, if at all, particularly manufacturing, marketing and distribution arrangements for our product candidates;
- the costs and timing of the implementation of commercial-scale manufacturing activities, including those associated with the manufacturing process and technology transfer to third-party manufacturers to facilitate such commercial-scale manufacturing of Vicineum;
- the costs and timing of establishing sales, marketing and distribution capabilities for Vicineum for the treatment of high-risk NMIBC, if approved;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- · our obligation to make milestone, royalty and other payments to third-party licensors under our licensing agreements;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies;
- the outcome, timing and cost of regulatory review by the FDA, EMA and comparable foreign regulatory authorities for Vicineum for the treatment of high-risk NMIBC, including the potential for the FDA, EMA or comparable foreign regulatory authorities to require that we perform more studies than those that we currently expect to perform;
- our ability to achieve certain future regulatory, development and commercialization milestones under the License Agreement with Roche and our License Agreement with Qilu;
- the effect of competing technological and market developments; and
- · the revenue, if any, received from commercial sales of Vicineum for the treatment of high-risk NMIBC, if approved.

Until such time, if ever, as we can generate substantial product revenues from commercial sales, we expect to finance our cash needs through a combination of equity offerings, debt financings, government or other third-party funding, strategic collaborations and alliances, and licensing arrangements. We do not have any committed external source of funds other than the amounts payable under the License Agreement with Roche and the License Agreement with Qilu. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of existing stockholders. Debt financing, if available, may involve agreements that include liens or other restrictive covenants limiting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through government or other third-party funding, strategic collaborations and alliances or licensing arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional

funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

The COVID-19 pandemic has negatively impacted the global economy, disrupted business operations and created significant volatility and disruption to financial markets. Significant uncertainty remains as to the potential impact of the COVID-19 pandemic on our operations, and on the global economy as a whole. The extent and duration of the pandemic could continue to disrupt global markets and may affect our ability to raise additional capital in the future.

Cash Flows

The following table sets forth a summary of our cash flows for the nine months ended September 30, 2020 and 2019 (in thousands):

	Nine	Nine Months ended September 30,		
		2020		2019
Net Cash Used in Operating Activities	\$	(22,328)	\$	(23,716)
Net Cash Used in Investing Activities		(8)		(137)
Net Cash Provided by Financing Activities		16,184		31,296
Net Increase (Decrease) in Cash, Cash Equivalents and Restricted Cash	\$	(6,152)	\$	7,443

Net Cash Used in Operating Activities

Net cash used in operating activities was \$22.3 million for the nine months ended September 30, 2020 and consisted primarily of a net loss of \$7.4 million, which includes \$11.2 million of revenue recognized pursuant to the License Agreement with Qilu, adjusted for non-cash items, including share-based compensation of \$1.4 million, a decrease in the fair value of contingent consideration of \$16.8 million and a net increase in operating assets and liabilities of \$0.4 million.

Net cash used in operating activities was \$23.7 million for the nine months ended September 30, 2019 and consisted primarily of a net loss of \$73.9 million, adjusted for non-cash items, including share-based compensation of \$0.9 million, an increase in the fair value of contingent consideration of \$46.6 million and a net increase in operating assets and liabilities of \$2.6 million.

Net Cash Used in Investing Activities

Net cash (used in) provided by investing activities consisted of purchases of equipment during each of the nine months ended September 30, 2020 and 2019

Net Cash Provided by Financing Activities

Net cash provided by financing activities was \$16.2 million for the nine months ended September 30, 2020 and consisted of net proceeds from the sale of common stock under the ATM Offering and sales of common stock under our 2014 ESPP. Net cash provided by financing activities for the nine months ended September 30, 2019 consisted of (i) \$27.8 million in net proceeds on the sale of 20.4 million shares of common stock and accompanying warrants to purchase an additional 20.4 million shares of common stock in an underwritten public offering in June 2019 and (ii) \$3.4 million in proceeds from the exercise of 3.4 million of warrants to purchase our common stock.

Critical Accounting Policies and Use of Estimates

The preparation of our consolidated financial statements in accordance with United States generally accepted accounting principles and the rules and regulations of the SEC require the use of estimates and assumptions, based on complex judgments considered reasonable, and affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting period. Our critical accounting policies are those policies which require the most significant judgments and estimates in the preparation of our consolidated financial statements. Management has determined that our most critical accounting policies are those relating to the fair value of intangible assets, goodwill and contingent consideration; income taxes (including the valuation allowance for deferred tax assets); research and development costs; revenue recognition and going concern considerations.

Indefinite-Lived Intangible Assets

Our intangible assets consist of indefinite-lived, acquired in-process research and development ("IPR&D") worldwide product rights to Vicineum as a result of the acquisition of Viventia in 2016. IPR&D assets acquired in a business combination are

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considered indefinite-lived until the completion or abandonment of the associated research and development efforts. Amortization over the estimated useful life will commence at the time of Vicineum's launch in the respective markets, if approved. If regulatory approval to market Vicineum for the treatment of high-risk NMIBC is not obtained, we will immediately expense the related capitalized cost.

Indefinite-lived intangible assets are quantitatively tested for impairment at least annually during the fourth quarter of the fiscal year, or more often if indicators of impairment are present. Impairment testing of indefinite-lived intangible assets requires management to estimate the future discounted cash flows of an asset using assumptions believed to be reasonable, but which are unpredictable and inherently uncertain. Actual future cash flows may differ from the estimates used in impairment testing. We recognize an impairment loss when and to the extent that the estimated fair value of an intangible asset is less than its carrying value. In addition, on a quarterly basis, we perform a qualitative review of our business operations to determine whether events or changes in circumstances have occurred which could indicate that the carrying value of our intangible assets was not recoverable. If an impairment indicator is identified, an interim impairment assessment is performed. Based on the annual testing and quarterly reviews performed, we concluded that the carrying value of our intangible assets was not impaired as of September 30, 2020 and December 31, 2019.

Goodwill

Goodwill on our consolidated balance sheet is the result of our acquisition of Viventia in September 2016 and represents the difference between the purchase price and the fair value of the identifiable tangible and intangible net assets acquired under the acquisition method of accounting. Goodwill is not amortized; rather than recording periodic amortization, goodwill is quantitatively tested for impairment at least annually during the fourth quarter of the fiscal year, or more often if indicators of impairment are present. Impairment testing of goodwill requires management to estimate the future discounted cash flows of a reporting unit using assumptions believed to be reasonable, but which are unpredictable and inherently uncertain. Actual future cash flows may differ from the estimates used in impairment testing. If the fair value of the equity of a reporting unit exceeds the reporting unit's carrying value, including goodwill, then goodwill is considered not to be impaired. We recognize a goodwill impairment when and to the extent that the fair value of the equity of a reporting unit is less than the reporting unit's carrying value, including goodwill. We have only one reporting unit. In addition, on a quarterly basis, we perform a qualitative review of our business operations to determine whether events or changes in circumstances have occurred which could have a material adverse effect on the estimated fair value of each reporting unit and thus indicate a potential impairment of the goodwill carrying value. If an impairment indicator is identified, an interim impairment assessment is performed. Based on the annual testing and quarterly reviews performed, we concluded that there was no goodwill impairment as of September 30, 2020 and December 31, 2019.

Contingent Consideration

Contingent consideration on our consolidated balance sheet is the result of our acquisition of Viventia in September 2016 and represents the discounted present value of future launch milestones and net sales royalties due to the former shareholders of Viventia pursuant to the Share Purchase Agreement. For additional information, see "Item 1. Financial Statements - Notes to Condensed Consolidated Financial Statements - Note 1. Description of Business" of this Quarterly Report on Form 10-Q. Contingent consideration is measured at its estimated fair value on a recurring basis at each reporting period, with fluctuations in value resulting in a non-cash charge to earnings (or loss) during the period. The estimated fair value measurement is based on significant unobservable inputs (Level 3 within the fair value hierarchy), including internally developed financial forecasts, probabilities of success and timing of certain milestone events and achievements, which are unpredictable and inherently uncertain. Actual future cash flows may differ from the assumptions used to estimate the fair value of contingent consideration. The valuation of contingent consideration requires the use of significant assumptions and judgments, which management believes are consistent with those that would be made by a market participant. Management reviews its assumptions and judgments on an ongoing basis as additional market and other data is obtained, and any future changes in the assumptions and judgments utilized by management may cause the estimated fair value of contingent consideration to fluctuate materially, resulting in earnings volatility.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and net operating loss ("NOL") and research and development credit ("R&D credit") carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. A valuation allowance is recorded to the extent it is more likely than not that some portion or all of the deferred tax assets will not be realized.

Unrecognized income tax benefits represent income tax positions taken on income tax returns that have not been recognized in the financial statements. We recognize the benefit of an income tax position only if it is more likely than not (greater than 50%) that the tax position will be sustained upon tax examination, based solely on the technical merits of the tax position. Otherwise, no benefit is recognized. The tax benefits recognized are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. We recognize accrued interest and penalties related to uncertain tax positions as income tax expense in our consolidated statements of operations. As of September 30, 2020 and December 31, 2019, we did not have any uncertain tax positions.

Revenue

The Company records revenue from its License Agreement with Roche and its License Agreement with Qilu. Under both agreements, the Company granted the counterparty an exclusive license to develop and commercialize the underlying licensed product. Both agreements contain up-front license fees, development and regulatory milestone payments, and sales-based royalty payments.

We determine whether our license agreements are in scope of ASC 606, which we adopted as of January 1, 2018. Under ASC 606, in determining the appropriate amount of revenue to be recognized as it fulfills its obligations under its license agreements, we perform the following steps:

- 1) Identification of the contract;
- 2) Determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract;
- 3) Measurement of the transaction price, including the constraint on variable consideration;
- 4) Allocation of the transaction price to the performance obligations;
- 5) Recognition of revenue when or as the Company satisfies each performance obligation.

Development and Regulatory Milestones and Other Payments

At the inception of an arrangement that includes development milestone payments, we evaluate whether the development milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated development milestone value is included in the transaction price. Development milestone payments that are not within our control or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The milestones are allocated entirely to the license performance obligation, as (1) the terms of milestone and royalty payments relate specifically to the license and (2) allocating milestones and royalties to the license performance obligation is consistent with the overall allocation objective, because management's estimate of milestones and royalties approximates the standalone selling price of the license. Other payments, such as amounts associated with withheld VAT, will also be included in the transaction price using the most likely method once recoverability is reasonably assured.

Research and Development Costs

Research and development activities are expensed in the period incurred. Research and development expenses consist of both internal and external costs associated with all basic research activities, clinical development activities and technical efforts required to develop a product candidate. Internal research and development consist primarily of personnel costs, including salaries, benefits and share-based compensation, facilities leases, research-related overhead, pre-approval regulatory and clinical trial costs, manufacturing and other contracted services, license fees and other external costs.

In certain circumstances, we are required to make advance payments to vendors for goods or services that will be received in the future for use in research and development activities. In such circumstances, the advance payments are recorded as prepaid assets and expensed when the activity has been performed or when the goods have been received.

Recently Issued Accounting Standards

Recently issued accounting standards are discussed in "Item 1. Financial Statements - Notes to Condensed Consolidated Financial Statements - Note 4. Recent Accounting Pronouncements" of this Quarterly Report on Form 10-Q.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

The information under this item is not required to be provided by smaller reporting companies.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures, as defined in Exchange Act Rules 13a-15(e) and 15d-15(e), that are designed to ensure information required to be disclosed by us in reports 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 principal executive officer and principle financial officer, to allow timely decisions regarding required disclosure.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as the end of the period covered by this Quarterly Report on Form 10-Q. Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2020.

Limitations on Effectiveness of Controls and Procedures

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are achieved. Further, the design of a control system must be balanced against resource constraints, and therefore, the benefits of controls must be considered relative to their costs. Given the inherent limitations in all systems of controls, no evaluation of controls can provide absolute assurance all control issues and instances of fraud, if any, within a company have been detected. These inherent limitations include the realities that judgments in decision making can be faulty and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions or the degree of compliance with the policies and procedures may deteriorate. Accordingly, given the inherent limitations in a cost-effective system of controls, financial statement misstatements due to error or fraud may occur and may not be detected. Our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance of achieving their objectives. We conduct periodic evaluations of our system of controls to enhance, where necessary, our control policies and procedures.

Changes in Internal Control Over Financial Reporting

During the nine months ended September 30, 2020, there were no changes in our internal control over financial reporting, as defined in Exchange Act Rules 13a-15(f) and 15d-15(f), which 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.

Item 1A. Risk Factors.

During the nine months ended September 30, 2020, other than as set forth below, there were no material changes to the "Risk Factors" included in our Annual Report on Form 10-K for the year ended December 31, 2019. You should carefully consider the information described therein and in this Quarterly Report on Form 10-Q, which could materially affect our business condition, results of operations and cash flows.

The COVID-19 coronavirus could adversely impact our business.

We continue to monitor the effect of the outbreak of the novel strain of coronavirus, COVID-19. The COVID-19 coronavirus has spread to multiple countries, including the United States, and has caused significant disruptions around the world. We may experience disruptions as a result of the COVID-19 pandemic that could severely impact our business, including:

- difficulties in raising additional capital needed to commercialize Vicineum for the treatment of high-risk NMIBC due to the slowing of our economy and near term and/or long term negative effects of the pandemic on the financial, banking and capital markets;
- delays in necessary interactions with regulators and other important agencies and contractors due to limitations in employee resources, travel restrictions or forced furlough of government employees;
- interruption of key business activities due to illness and/or quarantine of key individuals and delays associated with recruiting, hiring and training new temporary or permanent replacements for such key individuals, both internally and at our third party service providers;
- changes in local regulations as part of a response to the COVID-19 coronavirus outbreak that may require us to change the ways in which operate, which may result in unexpected costs;
- interruption of key commercialization, manufacturing, and related activities due to limitations on work and travel imposed or recommended by federal or state governments, employers and others; and
- delays or difficulties related to any future clinical trials that may be required, including delays in clinical trial sites receiving the supplies and
 materials needed to conduct clinical trials, difficulties in recruiting clinical site investigators and clinical site staff and difficulties in enrolling
 patients or treating patients in active trials.

The global outbreak of the COVID-19 coronavirus continues to rapidly evolve. The extent to which the COVID-19 coronavirus may impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the virus. The full impact of the COVID-19 pandemic on our operational and financial performance, including our ability to execute our business strategies and initiatives in the expected time frame, will depend on future developments, including the duration and spread of the pandemic and related restrictions on travel and transports, and shelter-in-place, social distancing, and similar measures, all of which are uncertain and difficult to predict. The broad-based business and economic disruptions caused by the pandemic could materially affect our business condition, results of operations and cash flows, including our ability to raise additional capital.

We will depend on Qilu for the development and commercialization of Vicineum in the greater China region.

On July 30, 2020 we entered into the License Agreement with Qilu. Under the terms of the License Agreement with Qilu, Qilu has an exclusive license to manufacture, develop and commercialize Vicineum in the greater China region, including mainland China, Hong Kong, Macau and Taiwan. The timing and amount of any milestone and royalty payments we may receive under the License Agreement with Qilu will depend in part on Qilu's efforts. We will also depend on Qilu to comply with all applicable laws relative to the manufacturing, development and commercialization of Vicineum in the greater China region. We do not control the individual efforts of Qilu, and any failure by Qilu to devote sufficient time and effort to the manufacture, development and commercialization of Vicineum could have a material adverse impact on our financial results and operations, such as by a failure of Qilu to meet its obligations to us, including for future milestone and royalty payments. In addition, if Qilu were to violate, or was alleged to have violated, any laws or regulations during the performance of its obligations for us, it is possible that we could suffer financial and reputational harm or other negative outcomes, including possible legal consequences.

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Any termination, breach or expiration of the License Agreement with Qilu could have a material adverse effect on our financial position by reducing or eliminating the potential for us to receive milestones and royalties. In such an event, we may be required to devote additional efforts and to incur additional costs associated with pursuing the manufacture, development and commercialization of Vicineum in greater China. If we breach our obligations under the Qilu License Agreement and are unable to cure such breach, Qilu may terminate the Qilu License Agreement and retain all rights to manufacture, develop and commercialize Vicineum in the greater China region with no obligation to make any additional milestone or royalty payments. Qilu has the right to receive a refund of all amounts paid to the Company in the event the Qilu License Agreement is terminated under certain circumstances. In addition, the royalty rate is subject to reduction under certain circumstances, including when there is no valid claim of a licensed patent for Vicineum in a particular region or no data or regulatory exclusivity for Viceneum in a particular region.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

We did not issue any unregistered equity securities during the nine months ended September 30, 2020.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Index

Exhibit <u>No.</u>	<u>Description</u>
3.1	Restated Certificate of Incorporation of Eleven Biotherapeutics, Inc. Incorporated by reference to Exhibit 3.1 to our Current Report on
3.1	Form 8-K filed on February 18, 2014 (File No. 001-36296).
3.2	Amended and Restated By-laws of Eleven Biotherapeutics, Inc. Incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K filed on April 16, 2015 (File No. 001-36296).
3.3	Certificate of Amendment of Certificate of Incorporation. Incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K filed on May 17, 2018 (File No. 001-36296).
3.4	Amendment to Amended and Restated By-laws. Incorporated by reference to Exhibit 3.2 to our Current Report on Form 8-K filed on May 17, 2018 (File No. 001-36296).
4.1	Specimen Stock Certificate evidencing the shares of common stock. Incorporated by reference to Exhibit 4.1 to our Registration Statement on Form S-1/A filed on January 23, 2014 (Reg. No. 333-193131).
4.2	Registration Rights Agreement, dated as of September 20, 2016 by and among Eleven Biotherapeutics, Inc. and the shareholders named therein. Incorporated herein by reference to Exhibit 4.1 to our Current Report on Form 8-K filed on September 21, 2016 (File No. 001-36296).
4.3	Form of Warrant issued to Silicon Valley Bank and Life Science Loans, LLC dated November 25, 2014. Incorporated by reference to Exhibit 10.23 to our Registration Statement on Form S-1 filed with the SEC on December 19, 2014 (Reg. No. 333-201176).
4.4	Form of Common Warrant. Incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K filed with the SEC on November 3, 2017 (File. No. 001-36296).
4.5	Form of Warrant. Incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K filed with the SEC on March 23, 2018 (File. No. 001-36296).
10.1* #	Exclusive License Agreement, dated July 30, 2020, by and among Sesen Bio, Inc., Viventia Bio, Inc. and Qilu Pharmaceutical Co., Ltd.
31.1*	Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of the Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of the Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	Interactive Data File (Form 10-Q for the Quarterly Period ended September 30, 2020 filed in XBRL). The financial information contained in the XBRL-related documents is "unaudited" and "unreviewed." The instance document does not appear in the interactive file because its XBRL tags are embedded within the Inline XBRL document.
104	Cover Page Interactive File (embedded within the Inline XBRL document and included in Exhibit 101).

