Sesen Bio Reports First Quarter 2021 Financial Results and Commercial Launch Readiness Update in the US for Vicineum™

May 10, 2021

Strengthened balance sheet with $110M in cash and cash equivalents as of March 31, 2021

Company remains on track for potential approval in the US in August 2021 and in Europe in early 2022

Company to host conference call at 8am ET

CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 10, 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 first quarter ended March 31, 2021. The Company's Biologics License Application (BLA) for the Company's lead program, Vicineum, is currently under Priority Review with the Food and Drug Administration (FDA) for the treatment of BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with a target Prescription Drug User Fee Act (PDUFA) date of August 18, 2021.

"We are very pleased with the tremendous progress we continue to make in our four biggest global markets: the US, Europe, the Middle East and North Africa region and China," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "In the US, we continue to work with the FDA as we approach our target PDUFA date, and we are making substantial progress toward launch readiness. We are laser focused on bringing a product to market that we believe will improve patient outcomes while reducing overall healthcare costs to patients globally, and we expect to continue to make progress around the world in the coming months."

US and OUS Regulatory Update

US:

- **In February 2021, Sesen Bio received notice from the FDA that the BLA for Vicineum was accepted for filing.** Along with the acceptance, the Company was granted Priority Review with a target PDUFA date of August 18, 2021 for a decision on the BLA. The FDA also stated that an advisory committee meeting was not currently planned to discuss the BLA.

Europe:

- **On March 25, 2021, the Company was notified by the European Medicines Agency (EMA) that the Company's Marketing Authorization Application (MAA) for Vysyneum™ was found to be valid and that the review procedure had officially started.** Sesen Bio submitted the MAA on March 5, 2021, and the Company remains on-track for potential approval of Vysyneum in the EU in early 2022.
- **On March 31, 2021, the Company received notice from the Committee for Medicinal Products for Human Use (CHMP) of the EMA that the CHMP has conditionally accepted the proprietary brand name Vysyneum for the Company's product candidate, oportuzumab monatox, in the EU.** The Company believes Vysyneum is a brand name with strong marketing potential given its identical pronunciation to the US proprietary brand name Vicineum. Final approval of the Vysyneum brand name is conditional on EMA product approval.

China:

- **The Investigational New Drug (IND) application for Vicineum for the treatment of BCG-unresponsive NMIBC submitted to the Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA) was approved on March 19, 2021 ahead of the original timeline of April 2021.** This approval triggers a $3M milestone payment to the Company, and authorizes Qilu Pharmaceutical, the Company's partner in China, to conduct the proposed clinical trial to assess the efficacy and safety of Vicineum in China, at the sole cost of Qilu Pharmaceutical. Assuming a successful trial, Qilu Pharmaceutical anticipates submission of the product market application for Vicineum in 2022, with potential approval in China expected in 2023.

Middle East and North Africa (MENA):

- **The Company continues to work closely with its partner, Hikma Pharmaceuticals, to submit marketing authorization applications for Vicineum in 2021 in four key markets in the region: the Kingdom of Saudi Arabia, Jordan, Morocco and Egypt.** These four markets represent a significant opportunity in the MENA region, as Saudi Arabia, Jordan and Morocco have some of the most advanced healthcare systems in the region while Egypt is the second largest economy in Africa. The Company anticipates the first wave of potential country approvals for Vicineum in the MENA region as early as 2022.

Commercial Update

- **The Company continues to build its commercial organization with key leadership appointments and a partnership with a leading contract sales organization (CSO), Syneos Health, as it prepares for the anticipated commercial launch of Vicineum in the US in 3Q 2021.** Sesen Bio has begun to hire key commercial roles and has entered into a partnership with Syneos Health who will provide speed and logistical support in the hiring and deployment of the sales force. The sales force will include 35 sales representatives across four regions to target approximately 2,000 high prescribers of BCG.

First Quarter 2021 Financial Results

- **Cash Position:** Cash, cash equivalents and restricted cash were $110 million as of March 31, 2021, compared to $55.4 million as of December 31, 2020.
- **R&D Expenses:** Research and development expenses for the first quarter of 2021 were $6.1 million compared to $8.9 million for the same period in 2020. The decrease of $2.8 million was due to decreased costs associated with technology transfer and manufacturing ($4.4 million) and lower clinical trial expense as a result of the Company's Phase 3 VISTA trial winding down ($0.1 million). This was partially offset by increases in professional services in support of the MAA submission to the EMA ($0.9 million), license milestone fees ($0.6 million) and employee-related compensation ($0.2 million).
- **G&A Expenses:** General and administrative expenses for the first quarter of 2021 were $5.3 million compared to $3.4 million for the same period in 2020. The increase of $1.9 million was due primarily to increases in legal fees ($0.7 million), employee-related compensation driven by increased headcount as part of the commercial build ($0.7 million), professional services ($0.3 million), and other increases ($0.2 million).
- **Net Loss:** Net loss was $55.5 million, or $0.35 per share, for the first quarter of 2021, compared to net income of $41.6 million, or $0.31 per basic share and $0.31 per diluted share, for the first quarter of 2020. The change from net income to net loss was attributable primarily 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

