Sesen Bio Reports Third Quarter 2020 Financial Results and Positive Progress Towards Completing the BLA Submission for VicineumTM in December 2020

November 9, 2020

Manufacturing of Vicineum drug substance and drug product PPQ batches has been completed

Emerging manufacturing data provides strong support for analytical comparability between clinical and commercial material

On track to complete BLA submission to the FDA in December 2020

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 9, 2020-- **Sesen Bio** (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, today reported operating results for the third quarter ended September 30, 2020. The Company's lead program, Vicineum ^{TM}, also known as VB4-845, is currently in the follow-up stage of a Phase 3 registration trial for the treatment of high-risk, BCG-unresponsive non-muscle invasive bladder cancer (NMIBC). In December 2019, the Company initiated the BLA submission for Vicineum to the FDA under Rolling Review.

"We are rapidly advancing toward the finalization of our BLA in December as well as a potential MAA submission in Europe in early 2021," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "We believe the probability of regulatory success is high in both the US and Europe due to the strong clinical profile of Vicineum enabled by the unique dual mechanism of action. Once approved, we think Vicineum has the potential to be the best-in-class therapeutic in BCG-unresponsive NMIBC with a significant global commercial opportunity. We remain laser-focused towards executing on upcoming key milestones to the benefit of both patients and shareholders."

Manufacturing Update

Manufacturing and release testing of the three drug substance PPQ batches has been completed and all quality acceptance criteria were met. Manufacturing of the three drug product batches has also been completed and release testing has been completed for the first and second batch, with all quality acceptance criteria met. Testing of the third drug product PPQ batch is expected to be completed in November 2020. Based on the results obtained thus far, the Company is confident that the remaining batch will also meet the required acceptance criteria in support analytical comparability.

As part of the analytical comparability plan submitted to the FDA, the Company also committed to conduct extensive biophysical characterization and forced degradation testing on Vicineum manufactured using the proposed commercial process. These studies were completed in October 2020, and the Company believes the data demonstrates that clinical and commercial material are highly similar, providing strong support for analytical comparability.

EMA Regulatory Process

On October 23, 2020, the Company completed a successful Pre-Submission meeting with the European Medicines Agency (EMA) for Vicineum. During the meeting, the EMA provided updated guidance on various administrative topics, which help to clarify the regulatory path forward. In addition, earlier in 2020, the EMA provided written notice of the Company's eligibility to file a MAA under the EMA's centralized procedure. These interactions with the EMA in 2020 confirm the Company's pathway to a MAA submission for Vicineum in early 2021 with anticipated approval in early 2022.

Supply Chain

The Company recently announced an exclusive agreement with Cardinal Health for third-party logistics and specialty pharmaceutical distribution services related to the commercial distribution of Vicineum in the United States. The addition of Cardinal Health completes the selection of major supply chain partners in support of the commercial distribution of Vicineum in the United States. All of Sesen Bio's major supply chain partners, including Fujifilm, Baxter and Cardinal Health, are recognized leaders within the industry, which the Company believes will help to ensure manufacturing and distribution excellence.

OUS Partnership

On July 31, 2020, the Company announced an exclusive license agreement with Qilu Pharmaceutical for the development and commercialization of Vicineum in Greater China. On September 29, 2020, the Company received $10.0 million in net proceeds associated with the $12 million upfront payment due under the license agreement. Under the terms of the agreement, the Company is also eligible to receive (i) a 12% royalty, subject to certain reductions, based upon annual net sales of Vicineum in Greater China, and (ii) payments totaling up to $23 million upon the achievement of certain technology transfer, development and regulatory milestones, the first of which the Company expects to receive in early 2021.

Third Quarter 2020 Financial Results

- **Cash Position:** Cash and cash equivalents were $42.0 million as of September 30, 2020, compared to $48.1 million as of December 31, 2019. This change includes $8.2 million of net proceeds received during the third quarter of 2020 provided by our ATM offering.

- **Revenue:** Revenue for the third quarter of 2020 was $11.2 million, which was due to the recognition of revenue from the Company's license agreement with Qilu. The Company did not record any revenue for the third quarter of 2019.
- **R&D Expenses:** Research and development expenses for the third quarter of 2020 were $10.2 million compared to $6.6 million for the same period in 2019. The third quarter increase was due primarily to costs related to the ongoing technology transfer process with Fujifilm and Baxter as the Company scales-up for commercial manufacturing, partially offset by lower clinical expenses related to the Phase 3 VISTA trial for Vicineum and lower regulatory consulting fees in support of the Company's ongoing BLA submission with the FDA.
- **G&A Expenses:** General and administrative expenses for the third quarter of 2020 were $4.1 million compared to $3.2 million for the same period in 2019. The third quarter increase was due primarily to increases in investment banking and legal fees related to the Company's license agreement with Qilu.
- **Net Loss:** Net loss was $22.6 million, or $0.19 per basic share and diluted share, for the three months ended September 30, 2020, compared to a net loss of $13.1 million, or $0.13 per basic and diluted share, for the same period in 2019. The change was due primarily to revenue recognized in the third quarter of 2020 related to the Company's license agreement with Qilu, offset by higher technology transfer costs and a non-cash change in fair value of contingent consideration due to changes in discount rates.