 ^{*} Filed herewith.

^{**} This certification is being furnished solely to accompany this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350 and is not being 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 it be deemed incorporated by reference into any filing of the registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

[#] Portions of this exhibit have been omitted in compliance with Item 601 of Regulation S-K.

SIGNATURES

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

SESEN BIO, INC.

(Registrant)

Date: November 9, 2020 By: /s/ Thomas R. Cannell, D.V.M.

Name: Thomas R. Cannell, D.V.M.

Title: President and Chief Executive Officer

(Principal Executive Officer and Duly Authorized Officer)

Portions of this exhibit indicated by bracketed asterisks have been omitted because they are not material and would likely cause competitive harm to Sesen Bio, Inc. if publicly disclosed.

Exclusive License Agreement

by and between

SESEN BIO, Inc.,

VIVENTIA BIO, INC.

and

QILU PHARMACEUTICAL CO., LTD.

July 30, 2020

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Exhibits

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Exhibit F	Product Documentation

EXCLUSIVE LICENSE AGREEMENT

This **EXCLUSIVE LICENSE AGREEMENT** (this "**Agreement**") is entered into as of the 30th day of July, 2020 (the "**Effective Date**"), by and between Sesen Bio, Inc., a Delaware corporation with its principal offices located at 245 First Street, Suite 1800, Cambridge, MA 02142, United States of America ("**Sesen US**"), Viventia Bio, Inc., a Canadian corporation with its principal offices located at 147 Hamelin St., Winnipeg, MD R3T 3Z1 Canada ("**Viventia**," and together with Sesen US, "**Sesen**"), and Qilu Pharmaceutical Co., Ltd., a company established pursuant to applicable laws and regulations of the People's Republic of China with its legal address located at 317 Xinluo Ave, Hi-Tech Zone, Ji'nan, Shandong, China ("**Qilu**"). Sesen and Qilu are each referred to herein by name or as a "**Party**" or, collectively, as "**Parties**."

RECITALS

Whereas, Sesen owns or controls the rights to VB4-845, also known as VicineumTM, a locally-administered targeted fusion protein composed of an anti-EPCAM, or epithelial cell adhesion molecule, antibody fragment tethered to a truncated form of *Pseudomonas exotoxin A* (the "**Licensed Compound**," as further defined below);

Whereas, Qilu is a specialty pharmaceutical company specializing in the development, manufacturing and sales of pharmaceutical products; and

WHEREAS, Sesen desires to grant to Qilu, and Qilu desires to obtain from Sesen, an exclusive license to certain intellectual property and Know-How owned or controlled by Sesen relating to the Licensed Compound to permit Qilu to Develop, Manufacture and Commercialize the Licensed Compound and Licensed Products in the Field in the Territory (as defined below), all upon the terms and conditions as more specifically described herein.

Now, therefore, in consideration of the premises and mutual covenants herein contained, and for other good and valuable consideration, the receipt and legal sufficiency of which are hereby acknowledged, accepted and agreed to, the Parties hereto agree as follows:

Article 1

DEFINITIONS

As used in this Agreement, the following terms shall have the meanings set forth in this Article 1:

- **1.1** "**Accounting Standards**" means (a) U.S. generally accepted accounting principles, or (b) International Financial Reporting Standards, as applicable to a Person and consistently applied.
 - **1.2** "**Action**" has the meaning set forth in <u>Section 6.2(c)</u>.
- **1.3** "**Affiliate**" means any Person that directly or indirectly through one (1) or more intermediaries controls, is controlled by or is under common control with a Party. For purposes of this definition, a Person shall be deemed to "control" another Person if it (a) owns,

directly or indirectly, beneficially or legally, at least fifty percent (50%) of the outstanding voting securities or capital stock (or such lesser percentage which is the maximum allowed to be owned by a Person in a particular jurisdiction) of such other Person, or has other comparable ownership interest with respect to any Person other than a corporation, or (b) has the power, whether pursuant to contract, ownership of securities or otherwise, to direct the management and policies of such Person.

- **1.4** "**Agreement**" has the meaning set forth in the Preamble.
- **1.5** "Alliance Managers" has the meaning set forth in Section 3.7.
- 1.6 "Applicable Laws" means individually and collectively, any federal, state, local, national and supra-national laws, treaties, statutes, ordinances, rules and regulations, including any rules, regulations, guidance, guidelines or requirements having the binding effect of law of national securities exchanges, automated quotation systems or securities listing organizations, Regulatory Authorities, courts, tribunals, Governmental Authorities other than Regulatory Authorities, legislative bodies and commissions that are in effect from time to time during the Term and applicable to a particular activity hereunder and, where the context permits, includes Applicable PRC Laws. Applicable Laws shall include GCP, GLP and GMP.
- 1.7 "Applicable PRC Laws" means any (local or national-level) laws, administrative regulations, decrees, provisions, rules, circulars, and other legislative, executive or judicial decisions or normative pronouncements of any Governmental Authority of the PRC which are publicly promulgated and available and in effect during the Term, including, where the context permits, any applicable mandatory or recommended standards in the PRC, as identified by the "GB" (国标) or "GB/T" (国标/推荐) prefix.
- **1.8** "Approval" means any consent, authorization, order, confirmation, qualification, permission, certification, approval, record-filing, registration, license, permit, designation and/or declaration or other act by a Regulatory Authority or Governmental Authority approving or consenting to a request or application.
 - **1.9** "Back License" has the meaning set forth in Section 2.5.
- **1.10 "Bankruptcy Code"** means Title 11, U.S. Code or foreign equivalent laws, including the PRC Enterprise Bankruptcy Law.
- **1.11** "**BLA**" means a Biologics License Application filed with the FDA in the United States with respect to a Licensed Product, as defined in Title 21 of the U.S. Code of Federal Regulations, Section 601.2 et seq.
 - **1.12** "**Breaching Party**" has the meaning set forth in <u>Section 10.2(a)</u>.
- **1.13** "Business Day" means a day on which banking institutions in Boston, Massachusetts, United States or Jinan, Shandong, China are open for business.
- **1.14** "Calendar Quarter" means a period of three (3) consecutive months ending on the last day of March, June, September, or December, respectively.

- **1.15** "Calendar Year" means a period of twelve (12) consecutive months beginning on January 1 and ending on December 31.
 - **1.16** "CDE" means the Chinese Center for Drug Evaluation of the NMPA, or any successor entity thereto.
- **1.17 "China"** or "**PRC**" means, for the purpose of this Agreement, the People's Republic of China, excluding Hong Kong, Macau and Taiwan.
 - **1.18** "Claims" has the meaning set forth in Section 9.1.
- **1.19** "Clinical Trial" means a clinical trial of a pharmaceutical product or compound in human patients, including Phase 1, Phase 2 or Phase 3 clinical trials, as defined in 21 C.F.R. 312.21, as amended from time to time, or the corresponding foreign regulations, as well as other clinical trials that may be conducted in connection with or in order to maintain a Regulatory Approval.
- **1.20** "Coda Agreement" means the Service Evaluation Agreement, dated as of February 7, 2006, between CODA Genomics Inc. and Viventia.
- **1.21** "Coda Technology" means the Licensed Patents and the Licensed Know-How that are licensed to Viventia under the Coda Agreement.
 - **1.22** "Combination Components" has the meaning set forth in Section 1.72.
- **1.23** "Commercialization" or "Commercialize" means all activities directed to marketing, distributing, detailing or selling a pharmaceutical or biologic compound or product (as well as importing and exporting activities in connection therewith), including all activities directed to obtaining pricing Approvals. For clarity, Commercialization shall not include Development or Manufacturing activities.
- 1.24 "Commercially Reasonable Efforts" means, with respect to a Party, efforts that are consistent with the efforts and resources commonly used in the pharmaceutical industry by a company of comparable size in connection with the research, development and commercialization of a pharmaceutical or biologic compound or product owned by it or to which it has exclusive rights, with similar product characteristics, which is of similar market potential at a similar stage in its development or product life, taking into account issues of patent coverage, safety and efficacy, product profile, the competitiveness of the marketplace, the proprietary position of the compound or product, the regulatory and legal structures involved, the potential or actual profitability of the applicable compound or product (including pricing and reimbursement status achieved or to be achieved) and other relevant factors, including technical, legal, scientific and/or medical factors. Commercially Reasonable Efforts shall be determined on a market-by-market and indication-by-indication basis for a particular product, and it is anticipated that the level of effort shall be different for different markets within the Territory and different indications, and shall change over time, reflecting changes in the status of the product and the market(s) and indication(s) involved.

- **1.25** "Confidential Information" means all information, including trade secrets, processes, formulae, Data, Know-How, improvements, inventions, chemical or biological materials, assays, techniques, marketing plans, strategies, customer lists, or other information that has been disclosed by or on behalf of one Party to the other Party under this Agreement, regardless of whether any of the foregoing are marked "confidential" or "proprietary" or communicated in oral, written, graphic, or electronic form, or by visual inspection. This Agreement shall be the Confidential Information of each Party.
- 1.26 "Control," "Controls," or "Controlled" when used in reference to any particular subject matter including Patents, Know-How, tangible materials or other intellectual property rights, means the legal authority or right of a Party to grant a license or sublicense to such subject matter to another Party, or to otherwise provide such other Party the right to access and use such subject matter, whether arising by ownership, license, or other authorization, without breaching the terms of any written agreement with a Third Party under which such Party first acquired rights to such subject matter, or misappropriating the proprietary or trade secret information of a Third Party.
- **1.27** "**Data**" means pre-clinical, clinical, chemical, manufacturing and analytical data and any other data and information generated or resulting from the Development or Commercialization of the Licensed Compound or Licensed Products.
 - **1.28** "**Defending Party**" has the meaning set forth in <u>Section 6.3</u>.
- **1.29** "**Development**" means, with respect to a pharmaceutical or biologic compound or product, all processes and activities that are reasonably required to obtain Regulatory Approval of such compound or product, including, without limitation, toxicology, pharmacology and other pre-clinical efforts, test method development and stability testing, statistical analysis, clinical studies and regulatory activities. When used as a verb, "**Develop**" means to engage in Development.
 - **1.30** "Development Plan" has the meaning set forth in Section 4.3.
 - **1.31** "**Disclosing Party**" has the meaning set forth in <u>Section 7.1</u>.
 - **1.32** "**Dollars**" or "\$" means the legal tender of the U.S.
 - **1.33** "**Effective Date**" has the meaning set forth in the Preamble.
 - **1.34** "Excluded Claim" has the meaning set forth in Section 11.2(e).
- **1.35** "Executive Officer" means (a) with respect to Qilu, the President or Legal Representative of Qilu, or any other person that such officer designates from time to time, and (b) with respect to Sesen, the Chief Executive Officer of Sesen, or any other person that such officer designates from time to time.
 - **1.36** "FDA" means the U.S. Food and Drug Administration, or any successor entity thereto.

- **1.37** "**Field**" means the prevention and treatment of cancers, including; but not limited to, high-risk non-muscle invasive bladder cancer ("**NMIBC**"), and various sub-types of NMIBC.
- **1.38** "First Commercial Sale" means, with respect to any Licensed Product, the first sale for which revenue has been recognized by Qilu or its Sublicensee for use or consumption by the general public of such Licensed Product in any Relevant Region in the Territory after all Regulatory Approvals have been granted in such Relevant Region. For avoidance of doubt, all sales for clinical trial purposes, for test marketing, sampling, promotional uses or compassionate use will not constitute a First Commercial Sale.
 - **1.39 "Force Majeure"** has the meaning set forth in <u>Section 11.5</u>.
- 1.40 "GCP" means current Good Clinical Practices as defined in Parts 50, 56 and 312 of Title 22 of the U.S. Code of Federal Regulations, as may be amended from time to time, or any successor thereto or foreign equivalents thereof, including Good Clinical Practice for Drugs (i.e. 药物临床试验质量管理规范) promulgated by the former State Food and Drug Administration of China (now NMPA) effective as of September 1, 2003 and proposed to be amended as of July 1, 2020, together with any guidelines and/or implementation rules issued by NMPA in connection thereto, in each case as amended from time to time.
- **1.41** "GLP" means current Good Laboratory Practices as defined in Part 58 of Title 21 of the U.S. Code of Federal Regulations, as may be amended from time to time, or any successor thereto and foreign equivalents thereof.
- 1.42 "GMP" means current Good Manufacturing Practices as defined in Parts 210 and 211 of Title 21 of the U.S. Code of Federal Regulations, as may be amended from time to time, or any successor thereto and foreign equivalents thereof, including Good Manufacturing Practice for Drugs (i.e.药品生产质量管理规范) promulgated by the Ministry of Health of China effective as of March 1, 2011, as may be amended from time to time.
- **1.43** "Governmental Authority" means any court, agency, department, authority or other instrumentality of any national, state, provincial, county, city or other political subdivision, including any entity authorized or delegated by the foregoing to exercise any administrative authority or function.
 - **1.44** "Hong Kong" has the meaning set forth in Section 1.109.
 - **1.45** "**ICC**" has the meaning set forth in <u>Section 11.2</u>.
 - 1.46 "Imported Drug License" means an imported drug license (进口药品注册证) issued by the NMPA.
- **1.47** "**Improvement**" means any invention, improvement, discovery, enhancement or Know-How Controlled by Sesen or its Affiliates during the Term that is an improvement, modification or adaptation of any technology, process or methodology claimed in, embodied by or covered by either of Licensed Patents or Licensed Know-How, as applicable.

- **1.48** "**Improvement IP**" means the Improvement Know-How and the Improvement Patents.
- **1.49** "**Improvement Know-How**" means any and all Know-How that is Controlled by Sesen or its Affiliates during the Term that constitutes an Improvement.
- **1.50** "**Improvement Patents**" means any and all Patents that are Controlled by Sesen or its Affiliates during the Term that claim or cover an Improvement.
- **1.51** "IND" means any investigational new drug application filed with the FDA pursuant to Part 312 of Title 21 of the U.S. Code of Federal Regulations prior to beginning clinical trials in humans in the United States, or any comparable application filed with any Regulatory Authority outside the United States.
 - **1.52** "**Indemnitee**" has the meaning set forth in <u>Section 9.3</u>.
 - **1.53** "**Infringement**" has the meaning set forth in <u>Section 6.2(a)</u>.
 - **1.54** "**Joint Steering Committee**" or "**JSC**" has the meaning set forth in <u>Section 3.1</u>.
- 1.55 "Know-How" means any proprietary Data, results, material(s), technology, and nonpublic information of any type whatsoever, in any tangible or intangible form, including: (a) information, techniques, technology, practices, trade secrets, discoveries, developments, inventions (whether patentable or not), methods, knowledge, know-how, skill, experience, Data, results (including assay development, compound screening, chemical, pharmacological, toxicological and clinical test Data and results), analytical and quality control Data, results or descriptions, software and algorithms, reports and study reports and other technologies or subject matters of any kind in each case that are generally not publicly known relating to the Licensed Compound or the Licensed Patents; and (b) compositions of matter, cells, cell lines, assays, animal models and physical, biological or chemical material.
- **1.56** "**Liabilities**" means any and all losses, costs, liabilities, expenses (including reasonable legal costs and fees), fines, damages, penalties, compensation, awards, proceedings, claims and demands and each is a "**Liability**".
 - **1.57** "**License**" has the meaning set forth in Section 2.1.
- **1.58** "**Licensed Compound**" means VB4-845, also known as VicineumTM, a locally-administered targeted fusion protein composed of an anti-EPCAM, or epithelial cell adhesion molecule, antibody fragment tethered to a truncated form of *Pseudomonas exotoxin A*, as further described on **Exhibit A** hereto.
 - **1.59** "Licensed IP" means the Licensed Know-How and the Licensed Patents.
- **1.60** "**Licensed Know-How**" means any Know-How owned or Controlled by Sesen or its Affiliates, as of the Effective Date or after the Effective Date during the Term, that is necessary or incidental for the Development, Manufacture or Commercialization of the Licensed

Compound or Licensed Products in the Field in the Territory. For clarity, the Licensed Know-How does not include Improvement Know-How.

- **1.61** "Licensed Patents" means any and all Patents that are Controlled by Sesen or its Affiliates, as of the Effective Date or after the Effective Date during the Term, that claim or cover the making, having made, using, selling, offering for sale, importation or exportation (as between the Relevant Regions) of the Licensed Compound or Licensed Products in the Field in the Territory. The Licensed Patents in existence as of the Effective Date are set forth on **Exhibit B** hereto, which shall be updated as needed from time to time during the Term. For clarity, the Licensed Patents do not include Improvement Patents.
- **1.62** "**Licensed Product(s)**" means any biologic product containing the Licensed Compound, in all forms, presentations, formulations and dosage forms.
 - **1.63** "**Losses**" has the meaning set forth in <u>Section 9.1</u>.
- **1.64** "MAA" means a Marketing Authorization Application, BLA, or similar application, as applicable, and all amendments and supplements thereto, submitted to the FDA, NMPA, or any equivalent filing in a country or regulatory jurisdiction with the applicable Regulatory Authority, to obtain marketing approval for a pharmaceutical or biologic product, in a country or in a group of countries, including in China an application for an Imported Drug License and a domestic Drug Registration Certificate.
 - **1.65** "Macau" has the meaning set forth in <u>Section 1.109</u>.
- **1.66** "Manufacture" or "Manufacturing" means all activities related to the manufacturing of a pharmaceutical or biologic compound or product, or any ingredient thereof, including but not limited to test method development and stability testing, characterization, formulation, process development, manufacturing for use in non-clinical or clinical studies, manufacturing scale-up, quality assurance/quality control development, quality control testing (including in-process release and stability testing), packaging, release of such compound or product or any component or ingredient thereof, quality assurance activities related to manufacturing and release of such compound or product, and regulatory activities related to all of the foregoing.
 - **1.67** "Manufacturing Know-How" has the meaning set forth in Section 4.7(a).
- **1.68** "**MOFCOM**" means the Ministry of Commerce of China or any successor agency with a similar scope of responsibility.
 - **1.69** "Micromet Field" means the Field as such term is defined under the Micromet License Agreement.
- **1.70** "**Micromet License Agreement**" means the Non-Exclusive Product License Agreement, dated as of October 18, 2005, between Micromet AG and Viventia Biotech (Barbados) Inc.

