Sesen Bio Reports Fourth Quarter and Full-Year 2020 Financial Results and Significant Regulatory and Commercial Readiness Progress for the Company's Lead Product Candidate Vicineum™

March 15, 2021

Strengthened balance sheet: $98 million in cash and cash equivalents as of February 28, 2021[1]

Biologics License Application accepted by the FDA under Priority Review

Marketing Authorization Application submitted in Europe with potential approval in early 2022

Company to host conference call at 8am ET

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Mar. 15, 2021-- **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 fourth quarter and full-year ended December 31, 2020. 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 BCG-unresponsive non-muscle invasive bladder cancer (NMIBC). In February 2021, the Food and Drug Administration (FDA) accepted for filing the Company's Biologics License Application (BLA) for Vicineum under Priority Review.

"We continue to make tremendous progress on our regulatory path with potential US approval later this year," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "Our talented and growing team is laser-focused on bringing a best-in-class treatment to the market that has the potential to improve patient outcomes while reducing healthcare costs. With a strong balance sheet and clear regulatory path forward in both the US and Europe, we are positioned to fully realize the potentially significant global opportunity for Vicineum. We expect 2021 to be a transformative year for Sesen Bio and the patients we serve."

US and European Regulatory Update

US:

- **On February 12, 2021, Sesen Bio received notice from the FDA that the BLA for Vicineum for the treatment of BCG-unresponsive NMIBC was accepted for filing as of February 16th and granted Priority Review**. The FDA set an accelerated 6-month target Prescription Drug User Fee Act (PDUFA) date of August 18, 2021 for a decision on the BLA. The FDA also stated that they are not currently planning to hold an advisory committee meeting to discuss the BLA for Vicineum.

Europe:

- **On March 5, 2021, Sesen Bio submitted the Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for Vicineum for the treatment of BCG-unresponsive NMIBC.** In December 2020, the Company successfully completed all pre-submission activities supporting the MAA. Sesen Bio anticipates potential approval of the MAA in early 2022.

[1]This amount is preliminary and is subject to change upon completion of the Company's financial statements for the quarterly period ended March 31, 2021.

Business Development Update

Middle East and North Africa (MENA):

- **In November 2020, Sesen Bio signed a partnership agreement with Hikma Pharmaceuticals for the registration and commercialization of Vicineum for the treatment of BCG-unresponsive NMIBC and other types of cancer in MENA.** Under the terms of the agreement, Sesen Bio granted Hikma an exclusive license to register and commercialize Vicineum in all 19 MENA markets in an arrangement anticipated to deliver equal value share to both parties. The Company believes

this partnership represents a further step in realizing the significant global opportunity for Vicineum.

China:

- **In December 2020, Sesen Bio entered into a commercial manufacturing and global supply framework agreement (the "Agreement") with its partner Qilu Pharmaceutical for the treatment of BCG-unresponsive NMIBC and other types of cancer.** Under the Agreement, Qilu will be part of the contract manufacturing network for the global commercial supply of Vicineum. In July 2020, the Company and Qilu entered into a partnership which grants Qilu an exclusive license to develop, manufacture and commercialize Vicineum in China. The Company believes that the technology transfer to Qilu for manufacturing of Vicineum is on track to be completed in mid-2021. Upon completion of the technology transfer, Sesen Bio is entitled to receive a $2M milestone payment. In addition to Fujifilm and Baxter, the global supply partnership with Qilu expands the Company's network of world-class partners committed to providing reliable supply of Vicineum around the world.
- **In January 2021, the Investigational New Drug Application (IND) for Vicineum for the treatment of BCG-unresponsive NMIBC was accepted for review by China's Center for Drug Evaluation (CDE).** In the next one to two months, the Company expects to receive an update from Qilu regarding the potential approval of the IND by the CDE, triggering a $3M milestone payment by Qilu to Sesen Bio.

Leiden University Medical Center (LUMC):

- **In December 2020, Sesen Bio entered into agreement with LUMC to advancetheir existing partnership for the continued co-development of an imaging agent (the "Imaging Agent") comprised of an antibody fragment of Vicineum and an imaging molecule supplied by LUMC.** A Phase 1/2 clinical trial of the Imaging Agent was successfully completed by LUMC with favorable tolerability and demonstrated tumor detection, which the Company believes further supports the targeting specificity of Vicineum. The agreement with LUMC provides Sesen Bio with an option to obtain an exclusive, worldwide license to any intellectual property related to the Imaging Agent and enables the parties to begin negotiating terms for the next clinical trial, which is anticipated to begin after the anticipated US approval of Vicineum for the treatment of BCG-unresponsive NMIBC.