Conference Call and Webcast Information

Members of the Sesen Bio management team will host a conference call and webcast today at 8:00 AM ET to review the Company's financial results and provide a general business update. To participate in the conference call, please dial (844) 831-3025 (domestic) or (315) 625-6887 (international) and refer to conference ID 9360749. The webcast can be accessed in the Investor Relations section of the Company's website at www.sesenbio.com. The replay of the webcast will be available in the investor section of the Company's website at www.sesenbio.com for 60 days following the call.

About the VISTA Clinical Trial

The VISTA trial is an open-label, multicenter, single-arm Phase 3 clinical trial evaluating the efficacy and tolerability of Vicineum™ as a monotherapy in patients with high-risk, bacillus Calmette-Guérin (BCG) unresponsive non-muscle invasive bladder cancer (NMIBC). The primary endpoints of the trial are the complete response rate and the duration of response in patients with carcinoma in situ with or without papillary disease. Patients in the trial received locally administered Vicineum twice a week for six weeks, followed by once-weekly treatment for another six weeks, then treatment every other week for up to two years. To learn more about the Phase 3 VISTA trial, please visit www.clinicaltrials.gov and search the identifier NCT02449239.

About Vicineum™

Vicineum, a locally administered fusion protein, is Sesen Bio's lead product candidate being developed for the treatment of high-risk non-muscle invasive bladder cancer (NMIBC). Vicineum is comprised of a recombinant fusion protein that targets epithelial cell adhesion molecule (EpCAM) antigens on the surface of tumor cells to deliver a potent protein payload, Pseudomonas Exotoxin A. Vicineum is constructed with a stable, genetically engineered peptide tether to ensure the payload remains attached until it is internalized by the cancer cell, which is believed to decrease the risk of toxicity to healthy tissues, thereby improving its safety. In prior clinical trials conducted by Sesen Bio, EpCAM has been shown to be overexpressed in NMIBC cells with minimal to no EpCAM expression observed on normal bladder cells. Sesen Bio is currently conducting the Phase 3 VISTA trial, designed to support the registration of Vicineum for the treatment of high-risk NMIBC in patients who have previously received a minimum of two courses of bacillus Calmette-Guérin (BCG) and whose disease is now BCG-unresponsive. Additionally, Sesen Bio believes that cancer cell-killing properties of Vicineum promote an anti-tumor immune response that may potentially combine well with immuno-oncology drugs, such as checkpoint inhibitors. The activity of Vicineum in BCG-unresponsive NMIBC is also being explored at the US National Cancer Institute in combination with AstraZeneca's immune checkpoint inhibitor durvalumab.

About Sesen Bio

Sesen Bio, Inc. is a late-stage clinical company advancing targeted fusion protein therapeutics for the treatment of patients with cancer. The Company's lead program, Vicineum™, also known as VB4-845, is currently in the follow-up stage of a Phase 3 registration trial for the treatment of high-risk, BCG-unresponsive non-muscle invasive bladder cancer (NMIBC). In December 2019, the Company initiated the BLA submission for Vicineum to the FDA under Rolling Review. Sesen Bio retains worldwide rights to Vicineum with the exception of Greater China, for which the Company has partnered with Qilu Pharmaceutical for commercialization. Vicineum is a locally administered targeted fusion protein composed of an anti-EpCAM antibody fragment tethered to a truncated form of Pseudomonas Exotoxin A for the treatment of high-risk NMIBC. For more information, please visit the company's website at www.sesenbio.com.

COVID-19 Pandemic Potential Impact

Sesen Bio continues to monitor the rapidly evolving environment regarding the potential impact of the COVID-19 pandemic on our Company. The Company has not yet experienced any disruptions to our operations as a result of COVID-19, however, we are not able to quantify or predict with certainty the overall scope of potential impacts to our business, including, but not limited to, our ability to raise capital and, if approved, commercialize Vicineum. Sesen Bio remains committed to the health and safety of patients, caregivers and employees.

Cautionary Note on Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, the Company's strategy, future operations, and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the Company's ability to successfully develop its product candidates and complete its planned clinical programs, expectations regarding the completion of the Company's PPQ runs; expectations that the Company's remaining PPQ batches will meet the required acceptance criteria in support analytical comparability, expectations that the Company will complete its BLA submission for Vicineum in December

2020, the Company's expectations to submit its MAA for Vicineum in early 2021 with anticipated approval in early 2022, expectations regarding the timing and amounts of any payments due under the Company's license agreement with Qilu, and other factors discussed in the "Risk Factors" section of the Company's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and other reports filed with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent the Company's views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

SESEN BIO, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except per share data)
(Unaudited)

	Three Months ended September 30,		Nine Months ended September 30,	
	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 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):				
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	-	-	(147)	-
Net Loss and Comprehensive Loss Available to Common Stockholders	**$ (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

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

	September 30,	December 31,
	2020	**2019**

Assets		
Current assets:		
Cash and cash equivalents	$ 41,969	$ 48,121
Prepaid expense and other current assets	7,072	6,326
Total current assets	49,041	54,447
Restricted cash	20	20
Property and equipment, net	154	238
Intangibles	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**

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