- **1.71** "**Micromet Technology**" means the Licensed Patents and the Licensed Know-How that are licensed to Viventia Biotech (Barbados) Inc. under the Micromet License Agreement.
- 1.72 "Net Sales" means, with respect to any Licensed Product, the gross invoiced sales price of such Licensed Product sold by or on behalf of Qilu or its Sublicensees (the "Selling Party"), in finished product form, packaged and labelled for sale in arm's-length transactions to Third Parties, less deductions allowed to the Third Party customer by the Selling Party, to the extent actually taken by such Third Party customer, on such sales for:
 - (a) sales taxes, excise taxes, use taxes, VAT and duties paid by the Selling Party in relation to the Licensed Product and any other equivalent governmental charges imposed upon the importation, use or sale of the Licensed Product;
 - (b) government-mandated and other rebates, credits issued or amounts refunded for returns of Licensed Product(s) or billing errors;
 - (c) transportation, inventory, storage charges and other charges directly related to the sale of the Licensed Product, such as insurance charges, in each case, to the extent actually incurred;
 - (d) customary trade, quantity and cash discounts allowed on the Licensed Product; and
 - (e) allowances or credits to customers on account of price reductions affecting the Licensed Product; and
 - (f) a reasonable estimate for bad debts.

Net Sales shall be calculated and accounted for in accordance with Accounting Standards.

Where a Licensed Product is sold in combination with or co-packaged with other active ingredients (collectively, "Combination Components"), the Net Sales applicable to such transaction shall be calculated by multiplying the total Net Sales of such combined or co-packaged product by the fraction A/(A+B), where A is the actual price of the Licensed Product in the same dosage amount or quantities in the applicable Relevant Region during the applicable Calendar Quarter if sold separately, and B is the sum of the actual prices of all Combination Components with which the Licensed Product is combined or co-packaged, in the same dosage amount or quantities in the applicable Relevant Region during the applicable Calendar Quarter if sold separately. If A or B cannot be determined because values for the Licensed Product or Combination Components with which the Licensed Product is combined or co-packaged are not available separately in a particular Relevant Region, then the Parties shall discuss an appropriate allocation for the fair market value of the Licensed Product and the Combination Components with which the Licensed Product is combined or co-packaged to mutually determine Net Sales for the relevant transactions based on an equitable method of determining the same that takes into account variations in potency, the relative contribution of each active ingredient, and the relative value to the end user of each active ingredient.

- **1.73** "**NMIBC**" has the meaning set forth in <u>Section 1.37</u>.
- **1.74** "**NMPA**" means the National Medical Products Administration in China, or any successor agency with a similar scope of responsibility regarding the regulation of human pharmaceutical and biologic products in China.
 - **1.75** "**Non-breaching Party**" has the meaning set forth in <u>Section 10.2(a)</u>.
 - **1.76** "**OFAC**" has the meaning set forth in <u>Section 8.4(e)</u>.
 - **1.77** "**Party**" or "**Parties**" has the meaning set forth in the Preamble.
- **1.78** "Patent" means (a) all patents and patent applications in any country or supranational jurisdiction, and (b) any substitutions, divisions, continuations, continuations-in-part, provisional applications, reissues, renewals, registrations, confirmations, re-examinations, extensions, supplementary protection certificates and the like of any such patents or patent applications.
 - **1.79** "**Payment**" has the meaning set forth in Section 5.6(a).
- **1.80** "**Person**" means any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, governmental authority or agency, or any other entity not specifically listed herein.
 - **1.81 "Pharmacovigilance Agreement"** has the meaning set forth in <u>Section 4.11</u>.
 - **1.82** "**Prior CDA**" has the meaning set forth in <u>Section 7.5</u>.
- **1.83 "Product Documentation"** means data, information and records relating to the Licensed Compound and Licensed Product as set forth in **Exhibit F** that is in Sesen's possession and Sesen's Control.
 - **1.84** "**Qilu**" has the meaning set forth in the Preamble.
 - **1.85** "Qilu IP" means the Qilu Patents and the Qilu Know-How.
- **1.86** "**Qilu Know-How**" means any Know-How Controlled by Qilu or its Affiliates, as of the Effective Date or after the Effective Date during the Term, that is reasonably necessary for the Development, Manufacture or Commercialization of the Licensed Compound or Licensed Products.
- **1.87** "**Qilu Patents**" means any Patents that are owned and Controlled by Qilu or its Affiliates, as of the Effective Date or after the Effective Date during the Term, that claim or cover the making, having made, using, selling, offering for sale, importation or exportation of the Licensed Compound or Licensed Products.
 - **1.88** "Quality Agreement" has the meaning set forth in Section 4.10.
 - **1.89** "**Receiving Party**" has the meaning set forth in <u>Section 7.1</u>.

- **1.90** "**Regulatory Approval**" means all Approvals, including if required by Applicable Laws, pricing Approvals, necessary for the marketing and sale of a Licensed Product in the Territory, which may include satisfaction of all applicable regulatory and notification requirements.
- **1.91** "**Regulatory Authority**" means any federal, national, supranational, state, provincial, directly administered municipality or local regulatory agency, department, bureau or other Governmental Authority, including the CDE and the NMPA, that has authority over the Manufacture, Development, Commercialization or other use or exploitation (including the granting of Regulatory Approval) of any Licensed Compound or Licensed Product in any applicable regulatory jurisdiction.
- **1.92** "Regulatory Materials" means materials developed or compiled in preparation for Regulatory Authority meetings, regulatory applications (including INDs and MAAs), submissions, dossiers, notifications, registrations, Regulatory Approvals (including Approvals of MAAs, supplements and amendments, pre- and post-approvals, pricing approvals, and labeling Approvals) and/or other filings made to or with, or other Approvals granted by, a Regulatory Authority or Governmental Authority that are necessary or reasonably desirable for or incidental to the Development, Manufacture or Commercialization of the Licensed Compound or a Licensed Product in a particular regulatory jurisdiction.
 - **1.93** "**Relevant Person**" has the meaning set forth in <u>Section 8.4(e)</u>.
 - **1.94** "**Relevant Region**" has the meaning set forth in <u>Section 1.109</u>.
 - **1.95** "**Renminbi**" means the legal tender of China.
 - **1.96** "Royalty Term" has the meaning set forth in Section 5.3(a).
 - **1.97** "**Selling Party**" has the meaning set forth in <u>Section 1.72</u>.
 - **1.98** "Sesen" has the meaning set forth in the Preamble.
- **1.99** "Sesen Territory" means the entire world other than the Territory and each Relevant Region within the Territory.
 - **1.100** "Sesen US" has the meaning set forth in the Preamble.
- **1.101** "**Sublicensee**" means an Affiliate or Third Party to whom Qilu or its Affiliate has granted a sublicense under the License.
 - **1.102** "Supply Agreement" has the meaning set forth in <u>Section 4.10</u>.
 - **1.103** "**Supply End Date**" has the meaning set forth in <u>Section 4.10</u>.
 - **1.104** "**Technical Assistance**" has the meaning set forth in <u>Section 4.8</u>.
- **1.105** "**Technology Transfer**" means the process by which Sesen shall transfer to Qilu the Licensed Know-How and Manufacturing Know-How and take other actions to enable

Qilu, an Affiliate or its permitted Sublicensee(s) to research, develop and Manufacture and Commercialize the Licensed Compound and Licensed Products for use in the Field in the Territory as further described in the Technology Transfer Plan.

- **1.106** "**Technology Transfer Completion**" means the completion of manufacturing the Licensed Product [***], using the Licensed Know-How and Manufacturing Know-How transferred from Sesen, with the batches and quality consistency of the Licensed Product that meets the acceptance criteria for the specifications set forth in the Technology Transfer Plan.
- **1.107** "**Technology Transfer Plan**" means the plan attached hereto as **Exhibit C**, detailing the terms of the Technology Transfer.
 - **1.108** "**Term**" has the meaning set forth in <u>Section 10.1</u>.
- **1.109** "**Territory**" means the Greater Area of China, including (a) China, (b) the Hong Kong Special Administrative Region ("**Hong Kong**"), (c) the Macau Special Administrative Region ("**Macau**"), and (d) Taiwan (each of the foregoing a "**Relevant Region**") and collectively, referred to as the "**Territory**".
 - **1.110** "**Territory Filings and Approvals**" has the meaning set forth in <u>Section 4.12</u>.
 - **1.111** "**Third Party**" means any Person other than Sesen or Qilu or an Affiliate of Sesen or Qilu.
 - **1.112** "United States" or "U.S." means the United States of America, including its territories and possessions.
- **1.113** "University of Zurich License Agreement" means the License Agreement, effective as of January 9, 2003, between The University of Zurich and Viventia.
- **1.114** "University of Zurich Patents" means the Licensed Patents that are licensed to Viventia under the University of Zurich License Agreement.
 - **1.115** "**Upfront Payment**" has the meaning set forth in <u>Section 5.1</u>.
 - **1.116** "**Upfront Payment Due Date**" has the meaning set forth in <u>Section 5.1</u>.
- **1.117** "**Upstream License Agreements**" means the Coda Agreement, the Micromet License Agreement, the University of Zurich License Agreement and the Xoma License Agreement.
- **1.118** "Valid Claim" means a claim of (a) an issued and unexpired Patent, or (b) a patent application where the earliest priority date of which claim is less than ten (10) years, that (in each case, as applicable) has not been finally rejected, dismissed, held invalid or unenforceable by a Governmental Authority of competent jurisdiction from which no request of review, re-examination, appeal, or an administrative or judicial challenge of similar nature can be

or has been taken and has not been held to be invalid or unenforceable through reexamination, nullity suit or otherwise and no appeal or retrial or similar procedure can be or has been taken.

- **1.119** "VAT" has the meaning set forth in Section 5.6(b).
- **1.120** "**Viventia**" has the meaning set forth in the Preamble.
- **1.121** "Withholding Tax" has the meaning set forth in Section 5.6(a).
- **1.122** "Xoma Field" means the Field as such term is defined in the Xoma License Agreement.
- **1.123** "Xoma License Agreement" means the Non-Exclusive License Agreement, dated as of November 30, 2001, between XOMA Ireland Limited and Viventia.
- **1.124** "**Xoma Technology**" means the Licensed Patents and the Licensed Know-How that are licensed to Viventia under the Xoma License Agreement.

Article 2

GRANT OF RIGHTS

- **2.1 License.** Subject to the terms and conditions of this Agreement, effective upon the Effective Date, Sesen hereby grants to Qilu (a) an exclusive (even as to Sesen and its Affiliates, subject to Section 2.4), royalty-bearing license, with the right to grant sublicenses (including through multiple tiers of Sublicensees, subject to Section 2.2), under the Licensed IP (other than the Micromet Technology and the Xoma Technology) to research, Develop, have Developed, Manufacture, have Manufactured, use, sell, offer for sale, import, export (as between the Relevant Regions) and otherwise Commercialize and have Commercialized the Licensed Compound and Licensed Products in the Field in the Territory, (b) a nonexclusive, royalty-bearing sublicense, with the right to grant further sublicenses (including through multiple tiers of Sublicensees, subject to Section 2.2), under the Micromet Technology to research, Develop, have Developed, Manufacture, have Manufactured, use, sell, offer for sale, import, export (as between the Relevant Regions) and Commercialize and have Commercialized and exploit the Licensed Compound and Licensed Products in the Micromet Field in the Territory, and (c) a nonexclusive, royalty-bearing sublicense, with the right to grant further sublicenses (including through multiple tiers of Sublicensees, subject to Section 2.2 and the terms of the Xoma License Agreement), under the Xoma Technology to make, have made, use, import, offer for sale and sell the Licensed Compound and Licensed Products in the Xoma Field in the Territory, and in each instance of (b) and (c), a non-exclusive sublicense to practice and use the Licensed Know-How in connection therewith (collectively, the "License").
- **2.2** <u>Sublicenses</u>. Qilu shall have the right to sublicense the rights granted to it under the License and <u>Section 2.6</u>, and each Sublicensee shall be entitled to further sublicense the rights granted to it under the License, subject in each case to the terms and conditions set forth in this <u>Section 2.2</u> and the Upstream License Agreements. [***] Each sublicense with a Sublicensee shall be granted pursuant to a written sublicense agreement consistent with the terms of this Agreement to the extent applicable to the sublicensed rights and Qilu shall provide Sesen

with a copy of such sublicense agreement, within [***] after execution of the sublicense agreement. Qilu shall (i) cause each of its Sublicensees to comply with the terms of this Agreement, and (ii) remain responsible for the performance and non-performance of its Sublicensees (except to the extent they are performed by any such Sublicensee(s) in accordance with this Agreement). For clarity, any sublicense to Qilu's Affiliates or a Third Party distributor, contract sales organization, wholesaler or similar vendor engaged to perform Commercialization activities on Qilu's behalf shall not require Qilu's prior written notice to Sesen or any other party under this Section 2.2.

- **2.3 No Implied Rights**. Except as expressly stated herein, Qilu shall have no other right to use, or interest in, the Licensed IP. Additionally, Qilu shall not have any interest in any other Patents, Know-How or other intellectual property owned, licensed, developed or Controlled by Sesen or its Affiliates, other than as expressly provided in this Agreement or other valid written agreements. Sesen makes no grant of intellectual property rights by implication.
- **2.4 Retained Rights**. All rights that are not specifically granted herein by Sesen to Qilu are reserved to Sesen. Sesen retains rights under the Licensed IP to perform its obligations under this Agreement. For clarity, Sesen does not retain rights to Develop, Commercialize, Manufacture or have Developed or Manufactured, and engage Third Parties to Manufacture or have Manufactured on Sesen's behalf, the Licensed Compound and Licensed Products in the Field in the Territory except as required for Sesen to perform its obligations under this Agreement.
- **2.5 Grant to Sesen.** In consideration of Sesen agreeing to grant the License to Qilu and bear Qilu's patent expenses as further set forth in Section 6.1(b), and subject to the terms and conditions of this Agreement and during the Term, Qilu hereby grants to Sesen (a) an exclusive (even with respect to Qilu and its Affiliates), royalty-free, fully paid-up, sublicensable (through multiple tiers), license under the Qilu IP to Develop, use (but not Manufacture), sell, offer for sale and import and export the Licensed Compound and Licensed Products (i) outside of the Field in the Territory, and (ii) in all fields of use in the Sesen Territory, and (b) a non-exclusive, worldwide, royalty-free, fully paid-up, sublicensable (through multiple tiers) license under the Qilu IP to Manufacture and have Manufactured the Licensed Compound and Licensed Products in the Sesen Territory ((a) and (b) collectively, the "Back License"). Upon the request of Sesen from time to time during the Term, Qilu shall promptly (x) deliver to Sesen a list of all Qilu Patents then in existence, and (y) transfer and deliver to Sesen copies in English of all tangible embodiments of the Qilu Know-How then within its Control. It is specifically understood and agreed that neither Sesen, its Affiliates or sublicensees shall have the right to offer for sale, sell, distribute or Commercialize Licensed Compounds and/or Licensed Products in the Field in the Territory. If Sesen, its Affiliates or sublicenses becomes aware of sales, distributions or Commercialization of Licensed Compounds and/or Licensed Product by any such Parties, then Sesen shall take all actions necessary to terminate such activities, including initiating a lawsuit(s).
- **2.6** <u>Grant Improvement to Qilu</u>. In consideration of the payment by Qilu of the upfront, milestones and royalty payments hereunder, and effective as of the Effective Date, Sesen hereby grants to Qilu: (a) an exclusive (even with respect to Sesen and its Affiliates), royalty-bearing, sublicensable (through multiple tiers of Sublicensees, subject to <u>Section 2.2</u>),

license under the Improvement IP to Develop, use (but not Manufacture), sell, offer for sale and import and export the Licensed Compound and Licensed Products in the Field in the Territory, (b) an exclusive, royalty-bearing, sublicensenable (through multiple tiers of Sublicensees, subject to Section 2.2), license under the Improvement IP, to Manufacture, have Manufactured, and engage Third Parties to Manufacture or have Manufactured on Qilu's behalf, the Licensed Compound and Licensed Products in the Field in the Territory. Upon generation of any Improvement during the Term, Sesen shall promptly (x) deliver Qilu a list of all Improvement Patents then in existence, and (y) transfer and deliver to Qilu copies of all tangible embodiments of the Improvement Know-How then within its Control.