Members of the Sesen Bio management team will host a conference call and webcast today at 8:00 AM ET to provide a corporate update and review the Company's financial results. To participate in the conference call, please dial (844) 831-3025 (domestic) or (315) 625-6887 (international) and refer to conference ID 6229838. 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 target 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 oportuzumab monatox, 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 target 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 the 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 target PDUFA date of August 18, 2021 and the need for an advisory meeting on the BLA, the timing of approval of the Company's MAA with the EMA if at all, the Company's commercial launch readiness for Vicineum in the US, if approved, the Company's expectations regarding Vicineum's potential to improve patient outcomes and reduce healthcare costs, the Company's ability to make progress on bringing Vicineum to market around the world, expectations regarding the final approval of the tradename for oportuzumab monatox by the EMA if at all, the Company's expectations regarding its partnership with Hikma to commercialize Vicineum in the MENA markets as early as 2022 and the market opportunity in the MENA region, the Company's expectation for Qilu Pharmaceutical to conduct the proposed clinical trial for Vicineum in patients with BCG-unresponsive NMIBC at the sole cost to Qilu Pharmaceutical and, if such trial is successful, anticipated submission of the product market application for Vicineum in the 2022 with potential approval in China in 2023, receipt by the Company of any related milestone payments, the Company's partnership with Syneos Health and its expectations related to its sales force, 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 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) INCOME
(In thousands, except per share data)
(Unaudited)

	Three Months ended March 31,		
	2021	**2020**	**Flux**
Revenue			
License revenue	$ 4,310	$ -	$ 4,310
Operating expenses:			
Research and development	$ 6,078	$ 8,867	$ (2,789)
General and administrative	$ 5,293	$ 3,448	$ 1,845
Change in fair value of contingent consideration	$ 48,160	$ (53,700)	$101,860
Total operating expenses	59,531	(41,385)	100,916
(Loss) Income from operations	(55,221)	41,385	(96,606)
Other (expense) income, net:			-
Other (expense) income, net	$ (3)	$ 179	$ (182)
Net (Loss) Income and Comprehensive (Loss) Income, Before Taxes	$ (55,224)	$ 41,564	$ (96,788)

Provision for income taxes	$ (288)	$ -	$ (288)
Net (Loss) Income and Comprehensive (Loss) Income After Taxes	**$ (55,512)**	**$ 41,564**	**$ (97,076)**
			$ -
Net (Loss) Income attributable to common stockholders - basic	$ (55,512)	$ 34,407	
Net (Loss) income attributable to common stockholders - diluted	$ (55,512)	$ 34,408	
Net (Loss) Income per common share - basic	$ (0.35)	$ 0.31	$ (0.67)
Weighted-average common shares outstanding - basic	157,032	109,808	47,224
			-
Net (Loss) Income per common share - diluted	$ (0.35)	$ 0.31	$ (0.67)
Weighted-average common shares outstanding - diluted	157,032	109,823	47,209

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

	March 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 109,965	$ 52,389
Accounts receivables	2,886	-
Prepaid expense and other current assets	13,728	7,478
Restricted Cash	-	3,000
Total current assets	126,579	62,867
Restricted cash	20	20
Property and equipment, net	93	123
Intangibles	46,400	46,400
Goodwill	13,064	13,064
Other assets	258	349
Total Assets	**186,414**	**$ 122,823**
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 2,004	$ 3,102
Accrued expenses	3,538	3,973
Deferred revenue	1,500	1,500
Contingent consideration	9,835	8,985
Other current liabilities	490	489
Total current liabilities	17,367	18,049
Contingent consideration, net of current portion	147,165	99,855
Deferred revenue, net of current portion	-	1,500
Deferred tax liability	12,528	12,528
Other liabilities	84	118
Total Liabilities	177,144	132,050
Commitments and contingencies		
Stockholders' Equity (Deficit):		
Preferred stock, $0.001 par value per share; 5,000,000 shares authorized at March 31, 2021 and December 31, 2020; no shares issued and outstanding at December 31, 2021 and December 31, 2020	-	-
Common stock. $0.001 par value per share; 200,000,000 shares authorized at March 31, 2021 and December 31, 2020; 171,978,799 and 140,449,647 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	172	140
Additional paid-in capital	380,531	306,554
Accumulated deficit	(371,433)	(315,921)
Total Stockholders' Equity (Deficit)	9,270	(9,227)
Total Liabilities and Stockholders' Equity (Deficit)	**$ 186,414**	**$ 122,823**

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