Commercial Update

- **In October 2020, Sesen Bio entered into an exclusive agreement with Cardinal Health for third-party logistics (3PL) and specialty pharmacy distribution services for Vicineum for the treatment of BCG-unresponsive NMIBC in the US.** As part of the agreement, Cardinal Health will provide comprehensive end-to-end 3PL, order-to-cash management and specialty pharmaceutical distribution services to Sesen Bio in support of commercialization in the US. In addition to Fujifilm and Baxter, the Cardinal Health relationship completes the selection of major supply chain partners in support of the commercial distribution of Vicineum, if approved. The Company believes that the supply chain will be ready to support the potential commercial launch of Vicineum with product supply available in Urology clinics by the fourth quarter of 2021.
- **In December 2020, the Institute for Clinical and Economic Review (ICER) issued favorable results for the cost-effectiveness of Vicineum in its final report**. ICER is the leading Health Technology Assessment body in the United States, and is an independent non-profit, research organization that conducts assessments to examine the clinical and economic value of health care innovations such as prescription medications. In the report, ICER cites that the majority of the ICER Council (8 yes votes; 3 no votes) judged Vicineum as superior to best supportive care with an estimate that treatment with Vicineum results in a decrease in cumulative health care costs compared to usual care of approximately $101,000 by year five. The Company believes that the results of the report further support that treatment with Vicineum has the potential to improve patient outcomes while reducing health care costs.

Fourth Quarter and Full-Year 2020 Financial Results

- **Cash Position:** Cash, cash equivalents and restricted cash were $55.4 million as of December 31, 2020, compared to $48.1 million as of December 31, 2019. As of the end of February 2021 cash and cash equivalents were $98 million. This amount is preliminary and is subject to change upon completion of the Company's financial statements for the quarterly period ended March 31, 2021.
- **R&D Expenses:** Research and development expenses for the fourth quarter of 2020 were $5.6 million compared to $5.4 million for the same period in 2019. For the year ended December 31, 2020, research and development expenses were $29.2 million compared to $24.7 million for the same period in 2019. The full year increase of $4.5 million was due primarily to increased costs associated with technology transfer and manufacturing scale-up for commercial supply ($6.0 million), license milestone fees ($1.2 million), and professional fees in support of regulatory activities ($0.4 million), partially offset by lower employee-related compensation ($1.1 million), lower clinical trial expenses ($1.6 million) as a result of the Company's Phase 3 VISTA Trial winding down, and other decreases ($0.4 million).
- **G&A Expenses:** General and administrative expenses for the fourth quarter of 2020 were $3.4 million compared to $3.3 million for the same period in 2019. For the year ended December 31, 2020, general and administrative expenses were

$14.3 million compared to $12.2 million for the same period in 2019. The full year increase of $2.1 million was due primarily to increases in employee-related compensation ($1.3 million), insurance ($0.5 million), legal fees ($0.6 million), and other increases ($0.2 million), partially offset by lower market research ($0.5 million).

- **Net Loss:** Net loss was $15.0 million, or $0.11 per share, for the fourth quarter of 2020, compared to $33.6 million, or $0.32 per share, for the same period in 2019. For the year ended December 31, 2020, net loss was $22.5 million, or $0.19 per share, compared to $107.5 million, or $1.18 per share, for the same period in 2019. The full year decrease in net loss was attributable to differences in the non-cash change in the fair value of contingent consideration that is recognized in earnings (or loss) for each respective period.

Conference Call and Webcast Information

Sesen Bio will host a conference call and webcast today at 8:00 AM ET with Dr. Neal Shore, medical director of the Carolina Urologic Research Center, who will provide a clinical perspective on Vicineum for the treatment of BCG-unresponsive NMIBC, and members of the management team who will provide a corporate update. Dr. Shore is a paid consultant to Sesen Bio and served as a clinical investigator for the Phase 2 and Phase 3 clinical trials of Vicineum. To participate in the conference call, please dial (844) 831-3025 (domestic) or (315) 625-6887 (international) and refer to conference ID 2441628. 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 Vicineum™

Vicineum, a locally administered fusion protein, is Sesen Bio's lead product candidate being developed for the treatment of BCG-unresponsive 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 in the follow-up stage of a Phase 3 registration trial in the US for the treatment of BCG-unresponsive NMIBC. In February 2021, the FDA accepted for filing the Company's BLA for Vicineum for the treatment of BCG-unresponsive NMIBC and granted the application Priority Review with a PDUFA date of August 18, 2021. 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. For this reason, 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 BCG-unresponsive non-muscle invasive bladder cancer (NMIBC). In February 2021, the FDA accepted for filing the Company's BLA for Vicineum for the treatment of BCG-unresponsive NMIBC and granted the application Priority Review with a PDUFA date of August 18, 2021. Sesen Bio retains worldwide rights to Vicineum with the exception of Greater China and the Middle East and North Africa (MENA), for which the Company has partnered with Qilu Pharmaceutical and Hikma Pharmaceuticals, respectively, 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 BCG-unresponsive 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 timing for the