- **2.7** Section 365(n) of the U.S. Bankruptcy Code. All rights and licenses granted under or pursuant to any section of this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101(35A) of the Bankruptcy Code. Each Party shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code or equivalent legislation in any other jurisdiction. Upon the commencement of a bankruptcy or other insolvency proceeding of either Party, the other Party shall further be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, and such, if not already in its possession, shall be promptly delivered to such other Party, unless the Party in bankruptcy or other insolvency proceeding elects to continue, and continues, to perform all of its obligations under this Agreement. If not delivered pursuant to the previous sentence, such intellectual property and such embodiments thereof shall be delivered upon the rejection of this Agreement by or on behalf of the non-bankrupt Party upon written request therefor.
- Registration of Agreement and Back License. In accordance with Applicable PRC Laws, within thirty (30) 2.8 Business Days after the Effective Date, Qilu shall complete the registration of this Agreement with (a) the competent local counterpart of MOFCOM as a technology importation contract pursuant to the PRC Technology Importation and Exportation Administrative Regulations (i.e.中华人民共和国技术进出口管理条例) promulgated by the State Council of China effective as of January 1, 2002 and amended as of March 2, 2019 and the Registration of Technology Importation and Exportation Contracts Administrative Measures (i.e.技术进出口合同登记管理办法) promulgated by MOFCOM and effective as of March 3, 2009, in each case, as may be amended from time to time, and (b) any other applicable Regulatory Authority as required under Applicable PRC Laws. Qilu shall also be responsible for filing this Agreement with National Intellectual Property Administration, PRC pursuant to Measures for the Filling of Patent Exploitation License Contracts (i.e. 专利实施许可合同备案办法). Qilu shall also be responsible for completing a registration of technology exportation with MOFCOM under the foregoing rules and registration with any other applicable Regulatory Authority in relation to the Back License, and Sesen shall provide reasonable assistance and cooperation in connection therewith. Upon successful registration of this Agreement, and where applicable, any separate agreement (if any) in relation to the Back License with each applicable Regulatory Authority in the Territory, Qilu shall promptly forward to Sesen certified true and complete copies of any registration certificates as well as any other relevant documentation received by Qilu in connection with the same. In connection with the registration and filling obligations by Qilu in this Section 2.8, Sesen shall fully cooperate to provide necessary assistance.

Article 3

GOVERNANCE

- 3.1 <u>Establishment of JSC</u>. The Parties will establish a joint steering committee to review and oversee the Development and Commercialization of the Licensed Compound and Licensed Products in the Field in the Territory and to coordinate the Parties' activities under this Agreement (the "Joint Steering Committee" or "JSC"). Within [***] after the Effective Date, each Party shall appoint two (2) representatives to the JSC, each of which shall have sufficient seniority and relevant expertise to make decisions within the scope of the JSC's responsibilities. The JSC may change its size from time to time by mutual consent of the Parties; provided, that the JSC will consist at all times of an equal number of representatives of each of Sesen and Qilu. Each Party may at any time and from time to time replace its JSC representatives upon written notice to the other Party.
- **3.2** Co-Chairpersons of JSC. Each of Sesen and Qilu will select from their representatives a co-chairperson for the JSC, and each Party may change, from time to time, its designated co-chairperson from time to time upon written notice to the other Party. The co-chairpersons of the JSC will be responsible, with the assistance of the Alliance Managers, for calling meetings, preparing and circulating an agenda and relevant materials (including drafts of, updates to, or any proposed changes to the Development Plan) to the other Party at least [***] in advance of each meeting, and preparing and issuing minutes of each meeting within [***] thereafter.

3.3 JSC Responsibilities. The JSC shall be responsible for:

- (a) coordinating the activities of the Parties under this Agreement and providing a forum to facilitate communications between the Parties under this Agreement;
- (b) reviewing and discussing the Development, Manufacture and Commercialization of the Licensed Compound and Licensed Products in the Field in the Territory, including the activities of Qilu and its Sublicensees to (i) Develop the Licensed Compound and Licensed Products in the Field in the Territory in accordance with the Development Plan, (ii) Manufacture quantities of the Licensed Compound and Licensed Products for use in the Field in the Territory, (iii) following Regulatory Approval, launch, market, distribute and sell Licensed Products in the Field in the Territory, and (iv) subject to Section 2.2 and any consent required by Sesen for a sublicense of the License, Qilu's selection of Third Party service providers to support Qilu's efforts to Develop, Manufacture and Commercialize the Licensed Compound and Licensed Products in the Field in the Territory;
- (c) reviewing, discussing and approving changes to the Development Plan, overseeing the implementation of the Development Plan, and reviewing and discussing the Data and results of the Development activities under the Development Plan, in each case, subject to the provisions of <u>Section 3.5</u>, below;
- (d) discussing at a high-level and exchanging relevant information relating to the Development, Manufacture and Commercialization activities for the Licensed Compound

and Licensed Products undertaken by Sesen and its Affiliates and sublicensees outside of the Field and outside of the Territory (i) to the extent relevant to the Development, Manufacture and Commercialization of the Licensed Compound and Licensed Products in the Field in the Territory, and (ii) to the extent that Sesen has the right to disclose such information to Qilu; and

- (e) performing such other functions as appropriate to further the purposes of this Agreement, as expressly set forth in this Agreement or allocated to it by the Parties in writing by mutual agreement.
- **3.4** JSC Meetings. The JSC will hold meetings (either in-person, by teleconference, videoconference or similar means) at such times and places as the co-chairpersons may reasonably determine; provided, that unless the Parties agree otherwise, the JSC will meet quarterly and only by teleconference, videoconference or other similar or mutually acceptable electronic means. Each Party will bear its own costs associated with attending meetings of the JSC. Each Party may from time to time invite a reasonable number of participants (including translators), in addition to its representatives, to attend the JSC meetings in a non-voting capacity. Each individual attending any JSC meeting hereunder (whether as a JSC member or invitee) shall be bound by written non-use and non-disclosure terms and conditions at least as restrictive as those set forth in this Agreement with respect to the Confidential Information of the other Party (for clarity, this may be through employment agreements with such individuals).
- 3.5 <u>JSC Decision-Making Authority</u>. The members of each Party on the JSC shall collectively have one vote. Except as otherwise provided in this <u>Section 3.5</u> or <u>Section 5.3(d)</u>, decisions of the JSC shall be made by unanimous vote; provided, that at least one (1) representative from each Party participates in such vote. If the JSC does not reach unanimity with respect to a particular matter, and the JSC is unable to resolve the dispute within [***], then either Party may, by written notice to the other Party, have such matter referred to the Executive Officers, who shall meet promptly and negotiate in good faith to resolve the dispute. If the Executive Officers are unable, for whatever reason, to reach agreement on any matter within [***], then [***] shall have final decision-making authority. The co-chairpersons of the JSC from each of Qilu and Sesen must have bilateral agreement (which is not subject to the rest of this Section 3.5) on any [***].
- **3.6** Limitations on Authority of JSC. The JSC will have sole authority with respect to the responsibilities assigned to the JSC in Section 3.3 and elsewhere in this Agreement. For clarity, the JSC shall not have responsibility for, oversight over or decision-making authority with respect to, the Development and Commercialization of the Licensed Compound and Licensed Products outside the Field or outside the Territory. Neither Party, in exercising its final decision-making authority, shall have the authority or power to (a) amend or modify the terms of this Agreement, (b) avoid or seek to avoid any obligation of such Party under this Agreement, (c) waive compliance with the terms of this Agreement, (d) permit a Party to take an action that requires the prior written consent or other approval of the other Party under this Agreement, or (e) impose additional financial or other obligations on a Party that are not otherwise specified in this Agreement or agreed to by such Party.
- **3.7 Alliance Managers**. Each Party shall appoint a single English-speaking individual to act as the primary point of contact between the Parties in connection with the

Development, Manufacture and Commercialization of the Licensed Compound and Licensed Products in the Field in the Territory (the "Alliance Managers"). Each Party may at any time, and from time to time, appoint a different Alliance Manager by written notice to the other Party and may elect, upon mutual agreement by the Parties, to eliminate the responsibilities of the Alliance Managers. The Alliance Managers will (a) use good faith efforts to attend all meetings of the JSC, and may also serve as voting members of the JSC, and (b) be the first point of referral for all matters of conflict resolution, and bring disputes to the attention of the JSC in a timely manner.

Article 4

DEVELOPMENT AND COMMERCIALIZATION

- **4.1** Responsibility. Following the Effective Date and at all times thereafter during the Term, Qilu shall be solely responsible for all costs and expenses required to Develop, Manufacture and Commercialize the Licensed Compound and Licensed Products in the Field in the Territory, as well as all other costs and expenses associated with the Commercialization of the Licensed Compound and Licensed Products in the Field in the Territory, shall, from and after the Effective Date, assume all Liabilities associated with the foregoing activities unless this Agreement expressly otherwise provides, and except as expressly set forth herein [***]. All Development, Manufacture and Commercialization activities undertaken by or on behalf of Qilu or its Sublicensees shall be in compliance with all Applicable Laws.
- **4.2 Diligence**. Following the Effective Date and at all times thereafter during the Term, Qilu shall, in accordance with this Agreement and subject to Section 11.5, hereof, directly or through one or more permitted Sublicensees, use Commercially Reasonable Efforts to Develop the Licensed Compound and Licensed Products to obtain Regulatory Approval in the Field in the Territory, including but not limited to, using Commercially Reasonable Efforts to carry out Development of the Licensed Compound and Licensed Products in accordance with the Development Plan and the terms of this Agreement. Without limitation of the foregoing, following the Effective Date and at all times thereafter during the Term, Qilu shall use Commercially Reasonable Efforts to Develop, seek Regulatory Approval for, and upon receipt of such Regulatory Approval, Commercialize at least one (1) Licensed Product in the Field in the Territory.
- **4.3 Development Plan**. The Development of the Licensed Compound and Licensed Products in the Field in the Territory shall be conducted by Qilu pursuant to a development plan that will include a description of the Development activities to be performed in support of obtaining Regulatory Approval for a Licensed Product in the Field in the Territory, including projected timelines for the completion of such activities (the "**Development Plan**"). The initial high-level Development Plan agreed to by the Parties is attached hereto as **Exhibit D**, which will be promptly updated by Qilu and submitted to the JSC for review and approval upon Qilu's receipt of clarification from the applicable Regulatory Authorities as to the additional Development activities necessary to submit an MAA for a Licensed Product in the Field in China. Not later than [***] after December 31 of each Calendar Year during the Term when Development of the Licensed Compound and Licensed Products in the Field in the Territory is ongoing, Qilu shall, if required, submit to the JSC for its review and approval an updated

Development Plan for the pending Calendar Year. Such update shall take into account completion, commencement, changes in or cessation of Development activities not contemplated by the then-current Development Plan in sufficient detail to reflect the continued diligence of Qilu and its Sublicensees. Any material changes to the Development Plan made outside of the annual process to update the Development Plan shall be drafted by Qilu, including the addition of any Clinical Trial protocols or any material changes thereto, and delivered to the JSC. Qilu shall make any and all proposed changes to the Development Plan as a result of any interaction with any Regulatory Authority or Governmental Authority, and report such changes to the JSC. Sesen shall have the right to review and comment on any updates to the Development Plan. In the event Sesen reasonably disagrees with an update to the Development Plan, Qilu shall consider in good faith Sesen's comments relating thereto, provided, however, that subject to the last sentence of Section 3.5 Qilu's decision shall be final and binding upon the Parties.

- **4.4 Development Records**. Qilu shall maintain complete and accurate records of all work conducted by or on behalf of Qilu in furtherance of the Development of the Licensed Compound and Licensed Products and all material results and Data generated in conducting such activities. Such records shall be maintained in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes and in accordance with Applicable Laws. Sesen shall have the right to (a) receive a copy of all Clinical Trial reports for each Clinical Trial for the Licensed Compound and Licensed Products in the Field in the Territory, and (b) review and receive a report on the material results and material Data in the Development activities upon request, while Qilu shall not be obligated to provide Sesen with copies of the Development records except as required under this Agreement.
- Regulatory Activities. Qilu shall apply for and maintain, at Qilu's sole cost and expense, all Approvals, including Regulatory Approvals, relating to the Licensed Compound and the Licensed Products in the Field in the Territory, and all such Approvals shall be in Qilu's name except for any Imported Drug License that is required under Applicable Laws to be filed in Sesen's name. Qilu shall be responsible for the preparation of all Regulatory Materials and all communications and interactions with Regulatory Authorities with respect to the Licensed Compound and Licensed Products in the Field in the Territory, both prior to and subsequent to receipt of any Regulatory Approvals, provided that Qilu shall provide prior written notice and copies of all proposed Regulatory Materials, including any IND or MAA, [***] (or such less times if [***] is not practicable, but not less than [***])[***] in advance of filing for Sesen's review and comment, and Qilu will consider in good faith Sesen's comments to such Regulatory Materials prior to filing such Regulatory Materials with the applicable Regulatory Authorities. Sesen shall provide reasonable assistance requested by Qilu with respect to such Regulatory Materials, subject to Section 4.8. All Regulatory Materials and Regulatory Approvals in Qilu's name shall be owned solely by Qilu. Upon the request by a Regulatory Authority or Governmental Authority in the Territory to Qilu for any information or materials relating to the Licensed Compound or Licensed Products that have not already been provided to Qilu under the terms of this Agreement, Sesen shall promptly provide to Qilu such information or materials to the extent that such information or materials are in Sesen's possession, readily available and within Sesen's Control, or can be obtained with reasonable efforts from its contract manufacturers. Qilu shall (a) promptly provide Sesen with an electronic copy of all material Regulatory Materials and material correspondence with Regulatory Authorities or Governmental Authorities, including any IND or MAA, and (b) upon the request of Sesen, provide Sesen with a

written summary in English of the Regulatory Materials and correspondence with Regulatory Authorities and Governmental Authorities, in each case by or on behalf of Qilu or its permitted Sublicensees with respect to the Development of the Licensed Compound and Licensed Products in the Field in the Territory. However, Qilu shall not be obligated to provide copies of the Regulatory Materials and correspondence with Regulatory Authorities and Governmental Authorities except as required under this Agreement.

4.6 Reporting Obligations.

- (a) *Development Reports*. On January 31 and July 31 of each Calendar Year during any period in which activities described in the Development Plan are ongoing, Qilu shall submit to Sesen a report summarizing in reasonable detail Qilu's and its permitted Sublicensees' activities related to the Development of the Licensed Compound and Licensed Products during the preceding six (6) month period. Sesen shall have the opportunity to discuss each such report and its contents with Qilu, either through the JSC or in any other manner reasonably acceptable to Sesen and Qilu, and Qilu shall provide to Sesen, when practicable, any additional documentation or information reasonably requested by Sesen relating to such reports.
- (b) *Commercialization Reports*. On [***] after the completion of the activities described in the Development Plan, Qilu shall submit to Sesen a report summarizing in reasonable detail Qilu's and its permitted Sublicensees' activities related to the Manufacture (to the extent that Qilu and its permitted Sublicensees are conducting Manufacturing activities under this Agreement) and Commercialization of the Licensed Compound and Licensed Products during the preceding year. Sesen shall have the opportunity to discuss each such report and its contents with Qilu, either through the JSC or in any other manner reasonably acceptable to Sesen, and Qilu shall provide, when practicable, to Sesen any additional documentation or information reasonably requested by Sesen relating to such reports.
- (c) Commercial Launch Plan and Marketing Materials. Approximately [***] prior to the anticipated First Commercial Sale of a Licensed Product in the Field in the Territory, Qilu shall submit to Sesen its proposed commercial launch plan for such Licensed Product for Sesen's review and comment. Upon the written request of Sesen from time to time after receipt of Regulatory Approval for the first Licensed Product in the Field in the Territory, Qilu shall provide to Sesen (i) Qilu's then-current marketing plan for the Licensed Products in the Field in the Territory, and (ii) the material marketing materials then being used by Qilu to market and promote the Licensed Products in the Field in the Territory.

4.7 <u>Technology Transfer</u>.

- (a) *Initial Technology Transfer*. (i) Within the later of [***] after the Effective Date and [***], Sesen shall transfer and deliver to Qilu, at no cost to Qilu, an electronic copy of all material Licensed Know-How (including Know-How reasonably necessary for the clinical and/or commercial manufacture of the Licensed Compound and Licensed Products, herein referred to as the "**Manufacturing Know-How**") as listed in the initial Product Documentation set forth in **Exhibit F** as having such deadline and in tangible form, including clinical and non-clinical Data. (ii) From time to time thereafter during the Term, Sesen shall transfer and deliver to Qilu all outstanding tangible embodiments of the Licensed Know-How (other than Data and reports that are subject to Section 4.9(a)) not previously transferred and delivered to Qilu, as well as other documents contained within the Licensed IP that are deemed necessary by both Parties for Development and Manufacture of the Licensed Compound and Licensed Products by Qilu.
- (b) Transfer of Manufacturing Know-How. Within [***] of the Effective Date, Sesen shall commence the Technology Transfer to Qilu or its designated contract manufacturing organization pursuant to the Technology Transfer Plan. Within [***] of the Effective Date, Sesen or its designated contract manufacturing organization shall initiate shipment to Qilu all the "Drug substance materials" (as defined in the Technology Transfer Plan). From time to time thereafter during the Term, Sesen shall use [***] to make available to, and cause its contract manufacturers, including FUJIFILM Diosynth Biotechnologies and Baxter Oncology GmbH (herein referred to as "CMO") to provide, (i) Qilu or its designee all Licensed IP in the Product Documentation that is necessary for the Development and Manufacture of the Licensed Product, including but not limited to providing the Product Documentation as set forth in Exhibit C and Exhibit F in accordance with the timelines set forth therein and other critical information Controlled by Sesen contained within the Licensed IP that are required by NMPA to ensure a successful IND filing and MAA in the Territory by Qilu; and (ii) provide Qilu or its designee with reasonable technical assistance in a timely manner to enable Qilu or its designee to manufacture the Licensed Product, provided however that Sesen shall be solely responsible for any technology transfer fee, license fee and other payment due to its contract manufacturer for such technology transfer.
- (c) *Continuing Obligations*. After the initial transfer of the Licensed Know-How contemplated by <u>Sections 4.7(a)</u> and <u>4.7(b)</u> above, Sesen shall use [***] to provide the subsequent Product Documentation as set forth in Exhibit F upon becoming available to Sesen, but not later than each deadline set out in Exhibit F. From time to time during the Term at Qilu's request, Sesen shall make [***], to transfer and deliver to Qilu all other tangible embodiments of the Licensed Know-How developed by Sesen following the Effective Date, including Manufacturing Know-How, not previously transferred and delivered to Qilu, as well as other documents contained within the Licensed IP that are deemed necessary by both Parties for Development and Manufacture of the Licensed Compound and Licensed Products by Qilu.
- (d) *Failure of fulfill of the Obligations*. In the event that [***], Qilu shall be entitled to terminate this Agreement, Sesen shall be obligated to refund the Upfront Payment to Qilu within 30 days upon Qilu request.

4.8 Technical Assistance. For a period beginning on the Effective Date until [***], Sesen shall, [***] provide Qilu with reasonable technical assistance as requested by Qilu with preparing Regulatory Materials and obtaining Regulatory Approval for the Licensed Compound and Licensed Products in the Field in the Territory. Sesen shall also provide assistance to enable Qilu or its permitted Sublicensee to Manufacture the Licensed Compound and Licensed Products as specified in the Technology Transfer Plan ("Technical Assistance"). The [***] hours of Technical Assistance shall be provided at [***], with each additional hour thereafter provided at the rate of [***] per hour, which may be prorated as necessary. Within [***] after the end of each Calendar Quarter, Sesen shall deliver to Qilu an invoice setting forth the number of hours of Technical Assistance provided by Sesen to Qilu during the prior Calendar Quarter and the amounts owed to Sesen with respect thereto, which invoice shall be paid in accordance with Section 5.4.

4.9 Data Sharing and Use.

- (a) *Data Sharing*. In addition to the technology transfer obligations under <u>Section 4.7</u> and the adverse event and safety reporting obligations under <u>Section 4.11</u>, each Party shall keep the other Party reasonably informed on the Development of the Licensed Product in its territory, and promptly provide the other Party, through the JSC if practicable or if not practicable directly to the other Party, with copies of all material Data, including non-clinical and clinical data, reports and Regulatory Materials (final report for Clinical Trials shall be completed within one (1) months after database lock), that is in each case (i) generated from its (or its Affiliates' or sublicensees') Development of the Licensed Compound and Licensed Products in its respective territory, (ii) Controlled by such Party and permitted to be disclosed by such Party to the other Party, and (iii) necessary for the Development of the Licensed Compound or Licensed Products in the other Party's territory. Upon requested by the JSC, Qilu shall provide to Sesen an English summary of any material Data, reports and Regulatory Materials delivered under this <u>Section 4.9(a)</u>. Each Party shall be responsible for obtaining all Approvals and completing all filings required under Applicable Laws for the transfer of Data, reports and Regulatory Materials to the other Party as required under this <u>Section 4.9(a)</u>.
- (b) *Use of Data and Results*. Each Party shall have the right to use and reference any Data, reports and Regulatory Materials disclosed to such Party under <u>Section 4.9(a)</u> in support of obtaining Regulatory Approval for the Licensed Compound and Licensed Products in its respective territory, without additional consideration, in each case consistent with the rights and licenses granted by each Party to the other Party under <u>Article 2</u>.
- **4.10** Supply Agreement and Quality Agreement. (a) Subject to this Section 4.10 and Section 4.12, Sesen shall be responsible for Manufacturing all quantities of the Licensed Compound and Licensed Products necessary for Qilu to Develop and Commercialize the Licensed Compound and Licensed Products in the Field in the Territory until the [***] (the "Supply End Date"). Within [***] after the Effective Date, the Parties shall negotiate in good faith the terms of and enter into a supply agreement in accordance with the term sheet attached hereto as **Exhibit E** (the "Supply Agreement") and a related quality agreement (the "Quality Agreement") pursuant to which Sesen shall supply to Qilu, directly or through an approved Third Party, quantities of the Licensed Compound and Licensed Products in [***] form to support the Development and Commercialization of Licensed Products in the Field in the

Territory. The Supply Agreement and Quality Agreement shall contain such other terms customary and reasonable for agreements of such type. Following the Supply End Date, Qilu shall be responsible at its sole cost for Manufacturing all quantities of the Licensed Compound and Licensed Products necessary for Qilu to Develop and Commercialize Licensed Products in the Field in the Territory. (b) For any transfer of the "Drug substance materials" and Drug Product Materials according to the Technology Transfer Plan, the Parties agree to sign separate material transfer agreements before shipment, the price thereof shall be deducted from the Upfront Payment or Milestone Payment due to Sesen.

- 4.11 Safety Data Exchange Agreement. Within [***] of the Effective Date, but in any event prior to commencement of any Clinical Trials with the Licensed Compound or Licensed Products in the Field in the Territory, the Parties will in good faith negotiate and finalize a separate safety Data exchange agreement (the "Pharmacovigilance Agreement"), the terms of which shall set forth the obligations, procedures and timelines for exchanging Data (such as the occurrence of adverse events and serious adverse events) observed in connection with the Licensed Compound and Licensed Products in order to enable each Party to comply with its safety reporting obligations to Regulatory Authorities in its respective territory. Prior to the execution of the Pharmacovigilance Agreement, each Party shall promptly notify the other Party of any information observed in connection with the Licensed Compound or Licensed Products necessary to enable such Party to comply with its safety reporting obligations to Regulatory Authorities or Governmental Authorities in its respective territory. Sesen shall maintain the global safety database for the Licensed Compound and Licensed Products, which shall include adverse events and other information relating to the safety of the Licensed Compound and Licensed Products. Upon reasonable advanced request by Qilu, Sesen shall make the Data maintained in the global safety database accessible and available to Qilu in the form in which such Data is then-currently maintained by Sesen.
- **4.12 Territory Filings and Approvals**. The Parties acknowledge and agree that this Agreement shall be subject in all respects to any applicable filings and Approvals required from any Governmental Authority in the Territory with respect to the execution and performance hereof ("**Territory Filings and Approvals**"). Qilu shall be solely responsible for making, obtaining and maintaining all such Territory Filings and Approvals, at its sole cost and expense. Sesen shall be solely responsible for making, obtaining and maintaining any applicable filings and Approvals required from the U.S. government with respect to the execution of this Agreement, [***]. As of the Effective Date or thereafter during the Term, [***], Qilu shall be entitled to terminate this Agreement, and Sesen shall refund Qilu all the payments that have been paid to Sesen hereunder.
- 4.13 <u>Development and Commercialization for Additional Indications</u>. The Parties acknowledge and agree that (a) Sesen has initiated the submission of a BLA with the FDA for a Licensed Product for the treatment of BCG-unresponsive NMIBC, and (b) the Licensed Compound has potential additional uses within the Field. If either Party desires to initiate Development activities for the use of the Licensed Compound or a Licensed Product for the prevention or treatment of cancer other than NMIBC or its subtypes, such Party shall notify the other Party in writing and the Parties shall negotiate in good faith any necessary amendments to this Agreement, including the Development Plan, to account for such Development activities.

Article 5

FINANCIAL PROVISIONS

- **5.1** <u>Upfront Payment</u>. Subject to <u>Section 4.10(b)</u> and receipt of all the Product Documentation pursuant to <u>Section 4.7(a)(i)</u> [***], within forty-five (45) Business Days of the Effective Date (the "**Upfront Payment Due Date**"), Qilu shall pay to Sesen a one-time, non-refundable, non-creditable upfront payment of twelve Million Dollars (\$12,000,000) (the "**Upfront Payment**").
- **5.2 Development Milestone Events**. Subject to the terms and conditions set forth in Section 4.10(b) and this Section 5.2, Qilu shall make each of the one-time, non-refundable, non-creditable milestone payments to Sesen that are set forth below upon the first occurrence of the corresponding milestone event by or on behalf of Qilu or its Sublicensee with respect to the first Licensed Product. Each milestone payment under this Section 5.2 shall be paid only once with respect to the first time such milestone event is achieved.

Milestone Number	<u>Milestone</u> <u>Event</u>	<u>Milestone</u> <u>Payment (US\$)</u>
1	Approval* of the first IND for a Licensed Product in China	\$[***]
2	Acceptance by the NMPA** of submission of the first MAA for a Licensed Product in China	\$[***]
3	Approval of an MAA for a Licensed Product by the NMPA in China for the first indication	\$[***]
4	Approval of an MAA for a Licensed Product by the NMPA in China for the second indication	\$[***]
5	Technology Transfer Completion	\$[***]

^{*} Approval of the first IND may be demonstrated by issuance of a "Clinical Trial Notice" (in Chinese: 临床试验通知书).

^{**}Acceptance may be demonstrated by issuance of a "Drug Registration Application Acceptance Notice" in respect of such submission.

⁽a) *Payment*. Qilu shall notify Sesen in writing promptly, but in no event later than [***], after the achievement of each milestone event set forth in this <u>Section 5.2</u>. Qilu shall pay all such milestone payments due to Sesen in Dollars within [***] following the achievement of the corresponding milestone event.

5.3 Royalties.

- (a) Royalty Rate and Royalty Term. Subject to the remainder of this Section 5.3, Qilu shall pay to Sesen on a Licensed Product-by-Licensed Product and Relevant Region-by-Relevant Region basis a royalty in the amount of twelve percent (12%) of Net Sales of Licensed Products sold by or on behalf of Qilu or its Sublicensees in the Territory. Qilu's obligation to pay royalties with respect to a Licensed Product in a Relevant Region in the Territory shall commence upon the First Commercial Sale of such Licensed Product in such Relevant Region and shall expire on the latest of (i) the expiration of the last Valid Claim of a Licensed Patent or Improvement Patent covering or claiming the composition of matter, method of treatment or method of manufacture of the Licensed Compound or such Licensed Product in such Relevant Region, (ii) the expiration of regulatory or Data exclusivity for such Licensed Product in such Relevant Region, and (iii) the date that is twelve (12) years after First Commercial Sale of such Licensed Product in such Relevant Region (the "Royalty Term"). The Parties acknowledge and agree that the foregoing royalty is intended to compensate Sesen for the value of the Licensed IP, including the value of the Licensed Know-How, and is not intended to be solely a Patent royalty.
- (b) Royalty Reduction for No Valid Claim or Obtaining of MAA of any Generic Drug. If a Licensed Product is generating Net Sales in a Relevant Region in the Territory during the Royalty Term at a time on the earlier of (i) when there is no Valid Claim in the Relevant Region of the Licensed Patent or Sesen's Improvement Patent (excluding Qilu patent) covering or claiming the composition of matter, method of treatment or method of manufacture of such Licensed Product that are utilized by Qilu, and (ii) any [***], then the royalty rate applicable to the Net Sales in such Relevant Region for such Licensed Product shall be reduced to [***]. For clarification, [***].
- (c) *Reports; Royalty Payments*. Until the expiration of all royalty payment obligations under this <u>Section 5.3</u>, Qilu shall make unaudited written reports to Sesen within [***] after the end of each Calendar Quarter during which there was Net Sales of a Licensed Product in the Territory, each such written report in reasonable detail stating, on a Licensed Product-by-Licensed Product and Relevant Region-by-Relevant Region basis, (i) gross sales of each Licensed Product sold by or on behalf of Qilu and its Sublicensees, in local currency and Dollars, during such Calendar Quarter and Calendar Year, (ii) a calculation of Net Sales of each Licensed Product sold by or on behalf of Qilu and its Sublicensees, in local currency and Dollars, during such Calendar Quarter and Calendar Year, (iii) a calculation of any royalty reduction applied in accordance with <u>Section 5.3(b)</u> or <u>Section 5.3(d)</u>, and (iv) a calculation of the royalties due to Sesen under this <u>Section 5.3</u> with respect to such Net Sales. [***].
- (d) *Royalty Stacking*. If Qilu, and its Affiliate or Sublicensee, determines that it is necessary or useful to obtain a license from any third party in order to exercise any of the rights granted to Qilu, and its Affiliate or Sublicensee hereunder, and the co-chairpersons of the JSC from each of Qilu and Sesen have bilateral agreement (which is not subject to Section 3.5) that a deduction may be taken under this Section 5.3(d), then up to [***], based on documentation regarding the payments to third parties for such in-licensed technology, of any royalties and/or a one-time upfront licensing fee paid to such third party under such license applicable to a Licensed Product may be deducted from royalties otherwise due to the Sesen

under this Agreement provided that, no such royalty payment shall be reduced by any such deduction to less than [***] of the amount otherwise due.

- **5.4** Method of Payments; Late Payments. All payments due from Qilu to Sesen under this Agreement shall be paid in Dollars by wire transfer to a bank account designated in writing by Sesen. Except as otherwise specified, all payments due from Qilu to Sesen under this Agreement shall be paid within [***] after receipt of an invoice for such payments. Late payments shall accrue interest at the rate of [***] per day until the late payment is paid up.
- **5.5 Audit.** Qilu shall keep and maintain for [***], and shall ensure that its Sublicensees keep and maintain for [***], complete and accurate records of sales of Licensed Products by or on behalf of Qilu and its Sublicensees in sufficient detail to allow Sesen to confirm the accuracy of royalties paid and/or payable under Section 5.3 hereunder. For avoidance of doubt, Sesen shall have the right to audit Sublicensees consistent with the terms of this Section 5.5. Sesen shall have the right during such [***] period to appoint at its expense an independent certified public accountant reasonably acceptable to Qilu to audit its relevant records for the purpose of verifying reports provided by Qilu under Section 5.3(c). Qilu shall make its records available for audit by such independent certified public accountant during regular business hours at such place or places where such records are customarily kept, upon [***] written notice from Sesen. All records made available for audit shall be deemed to be the Confidential Information of Qilu and, upon the request of Qilu, the independent certified public accountant selected by Sesen shall enter into a confidentiality agreement with Qilu in a form reasonably acceptable to Qilu regarding the use and disclosure of such Confidential Information. The results of each audit, if any, shall be binding on both Parties absent manifest error. [***] shall bear the full cost of such audit, except in the event that the results of the audit reveal an underpayment of royalties to Sesen under Section 5.3 of [***] or more over the period being audited, in which case the audit fees for such examination shall be paid by [***]. If such audit reveals an underpayment of royalties, Qilu shall pay any unpaid royalties to Sesen within [***] of the completion of the audit. If such audit reveals an overpayment of royalties, then Sesen shall either, at Qilu's request, pay any overpaid royalties to Oilu within [***] of the completion of the audit or Oilu shall be entitled to credit such overpayment against future amounts payable to Sesen under this Agreement.

5.6 Taxes.

(a) Withholding Tax. Under any Applicable Law, Qilu shall be required to deduct or withhold taxes ("Withholding Tax") with respect to any payment to be made by Qilu to Sesen pursuant to this Agreement (each such payment, a "Payment"), any and all Withholding Tax or similar taxes imposed or levied on account of the Payment which are required by the applicable tax authorities shall be deducted by Qilu prior to remittance and the remainder shall be remitted to Sesen. Qilu will furnish Sesen with proof of payment of such taxes within [***] following the payment thereof. Each Party shall provide reasonable assistance to the other Party to obtain a refund of taxes withheld, or obtain a credit with respect to taxes paid. Sesen shall not be responsible for any penalties and interest resulting from the failure by Qilu to collect or remit any Withholding Tax payable on the Payments.

- (b) *VAT*. Notwithstanding anything contained in Section 5.6(a), this Section 5.6(b) shall apply with respect to value added tax, ad valorem, sales and use, goods and services or similar tax and local surcharges chargeable on the supply or deemed supply of goods or services, sales and use taxes, transaction taxes, consumption taxes and other similar taxes required by Applicable Laws, including any interest, penalties or other additions to tax thereon (collectively, "VAT"). All Payments are inclusive of VAT. Any VAT that is chargeable in respect of any Payment shall be deducted by Qilu prior to remittance to Sesen, the remainder of the Payment shall be remitted to Sesen and Qilu shall be responsible for paying such VAT at the applicable rate in respect of the Payments. As requested by Sesen, and at Sesen's own cost, the Parties shall reasonably cooperate to obtain available reductions, credits, or refunds of VAT charged by applicable tax authorities in the Territory, and Qilu shall return to Sesen the amount of any such reductions, credits or refunds (less Qilu's administrative expenses relating thereto) received by Qilu within thirty (30) days thereof.
- 5.7 <u>Currency and Approvals</u>. With respect to sales of Licensed Products invoiced in Dollars, the Net Sales and the amounts due hereunder will be expressed in Dollars. With respect to sales of Licensed Products invoiced in a currency other than Dollars, the Net Sales and amounts due hereunder will be reported in Dollars, calculated using the average middle point rates published by the People's Bank of China over the last Calendar Quarter. Qilu shall, at its sole cost and expense, be responsible for applying for and obtaining all necessary Approvals, and making all other filings necessary for the conversion of any local currency (including Renminbi) to Dollars and the remittance to Sesen of any amounts payable to Sesen under this Agreement.

Article 6

INTELLECTUAL PROPERTY RIGHTS

6.1 **Prosecution and Maintenance of Patents**.

(a) *Licensed Patents*. Sesen shall have the first right, but not the obligation, to prepare, file, prosecute, and maintain each of the Licensed Patents throughout the Territory; and Sesen represents and warrants that it will do so in a timely and professional manner; provided, that Qilu acknowledges and agrees that (i) Sesen does not have any right to prepare, file, prosecute, and maintain the Patents included within the Coda Technology under the terms of the Coda Agreement, (ii) Micromet AG has the sole right under the terms of the Micromet License Agreement to prepare, file, prosecute and maintain the Patents included within the Micromet Technology, and (iii) XOMA Ireland Limited retains the right, at its sole discretion, to maintain the Patents included within the Xoma Technology under the terms of the Xoma License Agreement, and, in each case of the Patents referenced in (i), (ii) and (iii), this Section 6.1(a) shall not apply with respect thereto. Sesen shall invoice Qilu on a monthly basis for all reasonable and documented expenses related to the preparation, filing, prosecution and maintenance of the Licensed Patents in the Territory, and Qilu shall reimburse Sesen for such expenses within [***] of receipt of an invoice relating thereto. Upon the request of Qilu, Sesen shall provide to Qilu reasonable supporting documentation relating to the patent expenses set forth in an invoice. Sesen shall consult with Qilu and keep Qilu fully informed of the status of the Licensed Patents in the Territory, including without limitation by promptly providing Qilu with a copy of all material correspondence sent to and received from patent offices in the

Territory in connection with the Licensed Patents. Sesen shall provide Qilu a full opportunity to review in advance and comment in advance on all material filings and correspondence with patent offices with respect to the prosecution and maintenance of the Licensed Patents in the Territory, and Sesen shall consider Qilu's comments regarding such filings and correspondence in good faith. Sesen will provide Qilu such material filings and correspondence within [***] in advance of the filing due date whenever possible. If, during the Term, Sesen intends to allow any Licensed Patent to expire or intends to otherwise abandon any such Licensed Patent, Sesen shall notify Qilu of such intention or decision at least [***] prior to any filing or payment due date, or any other date that requires action, in connection with such Licensed Patent, and Qilu shall thereupon have the right, but not the obligation, to assume responsibility for the preparation, filing, prosecution or maintenance thereof in the Territory at its sole cost and expense; and Qilu will thereafter own all rights, title and interest in and to such Licensed Patent if owned by Sesen, and Sesen will execute and deliver such assignment documents when requested by Qilu. Each Party agrees to reasonably cooperate with the other Party to execute all lawful papers and instruments and to provide consultation and assistance as may be reasonably necessary in the prosecution and maintenance of the Licensed Patents in a manner consistent with this Section 6.1(a).