FDA's decision on the Company's BLA for Vicineum for the treatment of BCG-unresponsive NMIBC based on the FDA granting the BLA Priority Review, the PDUFA date of August 18, 2021 and the need for an advisory meeting on the BLA, the Company's expectations regarding Vicineum's potential to improve patient outcomes and reduce healthcare costs, the Company's ability to realize the global opportunity of Vicineum, the timing of approval of the Company's MAA with the EMA if at all, the Company's expectations regarding its partnership with Hikma to commercialize Vicineum in the MENA markets, the timing of the technology transfer with Qilu, possible approval of the IND for Vicineum by the CDE in China and receipt by the Company of any related milestone payments, the ability of the Company's CMO partners to provide reliable supplies of Vicineum, expectations regarding the timing of our next clinical trial in connection with the LUMC agreement, expectations regarding timing and readiness of the Company's supply chain readiness to support commercialization of Vicineum, if approved, the impact of COVID-19 on the Company, including its ability to raise capital, and, if approved, its ability to commercialize Vicineum for the treatment of BCG-unresponsive NMIBC, 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.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except per share data)
(Unaudited)

	Three Months ended December 31,		Twelve Months ended December 31,	
	2020	**2019**	**2020**	**2019**
Revenue				
License revenue	$ -	$ -	$ 11,236	$ -
Total revenue	-	-	11,236	-
Operating expenses:				
Research and development	$ 5,566	5,420	29,191	24,663
General and administrative	$ 3,421	3,298	14,302	12,208
Change in change in fair value of contingent consideration	$ 5,640	25,020	(11,180)	71,620
Total operating expenses	14,627	33,738	32,313	108,491
Loss from operations	(14,627)	(33,738)	(21,077)	(108,491)
Other income (expense):				
Other income (expense), net	$ (69)	185	125	991
Net loss and comprehensive loss, before taxes	**$ (14,696)**	**$ (33,553)**	**$ (20,952)**	**$ (107,500)**
Provision for income taxes	$ (313)	$ -	$ (1,445)	$ -
Net loss and comprehensive loss	**$ (15,009)**	**$ (33,553)**	**$ (22,397)**	**$ (107,500)**
Deemed dividend on adjustment of exercise price of certain warrants	$ -	$ -	$ (147)	$ -
Net loss and comprehensive loss available to common stockholders	**$ (15,009)**	**$ (33,553)**	**$ (22,544)**	**$ (107,500)**
Net loss per common share - basic and diluted	$ (0.11)	$ (0.32)	$ (0.19)	$ (1.18)
Weighted-average common shares outstanding - basic and diluted	131,522	103,848	118,221	90,929

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

	December 31,	
	2020	**2019**
Assets		
Current assets:		
Cash and cash equivalents	$ 52,389	$ 48,121
Prepaid expense and other current assets	7,478	6,326
Restricted Cash	3,000	-
Total current assets	62,867	54,447
Restricted cash	20	20
Property and equipment, net	123	238

Intangibles	46,400	46,400
Goodwill	13,064	13,064
Other assets	349	196
Total Assets	**$ 122,823**	**$ 114,365**
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 3,102	$ 1,902
Accrued expenses	3,973	6,169
Deferred revenue	1,500	-
Contingent consideration	8,985	-
Other current liabilities	489	446
Total current liabilities	18,049	8,517
Contingent consideration, net of current portion	99,855	120,020
Deferred revenue, net of current portion	1,500	-
Deferred tax liability	12,528	12,528
Other liabilities	118	-
Total Liabilities	132,050	141,065
Commitments and contingencies		
Stockholders' Deficit:		
Preferred stock, $0.001 par value per share; 5,000,000 shares authorized at December 31, 2020 and December 31, 2019; no shares issued and outstanding at December 31, 2020 and December 31, 2019	-	-
Common stock. $0.001 par value per share; 200,000,000 shares authorized at December 31, 2020 and December 31, 2019; 140,449,647 and 106,801,409 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	140	107
Additional paid-in capital	306,554	266,717
Accumulated deficit	(315,921)	(293,524)
Total Stockholders' Deficit	(9,227)	(26,700)
Total Liabilities and Stockholders' Deficit	**$ 122,823**	**$ 114,365**

View source version on businesswire.com: https://www.businesswire.com/news/home/20210315005210/en/

Erin Clark, Vice President, Corporate Strategy & Investor Relations
ir@sesenbio.com

Source: Sesen Bio