Qilu Patents. Qilu shall have the first right, but not the obligation, to prepare, file, prosecute, and maintain each of the Qilu Patents throughout the Sesen Territory, Qilu shall invoice Sesen for all reasonable and documented expenses related to the preparation, filing, prosecution and maintenance of the Qilu Patents in the Sesen Territory, and Sesen shall reimburse Qilu for such expenses within [***] of receipt of an invoice relating thereto. Upon the request of Sesen, Qilu shall provide to Sesen reasonable supporting documentation relating to the patent expenses set forth in an invoice. Sesen shall have the right to terminate its obligation to reimburse Qilu for expenses related to the preparation, filing, prosecution and maintenance of any Oilu Patent in the Sesen Territory by providing Oilu with written notice thereof, and upon receipt of such written notice by Qilu such Qilu Patent that is the subject of such written notice shall no longer be licensed to Sesen under <u>Section 2.5</u> or be subject to the terms of this Section 6.1(b). Oilu shall consult with Sesen and keep Sesen reasonably informed of the status of the Oilu Patents in the Sesen Territory, including without limitation by promptly providing Sesen a copy of all material correspondence to and received from patent offices in the Sesen Territory in connection with the Qilu patents. Qilu shall provide Sesen a reasonable opportunity to review in advance and comment in advance on all material filings and correspondence with patent offices with respect to the prosecution and maintenance of the Qilu Patents in the Sesen Territory, and Qilu shall consider Sesen's comments regarding such filings and correspondence in good faith. Oilu will provide Sesen with such material filings and correspondence [***] in advance of filing due dates whenever possible. If, during the Term, Oilu intends to allow any Oilu Patent in the Sesen Territory to expire or intends to otherwise abandon any such Qilu Patent, Qilu shall notify Sesen of such intention or decision at least [***] prior to any filing or payment due date, or any other date that requires action, in connection with such Qilu Patent, and Sesen shall thereupon have the right, but not the obligation, to assume responsibility for the preparation, filing, prosecution or maintenance thereof in the Sesen Territory at its sole cost and expense. Each Party agrees to reasonably cooperate with the other Party to execute all lawful papers and instruments and to provide consultation and assistance as may be reasonably necessary in the prosecution and maintenance of the Oilu Patents in a manner consistent with this Section 6.1(b).

6.2 Third Party Infringement.

(a) *Notice*. If either Party becomes aware of any suspected infringement or misappropriation by a Third Party of any Licensed Patents or Licensed Know-How (each, an "**Infringement**"), then that Party shall promptly notify the other Party and provide it with all material details of such activities of which it is aware.

(b) *Upstream License Agreements*.

- (i) The Parties acknowledge and agree that (x) Sesen does not have any right to enforce the Patents included within the Coda Technology under the terms of the Coda Agreement, (y) Micromet AG has the exclusive right and sole discretion to stop infringement of the Patents included within the Micromet Technology under the terms of the Micromet Agreement, and (z) XOMA Ireland Limited retains the right, at its sole discretion, to enforce and otherwise protect the Patents included within the Xoma Technology under the terms of the Xoma License Agreement, and, in each case of the Patents referenced in (x), (y) and (z), Section 6.2(c) through Section 6.2(g) (inclusive) shall not apply with respect thereto.
- (ii) The Parties acknowledge and agree that the right to enforce the University of Zurich Patents against any Infringement is limited by and subject to the terms of the University of Zurich License Agreement. Sesen shall coordinate with Qilu prior to (x) requesting the University of Zurich to take legal action relating to any Infringement of the University of Zurich Patents, and (y) bringing any legal action relating to any Infringement of the University of Zurich Patents. To the extent permitted under the University of Zurich License Agreement, Sesen shall permit Qilu to have the first right to address Infringement of the University of Zurich Patents in accordance with Section 6.2(c) below.
- (c) *Qilu Right to Enforce*. Subject to <u>Section 6.2(b)</u>, Qilu shall have the first right, but not the obligation, to address such Infringement in the Field in the Territory by taking reasonable steps, which may include the institution of legal proceedings or other actions (an "Action"), and to compromise or settle such Action; provided, that (i) Qilu shall keep Sesen reasonably informed about such Action and Sesen shall provide all reasonable cooperation to Qilu in connection with such Action, (ii) Qilu shall not take any position with respect to such Action in any way that is reasonably likely to directly and adversely affect the scope, validity or enforceability of the Licensed Patents, or compromise or settle any such Action, without the prior consent of Sesen, which consent shall not be unreasonably withheld, and (iii) if Qilu does not intend to prosecute or defend an Action, or ceases to diligently pursue such an Action, it shall promptly inform Sesen in such a manner that such Action will not be prejudiced and <u>Section 6.2(d)</u> shall apply.
- (d) Sesen Right to Enforce. In the event of an Infringement described in Section 6.2(a), if (i) Qilu informs Sesen that it does not intend to prosecute an Action in respect of the Licensed Patents or the Licensed Know-How, (ii) within [***] after notice of Infringement Qilu has not commenced any such Action, or (iii) if Qilu thereafter ceases to pursue such Action, then Sesen shall have the right, at its own expense, upon notice to Qilu to take appropriate action

to address such Infringement, including by initiating its own Action or taking over prosecution of any Action initiated by Qilu. In such event, Sesen shall keep Qilu fully informed about such Action and Qilu shall provide all reasonable cooperation to Sesen in connection with such Action.

- (e) *Right to Representation.* To the extent permitted by Applicable Laws, each Party shall have the right to participate and be represented by counsel that it selects, in any Action instituted under <u>Section 6.2(c)</u> or <u>Section 6.2(d)</u> by the other Party. If a Party with the right to initiate an Action to eliminate an Infringement lacks standing to do so and the other Party has standing to initiate such Action, then the Party with the right to initiate an Action may name the other Party as plaintiff in such Action or may require the Party with standing to initiate such Action at the expense of the other Party.
- (f) *Cooperation*. In any Action instituted under this <u>Section 6.2</u>, the Parties shall cooperate with and assist each other in all reasonable respects.
- (g) Share of Recoveries. Except as otherwise provided, the costs and expenses of the Party bringing suit under this Section 6.2 shall be borne by such Party, and any damages or other monetary awards recovered shall be shared as follows: (i) the amount of such recovery actually received by the Party controlling such Action shall first be applied to the out-of-pocket costs of each Party in connection with such Action; (ii) if Qilu is the Party controlling such Action, then any remaining proceeds shall be deemed to be Net Sales and subject to the payment of royalties in accordance with Section 5.3; or (iii) if Sesen is the Party controlling such Action, then any remaining proceeds shall be retained by Sesen; provided, that if Sesen and Qilu are both joined in such Action and the amount of recovery is allocated by a final and non-appealable adjudication, then any damages or other monetary awards recovered shall be shared pursuant to the division set out in such adjudication. A settlement or consent judgment or other voluntary final disposition of a suit under this Section 6.2 may not be entered into without the consent of the Party not bringing the suit, which consent shall not be unreasonably withheld.
- **6.3 Defense of Claims Brought by Third Parties.** In the event that any action, suit or proceeding is brought against either Party or an Affiliate or sublicensee of either Party alleging the misappropriation of the Know-How or the infringement of the Patents of a Third Party by the making, having made, use, sale, offering for sale, importation or exportation of the Licensed Compound or a Licensed Product in the Field in the Territory, such Party shall notify the other Party within [***] of the earlier of (a) receipt of service of process in such action, suit or proceeding, or (b) the date such Party becomes aware that such action, suit or proceeding has been instituted, and the Parties shall meet as soon as possible to discuss the overall strategy for defense of such matter. Unless the Parties otherwise agree in writing, each Party shall have the right to defend itself against a suit that names it as a defendant (the "**Defending Party**"). None of the Parties shall enter into any settlement of any claim described in this <u>Section 6.3</u> that admits to the invalidity or unenforceability of the Licensed Patents, incurs any financial or other liability on the part of the other Party without such other Party's prior written consent, not to be unreasonably withheld, conditioned or delayed. In any event, the other Party shall reasonably assist the Defending Party and cooperate in any such litigation at the Defending Party's reasonable request and expense. If both Parties are Defending Parties and are both deemed responsible in connection

with any suit or claim subject to this <u>Section 6.3</u>, any resulting damages, settlement amounts and expenses shall be borne by the Parties in proportion to their relative responsibility unless a final and non-appealable adjudication states otherwise. Notwithstanding the foregoing, if Qilu is the Defending Party with respect to the Licensed IP, Sesen shall, at Sesen's own cost and expense, assist Qilu in defending against or otherwise dismissing the allegation, accusation or charge, including, without limitation, providing modified Licensed IP that is non-infringing, or assisting Qilu to obtain a license from such Third Party, [***]. If [***], then Qilu may terminate this Agreement under <u>Section 10.4(c)</u> and Sesen shall refund all payments Qilu has paid.

6.4 Patent Marking. Qilu will mark, and will cause its Sublicensees to mark, the Licensed Products with all Licensed Patents in accordance with Applicable Laws, which marking obligation will continue for as long as (and only for as long as) required under Applicable Laws.

Article 7

CONFIDENTIALITY

- 7.1 Nondisclosure and Non-Use. Each Party agrees that, for so long as this Agreement is in effect and for the further period of [***] thereafter, a Party (the "Receiving Party") receiving or possessing Confidential Information of the other Party (the "Disclosing Party") shall, and shall cause its employees, representatives, Affiliates, consultants, contractors, agents and sublicensees to: (a) maintain in confidence such Confidential Information using not less than the efforts such Receiving Party uses to maintain in confidence its own proprietary industrial information of similar kind and value (but no less than reasonable care), (b) not disclose such Confidential Information to any Third Party without the prior written consent of the Disclosing Party, except for disclosures expressly permitted or required below, and (c) not use such Confidential Information for any purpose except those permitted by this Agreement, including in connection with exercising its rights or fulfilling its obligations under this Agreement (it being understood that this clause (c) shall not create or imply any rights or licenses not expressly granted under Article 2 hereof). Each Receiving Party shall be responsible for any breach of these obligations by any of its employees, representatives, Affiliates, consultants, contractors, agents and sublicensees to which it discloses or provides access to any Confidential Information of the Disclosing Party. Each Receiving Party shall take all reasonable action under Applicable Law to enforce the confidentiality obligations hereunder against any employees, representatives, Affiliates, consultants, contractors, agents and sublicensees to which it discloses or provides access to any Confidential Information of the Disclosing Party.
- **7.2 Exceptions**. The obligations in Section 7.1 shall not apply with respect to any portion of the Confidential Information that the Receiving Party can show by competent proof:
- (a) was known to the Receiving Party or any of its Affiliates, without any obligation to keep it confidential or any restriction on its use, prior to disclosure by the Disclosing Party;
- (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;

- (c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the Receiving Party in breach of this Agreement;
- (d) is subsequently disclosed to the Receiving Party or any of its Affiliates by a Third Party lawfully in possession thereof and without any obligation to keep it confidential or any restriction on its use; or
- (e) has been independently developed by employees or contractors of the Receiving Party or any of its Affiliates without the aid, application or use of Confidential Information of the Disclosing Party as demonstrated by documented evidence prepared contemporaneously with such independent development and maintained in the ordinary course of business.
- **7.3 Authorized Disclosure**. The Receiving Party may disclose Confidential Information belonging to the Disclosing Party to the extent (and only to the extent) such disclosure is reasonably necessary in the following instances:
- (a) preparing, filing or prosecuting Patents; preparing, filing or prosecuting Regulatory Materials with respect to obtaining and maintaining Approvals from Regulatory Authorities relating to the Licensed Products, including Regulatory Approvals, and prosecuting or defending litigation;
- (b) subject to Section 7.6, complying with Applicable Laws (including the rules and regulations of any national securities exchange on which the securities of the Receiving Party or its Affiliates are listed, Applicable PRC Laws and rules issued by SAFE and by the State Intellectual Property Office of China) and with judicial process, if in the reasonable opinion of the Receiving Party's counsel, such disclosure is necessary for such compliance, provided that the Receiving Party shall promptly notify the other Party of such required disclosure so that the Disclosing Party can seek a protective order or other appropriate remedies and, at the Disclosing Party's request and expense, reasonably assist the Disclosing Party in seeking such protective order or other reasonable remedies; and
- (c) disclosure (i) in connection with the performance of this Agreement and solely on a "need to know basis", to Affiliates, potential or actual investors, investments bankers, collaborators (including potential sublicensees), or employees, contractors, or agents, or (ii) solely on a "need to know basis" to potential or actual investment bankers, consultants, advisors, investors, partners, collaborators, lenders, or acquirers, each of whom in the case of clause (i) or (ii) prior to disclosure must be bound by written obligations of confidentiality and non-use no less restrictive than the obligations set forth in this <u>Article 7</u>.
- **7.4** Press Release; Disclosure of Agreement. Except to the extent required by Applicable Laws or the rules of a securities exchange or securities listing organization, neither Party shall issue any other press release, published scientific articles or reports, or other public disclosures concerning this Agreement, the subject matter hereof or the Parties' activities hereunder, or any results or Data arising hereunder, except with the other Party's prior written consent not to be unreasonably withheld, delayed or conditioned. The Parties agree to consult

with each other reasonably and in good faith with respect to the text and timing of any such press releases and disclosures prior to the issuance thereof, and a Party may not unreasonably withhold, condition or delay consent to such releases and disclosures, and shall give due consideration to any reasonable comments by the non-filing Party relating to such releases and disclosures, including where applicable subject matter for which confidential treatment may be sought. A Party may publicly disclose without regard to the preceding requirements of this <u>Section 7.4</u> any information that was previously publicly disclosed pursuant to this <u>Section 7.4</u>; provided that such disclosure does not materially alter the meaning of the information disclosed previously.

- **7.5 Prior CDA**. This Agreement supersedes the Confidentiality Agreement between the Parties dated November 1, 2019 (the "**Prior CDA**") with respect to information disclosed thereunder. All information exchanged between the Parties under the Prior CDA shall be deemed Confidential Information of the Disclosing Party and shall be subject to the terms of this <u>Article 7</u>.
- **7.6** Securities Filings. Notwithstanding the provisions of this Article 7, each Party, in its capacity as a Disclosing Party, acknowledges and agrees that the Receiving Party may (a) disclose the Disclosing Party's Confidential Information in order to comply with the rules and regulations of the U.S. Securities and Exchange Commission or any other applicable national securities exchange in any jurisdiction (collectively, the "Securities Regulators") if, in the reasonable opinion of the Receiving Party's counsel, such disclosure is necessary for such compliance, or (b) submit this Agreement or the terms thereof to, or file this Letter Agreement with, the Securities Regulators.
- **7.7 Equitable Relief**. Each Receiving Party acknowledges and agrees that a breach of this <u>Article 7</u> cannot reasonably or adequately be compensated in damages in an action at law and that such a breach may cause the Disclosing Party irreparable injury and damage. By reason thereof, the Parties agree that each Party shall be entitled, in addition to any other remedies it may have under this Agreement or otherwise, to seek preliminary and permanent injunctive and other equitable relief to prevent or curtail any breach of the obligations relating to Confidential Information set forth herein.

Article 8

REPRESENTATIONS, WARRANTIES AND COVENANTS

- **8.1 Representations and Warranties of Both Parties**. Each Party hereby represents and warrants to the other Party, as of the Effective Date, that:
- (a) such Party is duly organized, validly existing and in good standing under Applicable Laws of the jurisdiction of its incorporation and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;
- (b) such Party has taken all necessary action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder;

- (c) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid and binding obligation, enforceable against it in accordance with the terms hereof, except as enforcement may be affected by bankruptcy, insolvency or other similar laws and by general principles of equity;
- (d) the execution, delivery and performance of this Agreement by such Party does not conflict with any material agreement, instrument or understanding, oral or written, to which it is a party or by which it is bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over such Party; and
- (e) except as otherwise provided herein, no government authorization, consent, Approval, license, exemption of or filing or registration with any court or governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, under any Applicable Laws currently in effect, is necessary for the transaction contemplated by this Agreement or any other agreement or instrument executed in connection herewith.
- **8.2** Representations and Warranties of Sesen. Sesen hereby represents, warrants, and covenants to Qilu, as of the Effective Date, that:
 - (a) **Exhibit B** sets forth a complete and accurate list of the Licensed Patents existing as of the Effective Date;
 - (b) Sesen Controls the Licensed Know-How and Licensed Patents existing as of the Effective Date;
- (c) to the actual knowledge of Sesen, (i) each Licensed Patent existing as of the Effective Date is valid and enforceable, and (ii) except for any Licensed IP that is the subject of the Upstream License Agreements, the Licensed IP existing as of the Effective Date is free and clear of any liens, charges and encumbrances and no other Person has any claim of ownership whatsoever with respect to such Licensed Know-How and Licensed Patents;
- (d) Sesen has the right to grant all rights and licenses it purports to grant to Qilu with respect to the Licensed Know-How and Licensed Patents under this Agreement and, to the actual knowledge of Sesen and except as set forth in the Upstream License Agreements, Sesen has not previously assigned, transferred, conveyed or otherwise encumbered its rights, title and interest in the Licensed Know-How and Licensed Patents in a manner that would prevent Sesen from granting the rights and licenses under the Licensed Know-How and Licensed Patents as purported to be granted to Qilu in this Agreement;
- (e) Sesen has no knowledge of any settled, pending or threatened claim or lawsuit or legal proceeding of a Third Party against Sesen alleging that the Licensed Know-How or Licensed Patents misappropriate or infringe, in part or in whole, the intellectual property or intellectual property rights of such Third Party in the Territory;
- (f) Sesen has not granted any right or license to any Third Party relating to any of the Licensed Know-How or Licensed Patents that would conflict or interfere with any of the rights or licenses granted to Qilu hereunder;

- (g) Sesen has disclosed to Qilu all material information received by Sesen concerning the institution of any interference, opposition, reexamination, reissue, revocation, nullification or any official proceeding involving any Licensed Patent anywhere in the Territory, and
- (h) To the actual knowledge of Sesen, [***]. In case of any such situations that lead to termination of this Agreement, Sesen shall refund all payment Qilu has paid;
- (i) Sesen had made available to Qilu, via access to electronic data room, all available material information in its possession or control concerning the quality, toxicity, safety and/or efficacy concerns existing as of the Effective Date that may materially impair the utility and/or safety of the Licensed Compound and Licensed Product in the Field;
- (j) Sesen shall (i) use commercially reasonable efforts to obtain written agreement from Verdezyne (ABC) LLC, as assignee of the Coda Agreement from CODA Genomics Inc., similar to the written agreements obtained by Sesen with respect to the other Upstream License Agreements providing Sesen's sublicensees with a direct license under certain circumstances if the Coda Agreement is terminated, and (ii) file to register the University of Zurich License Agreement with National Intellectual Property Administration, PRC pursuant to Measures for the Filling of Patent Exploitation License Contracts (i.e. 专利实施许可合同备案办法) within sixty (60) days of the Effective Date; and
- (k) All licenses, authorizations or consents necessary to grant the License to Qilu upon this Agreement have been obtained by Sesen and any royalty, fee, remuneration or other payment due to any Third Party for, or any author or inventor of, the Licensed IP existing as of the Effective Date have been made.

8.3 Mutual Covenants. Each Party hereby covenants to the other Party that:

- (a) such Party shall, to the extent applicable, perform its activities pursuant to this Agreement in compliance with all Applicable Laws, including GLP, GMP and GCP, as well as any Applicable PRC Laws concerning the protection, collection, use, storage, processing or transfer of personal data, important commercial data and human genetic resources materials and information (as such terms are defined under the PRC Human Genetic Resources Administrative Regulations (i.e.中华人民 共和国人体遗传资源管理条例) promulgated by the State Council of the PRC effective as of July 1, 2019, as may be amended from time to time), the published standards of any applicable Regulatory Authorities, and the scientific standards applicable to the conduct of such activities, if any; and
- (b) such Party shall notify the other Party in writing promptly in the event that it has actual knowledge of the material breach of any covenant under this <u>Article 8</u> or the material breach of any representation or warranty provided by either Party under Section 8.1 or by Sesen under Section 8.2.
 - **8.4 Qilu Covenants**. Qilu hereby covenants to Sesen that when performing its activities pursuant to this Agreement:

- (a) it will prepare, maintain and retain all Regulatory Materials in the Territory pursuant to and in accordance in all material respects with all Applicable Laws and will not make any materially false or misleading statement to a Regulatory Authority in connection with such Regulatory Materials;
- (b) it will not knowingly employ any personnel or knowingly use a contractor or consultant that has been debarred or subject to a similar sanction by any Regulatory Authority or that is the subject of any investigation or proceeding with respect thereto;
- (c) it will, and will cause each of its Affiliates and Sublicensees and any of their respective directors, officers, managers, employees, independent contractors, representatives or agents to, at all times, (i) comply with all Applicable Laws, including those relating to foreign investment, human genetic resources, healthcare and pharmaceuticals, clinic trials, advertisement, data privacy, intellectual property rights, foreign exchange, environment protection, anti-unfair competition, anti-monopoly, taxation, employment, and social welfare and benefits in all material respects, and (ii) duly obtain and maintain all Approvals from and complete all filings and registrations with the Governmental Authorities as required by Applicable Laws in a timely manner for conducting its business and engaging in the activities as contemplated hereunder in compliance with all Applicable Laws;
- (d) it will not, and will cause each of its Affiliates and Sublicensees and any of their respective directors, officers, managers, employees, independent contractors, representatives or agents not to, promise, authorize or make any payment to, or otherwise contribute any item of value to, directly or indirectly, to any Third Party, including any governmental officials, in each case, in violation of any Applicable PRC Laws relating to the prevention or prohibition of bribery and corruption, the U.S. Foreign Corrupt Practices Act or any other Applicable Laws relating to anti-bribery or anti-corruption of any other jurisdiction; and
- (e) it will not, and will cause each of its Affiliates and Sublicensees and any of their respective directors, officers, managers, employees, independent contractors, representatives or agents (collectively, "**Relevant Persons**") not to, engage directly or indirectly in transactions connected with any of North Korea, Iraq, Libya, Cuba, Iran, Myanmar or Sudan, or otherwise engage directly or indirectly in transactions connected with any government, country or other entity or person that is the target of U.S. economic sanctions administered by the Office of Foreign Assets Control of the United States Treasury Department ("**OFAC**"), including those designated on its list of Specially Designated Nationals and Blocked Persons. No Relevant Person will receive unlicensed donations or engaged in any financial transaction while knowing or having reasonable cause to believe that such transaction poses a risk of furthering terrorist attacks anywhere in the world.
- **8.5 Sesen Covenant**. During the Term, Sesen shall not grant any right or license in the Territory to any Third Party relating to any of the intellectual property rights it Controls, including the Licensed IP, which would conflict or interfere with any of the rights or licenses granted to Qilu hereunder.

8.6 Covenants relating to Upstream License Agreements.

- (a) Generally. The Parties acknowledge and agree that to the extent that the License constitutes the grant of a sublicense to Qilu of Patents or Know-How licensed to Sesen under an Upstream License Agreement, such sublicense is subject to and limited by the terms of such Upstream License Agreement and is otherwise encumbered by obligations that would be binding on Sesen under such Upstream License Agreement, as further set forth in such Upstream License Agreement. The terms of each Upstream License Agreement to the extent applicable to the License granted to Qilu hereunder are hereby incorporated by reference and if there is any conflict between any applicable term of an Upstream License Agreement and this Agreement to the extent relating to any rights sublicensed to Qilu hereunder, the terms of the Upstream License Agreement shall control. Sesen has provided to Qilu a complete and accurate copy of each Upstream License Agreement prior to the Effective Date. Notwithstanding anything else herein to the contrary, Qilu hereby consents to Sesen (i) providing a copy of this Agreement to the counterparties to the Upstream License Agreement to the Confidential Information of Qilu that is required to be disclosed to them under the terms of the Upstream License Agreements.
 - (b) *Covenants by Qilu*. Qilu hereby covenants and agrees that:
 - (i) Qilu agrees to be bound by the terms and conditions of the Upstream License Agreements applicable to sublicensees to the extent of the sublicenses granted hereunder;
 - (ii) Qilu shall faithfully and timely perform its obligations pursuant to this Agreement in accordance with the terms of the Upstream License Agreements to the extent applicable to such obligations;
 - (iii) without limitation of subsections (i) and (ii) above, Qilu shall promptly, and in any event within the relevant time period required under the Upstream License Agreements, cure any breach of the Upstream License Agreements caused by the action or omission of Qilu, and shall provide Sesen with written notice of such cure upon completion thereof; and
 - (iv) Qilu shall promptly, and in any event at least [***] prior to the date when any information, report or notice is required to be provided to the counterparties under the Upstream License Agreements, provide to Sesen (or, upon the request of and at the direction of Sesen, provide directly to the relevant counterparty) any information, report or notice required under the Upstream License Agreements based on Qilu's activities under this Agreement.
 - (c) Covenants by Sesen. Sesen hereby covenants and agrees that:
 - (i) Sesen shall faithfully and timely perform its obligations pursuant to the Upstream License Agreements in order to maintain the Upstream License Agreements in full force and effect, Sesen is in full compliance with all of its obligations under each of the Upstream License Agreement (except for a [***] payment under the Coda Agreement that was paid past its due date), and Sesen shall have the right to grant a sublicense to Qilu under each Upstream License Agreement; and

- (ii) Sesen shall not terminate the Upstream License Agreements or modify or amend the Upstream License Agreements in a manner that adversely affects the Licensed IP or Qilu's rights, licenses or obligations under this Agreement and compensate Qilu any damage caused by the Upstream Agreement.
- 8.7 <u>Disclaimer</u>. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, SESEN MAKES NO REPRESENTATION AND EXTENDS NO WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY THAT ANY PATENTS ARE VALID OR ENFORCEABLE OR THAT THEIR EXERCISE DOES NOT INFRINGE ANY PATENT RIGHTS OF THIRD PARTIES AND EXPRESSLY DISCLAIMS ALL WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, SESEN DISCLAIMS ANY WARRANTIES WITH RESPECT TO (A) THE SAFETY OR USEFULNESS FOR ANY PURPOSE OF THE LICENSED COMPOUND AND LICENSED PRODUCTS, AND (B) THE VALIDITY, ENFORCEABILITY, OR NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OR TECHNOLOGY IT PROVIDES OR LICENSES TO QILU UNDER THIS AGREEMENT.
- 8.8 LIMITATION OF LIABILITY. EXCEPT FOR A BREACH OF ARTICLE 7 OR FOR ACTS OF GROSS NEGLIGENCE OR WRONGFUL INTENTIONAL ACTS OR OMISSIONS, NEITHER SESEN NOR QILU, NOR ANY OF THEIR AFFILIATES OR SUBLICENSEES SHALL BE LIABLE TO THE OTHER PARTY, ITS AFFILIATES OR ANY OF THEIR SUBLICENSEES FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, RELIANCE OR PUNITIVE DAMAGES OR LOST OR IMPUTED PROFITS, WHETHER LIABILITY IS ASSERTED IN CONTRACT, TORT (INCLUDING NEGLIGENCE AND STRICT PRODUCT LIABILITY), INDEMNITY OR CONTRIBUTION, AND IRRESPECTIVE OF WHETHER THAT PARTY OR ANY REPRESENTATIVE OF THAT PARTY HAS BEEN ADVISED OF, OR OTHERWISE MIGHT HAVE ANTICIPATED THE POSSIBILITY OF, ANY SUCH LOSS OR DAMAGE; provided, THAT THIS LIMITATION WILL NOT LIMIT THE INDEMNIFICATION OBLIGATION OF A PARTY UNDER THE PROVISIONS OF ARTICLE 9 FOR SUCH DAMAGES CLAIMED BY A THIRD PARTY.

Article 9

INDEMNIFICATION

- **9.1** Indemnification by Qilu. Qilu shall indemnify, defend and hold harmless Sesen, and its Affiliates, and its or their respective directors, officers, employees and agents, from and against any and all liabilities, damages, losses, costs and expenses including the reasonable fees of attorneys and other professionals (collectively, "Losses"), arising out of or resulting from any and all Third Party suits, claims, actions, proceedings or demands ("Claims") based upon:
- (a) the gross negligence or wrongful intentional acts or omissions of Qilu, its Affiliates or Sublicensees, or their respective directors, officers, employees and agents, in connection with Qilu's performance of its obligations or exercise of its rights under this Agreement;

- (b) any breach of any representation, warranty or covenant made by Qilu under this Agreement;
- (c) any action or omission of Qilu, its Affiliates or Sublicensees that causes a breach of or results in non-compliance under an Upstream License Agreement; or
- (d) the Development, Manufacture and Commercialization activities conducted by or on behalf of Qilu, its Affiliates or Sublicensees of the Licensed Compound or Licensed Products;

except, in each case of <u>Section 9.1(a)</u> through <u>Section 9.1(d)</u> (inclusive), to the extent Sesen is obligated to indemnify Qilu with respect to such Losses under <u>Section 9.2</u>.

- **9.2** Indemnification by Sesen. Sesen shall indemnify, defend and hold harmless Qilu and its Affiliates, and its or their respective directors, officers, employees and agents, from and against any and all Losses, arising out of or resulting from any and all Third Party Claims based upon:
- (a) the gross negligence or wrongful intentional acts or omissions of Sesen and its Affiliates, or their respective directors, officers, employees and agents, in connection with Sesen's performance of its obligations or exercise of its rights under this Agreement;
 - (b) any breach of any representation, warranty or covenant made by Sesen under this Agreement;
- (c) the Development, Manufacture and Commercialization activities conducted by or on behalf of Sesen, its Affiliates, subcontractors or sublicensees of the Licensed Compound of Licensed Products; or
- (d) any action or omission of Sesen, its Affiliates or sublicensees that causes a breach or results in non-compliance under an Upstream License Agreement.

except, in each case of <u>Section 9.2(a)</u> through <u>Section 9.2(c)</u> (inclusive), to the extent Qilu is obligated to indemnify Sesen with respect to such Losses under <u>Section 9.1</u>.

9.3 Procedure. In the event that any person (an "**Indemnitee**") entitled to indemnification under <u>Section 9.1</u> or <u>Section 9.2</u> is seeking such indemnification, such Indemnitee shall (a) inform, in writing, the indemnifying Party of the Claim as soon as reasonably practicable after such Indemnitee receives notice of such Claim, (b) permit the indemnifying Party to assume direction and control of the defense of the Claim (provided, that the indemnifying Party may not settle the Claim without the prior consent of the Indemnitee, not to be unreasonably withheld), (c) cooperate as reasonably requested (at the expense of the indemnifying Party) in the defense of the Claim, and (d) undertake all reasonable steps to mitigate any loss, damage or expense with respect to the Claim(s). Without limiting the foregoing, any Indemnitee will be entitled to participate in the defense of a Claim for which it has sought indemnification hereunder and to employ counsel of its choice for such purpose; provided, that such employment will be at the Indemnitee's own expense unless (i) the employment thereof has been specifically authorized by the indemnifying Party in writing, or (ii)

the indemnifying Party has failed to assume the defense (or continue to defend such Claim in good faith) and employ counsel in accordance with this <u>Section 9.3</u>, in which case the indemnified Party will be allowed to control the defense.

Article 10

TERM AND TERMINATION

10.1 Term; Expiration. The term of this Agreement (the "Term") shall begin on the Effective Date and, unless earlier terminated pursuant to the other provisions of this Article 10, shall continue in full force and effect on a Licensed Product-by-Licensed Product and Relevant Region-by-Relevant Region basis until the expiration of all of Qilu's payment obligations to Sesen under Article 5. Upon expiration of the Term, the License shall become fully paid-up, freely transferable, perpetual and irrevocable and with the right to grant sublicenses through all tiers, and Sesen's representations, warranties and covenants shall continue until such time as Qilu is no longer selling Licensed Product in the Field in the Territory.

10.2 Termination for Cause.

- Termination for Material Breach. Either Party (the "Non-breaching Party") may, without prejudice to any other remedies available to it at law or in equity, terminate this Agreement in the event the other Party (the "Breaching Party") shall have materially breached or defaulted in the performance of any of its obligations under this Agreement and such material breach or default shall have continued for [***] after written notice thereof was provided to the Breaching Party by the Nonbreaching Party, such notice describing with particularity and in detail the alleged material breach. Any such termination of this Agreement under this Section 10.2(a) shall become effective at the end of such [***] period, unless the Breaching Party has either (i) cured any such material breach or default prior to the expiration of such [***] period, or (ii) if such material breach or default is not susceptible to cure within such [***] period, the Breaching Party has, within such [***] period, provided to the Non-breaching Party a written plan that is reasonably calculated to effect a cure and such plan is reasonably acceptable to the Non-breaching Party. Where the Non-breaching Party has accepted any such plan in accordance with the preceding sentence, the Non-breaching Party may terminate this Agreement immediately upon written notice to the Breaching Party if the Breaching Party subsequently fails to carry out such plan. The right of either Party to terminate this Agreement as provided in this Section 10.2(a) shall not be affected in any way by such Party's waiver or failure to take action with respect to any previous default. Notwithstanding anything to the contrary herein contained Sesen shall not have the right to terminate this Agreement under this Section 10.2(a) for any action or inaction of a Sublicense(s) if Qilu terminates the sublicense(s) during the aforesaid [***] cure period.
- (b) *Disagreement*. If the Parties reasonably and in good faith disagree as to whether there has been a material breach or default, the Party which seeks to dispute that there has been a material breach or default may contest the allegation in accordance with <u>Sections 11.1</u> and <u>11.2</u>; provided, that (i) the negotiation period between the Parties under <u>Section 11.1</u> shall be limited to [***], (ii) the negotiation period between the Executive Officers under <u>Section 11.1</u> shall be limited to [***], and (iii) the binding arbitration under <u>Section 11.2</u> shall be conducted

and completed within [***] of the appointment of the arbitrator under <u>Section 11.2(a)</u>, and the Parties shall adopt and comply with any additional rules or procedures instituted by the arbitrator in order to conduct and complete the arbitration within this expedited period. From the date any claim of material breach is referred to the Executive Officers in accordance with <u>Section 11.1</u> until such time as the dispute regarding such claimed material breach or default has become finally settled, the time period during which a Breaching Party must cure an alleged breach that is the subject matter of the dispute shall be suspended and no termination under <u>Section 10.2(a)</u> shall become effective.

- (c) *Termination Due to Patent Challenge*. Sesen may terminate this Agreement, without incurring any liability on its part for such termination, upon [***] prior written notice if Qilu or any of its Affiliates or Sublicensees of the Licensed Patents or Improvement Patents directly or indirectly initiate or prosecute any lawsuit or any other civil or administrative proceeding, or the making of any claim or counterclaim, of any kind in any court, tribunal, agency or governmental entity anywhere in the world challenging the validity or enforceability of any Licensed Patent or Improvement Patent licensed or sublicensed to it under this Agreement by Sesen and Qilu or its Affiliates or Sublicensees have not withdrawn said challenge or lawsuit.
- (d) *Termination for Failure to Pay Upfront Payment*. Sesen may terminate this Agreement if Sesen has not received the Upfront Payment on or before the Upfront Payment Due Date. Sesen shall provide a written notice in which offering a [***] grace period to pay the Upfront Payment. If Qilu fails to pay the Upfront Payment within such [***], Sesen may terminate this Agreement upon written notice to Qilu.
- **Termination for Insolvency**. Each Party shall have the right to terminate this Agreement in its entirety immediately upon written notice to the other Party if (a) such other Party files in any court or agency pursuant to any statute or regulation of any jurisdiction a petition in bankruptcy or insolvency or for reorganization or similar arrangement for the benefit of creditors or for the appointment of a receiver or trustee of such other Party or its assets, (b) such other Party is served with an involuntary petition against it in any insolvency proceeding, and upon the [***] after such service, such involuntary petition has not been stayed or dismissed, (c) such other Party makes an assignment of substantially all of its assets for the benefit of its creditors, or (d) such other Party fails to maintain in force any Approval required for it to carry out its business to the extent necessary for performing its obligations hereunder.

10.4 Effects of Termination.

- (a) *Generally*. In the event of a termination of this Agreement for any reason other than a termination by Qilu under <u>Section 10.2(a)</u>, the following terms shall apply:
 - (i) all licenses and other rights granted by Sesen to Qilu shall terminate, and all rights of Qilu under the Licensed Patents and Licensed Know-How and Improvement IP shall revert to Sesen;
 - (ii) the Parties shall have no further obligation to perform any activities under this Agreement other than as provided for or referenced in this

<u>Section 10.4</u> or in <u>Section 10.5</u>, and Qilu shall cease any and all Development, Manufacture and Commercialization activities relating to the Licensed Compound and the Licensed Products;

- (iii) each Party shall comply with its obligations pursuant to Section 10.5;
- (iv) Qilu shall promptly return to Sesen, at no cost to Sesen, all tangible Licensed Know-How and Confidential Information of Sesen;
- (v) upon the request of Sesen, Qilu shall, within [***] of the effective date of termination of this Agreement, transfer to Sesen all Data within Qilu's control, and Sesen shall have the right to use such Data for any and all purposes;
- (vi) except in the case of a termination of this Agreement by Qilu under Section 10.2 or Section 10.3, the Back License under Section 2.5 shall survive and become perpetual and irrevocable and Qilu hereby grants to Sesen and its Affiliates a perpetual and irrevocable, royalty-free and fully paid-up, exclusive license, with the right to grant sublicenses through multiple tiers, under Know-How and Patents that are Controlled by Qilu or any of its Affiliates and their respective Sublicensees that are necessary or useful to Develop, Manufacture or Commercialize the Licensed Compound or Licensed Products in the Field in the Territory;
- (vii) with respect to any ongoing Clinical Trials of the Licensed Products conducted by Qilu, (x) Qilu shall wind down at its sole cost the conduct of such Clinical Trials as soon as reasonably practicable, subject to requirements of Applicable Laws, or, upon the request of Sesen, transfer to Sesen the conduct of such Clinical Trials as soon as reasonably practicable pursuant to the requirements of Applicable Laws, and (y) until such time as the conduct of such Clinical Trials has been successfully terminated or transferred to Sesen, Qilu shall continue such Clinical Trials at its sole cost; and
- (viii) upon the request of Sesen, (x) Qilu shall assign and transfer to Sesen or its designee any and all Regulatory Materials, including regulatory filings made with and all Regulatory Approvals (including any MAAs) obtained from the Regulatory Authorities in the Territory, relating to the Licensed Compound and Licensed Products in the Field in the Territory pursuant to the requirements of Applicable Laws, and (y) Qilu shall cooperate with Sesen to facilitate the orderly transition and uninterrupted Development, Manufacturing and Commercialization of the Licensed Compound and Licensed Products in the Field in the Territory, including by assigning or otherwise transferring (to the extent permissible) to Sesen or its designee all right, title and interest in all Third Party contracts (or portions thereof) related to such Development, Manufacturing and Commercialization, as reasonably requested by Sesen.
- (b) *Termination by Qilu for Sesen Breach*. In the event this Agreement is terminated by Qilu in connection with an uncured material breach by Sesen under <u>Section 10.2(a)</u>, the following shall apply: (1) the licenses granted to Qilu under Section 2.1 shall become

fully paid-up, royalty-free, perpetual, transferrable and exclusive licenses with the right to grant sublicense through all tiers, in the Field in the Territory. [***].

(c) *Termination by Qilu for Convenience*. Qilu shall have the right at any time and from time to time during the Term for any reason or no reason, to terminate this Agreement upon a ninety (90) days prior written notice to Sesen. Upon termination of this Agreement pursuant to this <u>Section 10.4(c)</u>, <u>Section 10.4(a)</u> shall apply except that Qilu shall not have any obligation to pay any Milestones or Royalties except for any inventory sold by Qilu prior to the expiration of the aforesaid [***].

10.5 Accrued Rights; Surviving Provisions of this Agreement.

- (a) Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of any Party prior to such termination or expiration and any and all damages arising from any breach hereunder. Such termination or expiration shall not relieve any Party from obligations which are expressly indicated to survive termination of this Agreement.
- (b) The following provisions shall survive the termination or expiration of this Agreement for any reason, in accordance with their respective terms and conditions, and for the duration stated, and where no duration is stated, shall survive for so long as required to give effect to the subject matter of the provision: Sections 5.2, 5.3, 5.4 and 5.7 (in each case to the extent applicable to payment obligations that accrued prior to the effective date of termination or expiration); Section 5.5; Section 5.6; Article 7; Section 8.7; Section 8.8; Article 9; Section 10.4 (including any other sections of the Agreement noted therein to survive termination); this Section 10.5; and Article 11, as well as any applicable definitions in Article 1 and any other provisions which are expressed to survive termination or expiration or which are required to give effect to such termination or expiration.

Article 11

MISCELLANEOUS

- **11.1 Internal Resolution**. Other than disputes subject to final decision-making authority by a Party pursuant to <u>Section 3.5</u> or determinations made by certified accountants as provided in <u>Section 5.5</u>, in the event of any dispute between the Parties relating to or arising out of this Agreement, the formation, construction, breach or termination hereof, or the rights, duties or liabilities of either Party hereunder, the Parties shall first attempt in good faith to resolve such dispute by negotiation and consultation between themselves, utilizing the Alliance Managers. In the event that such dispute is not resolved on an informal basis within [***], either Party may, by written notice to the other Party, refer the dispute to the Executive Officers for attempted resolution by good faith negotiation within [***] after such notice is received.
- **11.2 Binding Arbitration**. If the Executive Officers are not able to resolve such disputed matter within [***] and any Party wishes to pursue the matter, each such dispute, controversy or claim that is not an Excluded Claim (defined in Section 11.2(e) below) shall be finally resolved by final and binding arbitration administered by the International Chamber of

Commerce ("ICC") in Hong Kong pursuant its then prevailing arbitration rules, and judgment on the arbitration award may be entered in any court having jurisdiction thereof. The Parties agree that:

- (a) The arbitration shall be conducted by a single arbitrator appointed by the ICC, who shall (i) be a lawyer of not less than fifteen (15) years' standing who is experienced in the pharmaceutical business in the relevant country, (ii) not be or have been an employee, consultant, officer, director or stockholder of either Party or any Affiliate of either Party, and (iii) not have a conflict of interest under any applicable rules of ethics. The place of arbitration shall be Hong Kong, and all proceedings and communications shall be in English, unless otherwise agreed by all Parties involved in such dispute.
- (b) Any Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Any Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending the arbitration award.
- (c) The arbitrator shall have no authority to award punitive or any other type of damages not measured by a Party's compensatory damage. Each Party shall bear its own costs and expenses and attorneys' fees and an equal share of the arbitrator's fees and any administrative fees of arbitration regardless of the outcome of such arbitration.
- (d) Except to the extent necessary to confirm an award or as may be required by law, neither a Party nor the arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of all Parties. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding, based on the dispute, controversy or claim, would have been barred by the applicable statute of limitations.
- (e) As used in this <u>Section 11.2</u>, the term "**Excluded Claim**" shall mean a dispute, controversy or claim that concerns the scope, validity, enforceability, inventorship or infringement of a patent, patent application, trademark or copyright. Any Excluded Claim shall be submitted to a court of competent jurisdiction.
 - (f) The governing law of this <u>Section 11.2</u> is the laws of Hong Kong.
- **11.3 Governing Law.** This Agreement shall be governed by, enforced, and shall be construed in accordance with the laws of the State of New York, U.S., without regard to its conflicts of law provisions.
- **11.4** Assignment. Neither this Agreement nor any obligation of a Party hereunder may be assigned by either Party without the prior consent of the other Party, which shall not be unreasonably withheld or delayed, except that each Party may assign this Agreement, provided the assigning Party is not in material default of any of its obligations hereunder and providing with a written notice, without the consent of the other Party (i) to any of its Affiliates, (ii) to any purchaser of all or substantially all of its securities, assets or all or substantially all of its assets to which this Agreement relates, or (iii) to any successor corporation or limited liability company resulting from any merger, consolidation, share exchange or other similar transaction; provided,

that in each instance the assignee or resulting entity in such transaction (if not the Party) expressly assumes all obligations imposed on the assigning Party by this Agreement in writing and agrees to be bound by all of the terms of this Agreement. This Agreement shall bind and inure to the benefit of the Parties hereto and their respective successors and permitted assigns. Any purported assignment in violation of this <u>Section 11.4</u> shall be null and void. Notwithstanding the foregoing, if this Agreement or any obligation hereunder by either Party is assigned to any third party that compete with the other Party in business, the other Party shall be entitled to immediately terminate this Agreement.

- 11.5 Force Majeure. Neither Party shall be liable for delay or failure in the performance of any of its obligations hereunder if such delay or failure is due to causes beyond its reasonable control, including, without limitation, acts of God, fires, earthquakes, previously unknown pandemics or epidemics, strikes and labor disputes, acts of war, terrorism, civil unrest or intervention of any governmental authority ("Force Majeure"); provided, that the affected Party promptly notifies the other Party; provided, further, that the affected Party shall use its commercially reasonable efforts to avoid or remove such causes of non-performance and to mitigate the effect of such occurrence, and shall continue performance with the utmost dispatch whenever such causes are removed. When such circumstances arise, the Parties shall negotiate in good faith any modifications of the terms of this Agreement that may be necessary or appropriate in order to arrive at an equitable solution.
- **11.6 Notices.** Any notice or request required or permitted to be given under or in connection with this Agreement shall be deemed to have been sufficiently given if in writing and personally delivered or sent by overnight express courier service (signature required), prepaid, to the Party for which such notice is intended, at the address set forth for such Party below:

If to Sesen, addressed to:

Sesen Bio, Inc. 245 First Street, Suite 1800 Cambridge, MA 02142 Attn: Chief Executive Officer

With copies (which shall not constitute notice) to:

Hogan Lovells US LLP

1735 Market Street, Suite 2300 Philadelphia, PA 19103 Attn: Steven J. Abrams

Hogan Lovells US LLP 100 International Drive, Suite 2000 Baltimore, MD 21202 Attn: Adriana V. Tibbitts

If to Qilu, addressed to:

Qilu Pharmaceutical 50 Soldiers Field Place Boston, MA 02135 Attn: Jiawen Han

With a copy (which shall not constitute notice) to:

Rubin and Rudman LLP 53 State Street, 15th Floor Boston, MA 02109 Attn: Peter B. Finn, Esq.

or to such other address for such Party as it shall have specified by like notice to the other Party, provided, that notices of a change of address shall be effective only upon receipt thereof. If delivered personally, the date of delivery shall be deemed to be the date on which such notice or request was given. If sent by overnight express courier service, the date of delivery shall be deemed to be the next Business Day after such notice or request was deposited with such service. Notwithstanding the foregoing, for any notice delivered outside normal business hours (which shall for these purposes mean in the country of the recipient of the notice), delivery shall be deemed to occur on the Business Day following such delivery.

- Maivers and Modifications. The failure of any Party to insist on the performance of any obligation hereunder shall not be deemed to be a waiver of such obligation. Waiver of any breach of any provision hereof shall not be deemed to be a waiver of any other breach of such provision or any other provision on such occasion or any succeeding occasion. No waiver, modification, release or amendment of any obligation under or provision of this Agreement shall be valid or effective unless in writing and signed by all Parties hereto.
- **11.8** <u>Severability</u>. If any one or more of the provisions of this Agreement is held to be invalid or unenforceable, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. 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 the Parties when entering this Agreement may be realized.
- **11.9 Independent Contractors**. Each Party is an independent contractor under this Agreement. Nothing contained herein is intended or is to be construed so as to constitute Sesen and Qilu as partners, agents or joint venturers. Neither Party shall have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any contract, agreement or undertaking with any Third Party.
- **11.10 Headings**. Headings and captions are for convenience only and are not be used in the interpretation of this Agreement.
- **11.11 Further Assurances**. Each Party agrees to do and perform all such further acts and things and shall execute and deliver such other agreements, certificates, instruments and documents necessary or that the other Party may deem advisable in order to carry out the intent

and accomplish the purposes of this Agreement and to evidence, perfect or otherwise confirm its rights hereunder.

- 11.12 Construction of Agreement. The terms and provisions of this Agreement represent the results of negotiations between the Parties and their representatives, each of which has been represented by counsel of its own choosing, and neither of which has acted under duress or compulsion, whether legal, economic or otherwise. Accordingly, the terms and provisions of this Agreement shall be interpreted and construed in accordance with their usual and customary meanings, and each of the Parties hereto hereby waives the application in connection with the interpretation and construction of this Agreement of any rule of law to the effect that ambiguous or conflicting terms or provisions contained in this Agreement shall be interpreted or construed against the Party whose attorney prepared the executed draft or any earlier draft of this Agreement. This Agreement, the Exhibits and any amendments hereto may only be written in English, and the Chinese version of any language included in this Agreement or any Exhibit or amendment hereto is included solely for convenience and shall not be binding.
- 11.13 <u>Counterparts</u>. This Agreement may be signed in counterparts, each and every one of which shall be deemed an original, notwithstanding variations in format or file designation which may result from the electronic transmission, storage and printing of copies of this Agreement from separate computers or printers. Facsimile signatures and signatures transmitted via PDF shall be treated as original signatures, unless any relevant Governmental Authority requires otherwise, in which case this Agreement shall be executed in compliance with such requirement.

11.14 <u>Interpretation</u>.

- (a) Each of the Parties acknowledges and agrees that this Agreement has been diligently reviewed by and negotiated by and between them, that in such negotiations each of them has been represented by competent counsel and that the final agreement contained herein, including the language whereby it has been expressed, represents the joint efforts of the Parties hereto and their counsel. Accordingly, in interpreting this Agreement or any provision hereof, no presumption shall apply against any Party hereto as being responsible for the wording or drafting of this Agreement or any such provision, and ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision. This Agreement is made in English. In the event that this Agreement is translated into any other language, it shall be for reference purposes only and the English language version of this Agreement shall control any interpretations of the provisions of this Agreement.
- (b) The definitions of the terms herein shall apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. The words "includes" and "including" shall be deemed to be followed by the phrase "without limitation" whether or not such phrase is included. The word "will" shall be construed to have the same meaning and effect as the word "shall". The word "any" shall mean "any and all" unless otherwise clearly indicated by context.

- (c) Unless the context requires otherwise, (i) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (ii) any reference to any Applicable Law herein shall be construed as referring to such Applicable Law as from time to time enacted, repealed or amended, (iii) any reference herein to any Person shall be construed to include the Person's successors and assigns, (iv) the words "herein", "hereof" and "hereunder", and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, and (v) all references herein to Articles, Sections or Exhibits, unless otherwise specifically provided, shall be construed to refer to Articles, Sections and Exhibits of this Agreement.
- 11.15 Entire Agreement. This Agreement (including all Exhibits attached hereto, which are incorporated herein by reference) (a) sets forth all of the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof, (b) constitutes and contains the complete, final and exclusive understanding and agreement of the Parties with respect to the subject matter hereof, and (c) cancels, supersedes and terminates all prior agreements (including the Prior CDA and the Non-Binding Term Sheet exchanged by the Parties) and understanding between the Parties with respect to the subject matter hereof. There are no covenants, promises, agreements, warranties, representations, conditions or understandings with respect to the subject hereof, whether oral or written, between the Parties other than as set forth herein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties hereto unless reduced to writing and signed by the respective authorized officers of the Parties.

*_*_*

IN WITNESS WHEREOF, the Parties have caused this Exclusive License Agreement to be executed by their legal or duly authorized representatives as of the Effective Date.

SESEN BIO, INC.

By:/s/ Thomas R. Cannell
Name: Thomas R. Cannell

Title: President and Chief Executive Officer

VIVENTIA BIO, INC.

By: <u>/s/ Thomas R. Cannell</u> Name: Thomas R. Cannell

Title: President and Chief Executive Officer

QILU PHARMACEUTICAL CO., LTD. (SIGN AND CHOP)

By: <u>/s/ Haizhong Bao</u> Name: Haizhong Bao Title: Legal Representative

EXHIBIT A

LICENSED COMPOUND

[***]

Exhibit A-1

EXHIBIT B

LICENSED PATENTS

[***]

Exhibit B-1

EXHIBIT C

TECHNOLOGY TRANSFER PLAN

[***]

Exhibit C-1

EXHIBIT D

DEVELOPMENT PLAN

[***]

Exhibit D-1

EXHIBIT E

SUPPLY AGREEMENT TERM SHEET

[***]

Exhibit E-1

EXHIBIT F

PRODUCT DOCUMENTATION

[***]

Exhibit F-1

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Thomas R. Cannell, D.V.M., certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2020 of Sesen Bio, 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 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 and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2020 By: /s/ Thomas R. Cannell, D.V.M.

Name: Thomas R. Cannell, D.V.M.

Title: President and Chief Executive Officer

(Principal Executive Officer)

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Monica Forbes, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2020 of Sesen Bio, 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 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 and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2020 By: /s/ Monica Forbes

Name: Monica Forbes
Title: Chief Financial Officer

(Principal Financial Officer)

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Sesen Bio, Inc. (the "Company") for the fiscal quarter ended September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) the Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 9, 2020 By: /s/ Thomas R. Cannell, D.V.M.

Name: Thomas R. Cannell, D.V.M.

Title: President and Chief Executive Officer

(Principal Executive Officer)

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Sesen Bio, Inc. (the "Company") for the fiscal quarter ended September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) the Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 9, 2020 By: /s/ Monica Forbes

Name: Monica Forbes

Title: Chief Financial Officer

(Principal Financial Officer)