Sesen Bio Reports First Quarter 2020 Financial Results and Meaningful Progress Towards Demonstrating Analytical Comparability

May 11, 2020

Manufacturing and release testing of the Fujifilm pre-PPQ batch completed successfully

Positive Interactions with EMA on Regulatory Pathway for Vicinium® in Europe

Market research conducted in 1Q 2020 supports Urologists prefer Vicinium to Keytruda®

CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 11, 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 first quarter ended March 31, 2020. The Company also provided an update on the progress of manufacturing activities related to demonstrating analytical comparability between clinical batches of Vicinium and validation batches of Vicinium intended for potential future commercial use. The Company's lead program, Vicinium, 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 Vicinium to the FDA under Rolling Review.

"In the first quarter of 2020, we successfully completed manufacturing of the pre-PPQ batch at Fujifilm," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "We believe the commercial-scale cGMP batches of Vicinium manufactured to date at our CMOs are comparable to Vicinium previously manufactured by Sesen for use in our clinical trials. This reinforces our confidence in the upcoming PPQ campaign and our ability to demonstrate analytical comparability between clinical and commercial drug supply. The Company's focus for 2020 remains the flawless execution of the PPQ campaign and the finalization of Module 3 to complete the Vicinium BLA submission."

Manufacturing Update

- In February 2020, manufacturing of the pre-PPQ bulk drug substance batch was completed at Fujifilm. In April, quality release testing of the bulk drug substance from this batch was completed and all quality acceptance criteria were met. The Company believes these data de-risk the PPQ campaign and increase the likelihood of demonstrating analytical comparability. In addition, in April 2020, this batch from Fujifilm was used to manufacture the first PPQ drug product batch at Baxter and release testing is currently underway. The Company remains on track to complete the Vicinium BLA submission in the second half of 2020 and anticipates potential approval in first half of 2021. At this time, the Company does not expect any impact to the manufacturing activities or regulatory processes related to Vicinium due to COVID-19.

CHMP Scientific Advice Update

- On May 7, 2020 the Company 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 the Company's 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 Vicinium. Based on the guidance received, the Company expects to submit the MAA for Vicinium to the EMA in early 2021, with potential approval anticipated in early 2022.

Commercial Opportunity

- In the first quarter of 2020, the Company conducted 30-minute interviews with 34 randomly selected, high-prescribing Urologists to assess their views of a blinded clinical profile of Vicinium as well as an unblinded profile of Keytruda, which was recently approved by the FDA for BCG-unresponsive NMIBC patients with carcinoma in situ (CIS) with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy. The research revealed that, when prescribing a branded agent, Urologists would prescribe Vicinium to 83% of their patients compared to 17% for Keytruda. The overall preference for Vicinium was driven by comparable efficacy data to Keytruda with a favorable safety profile and mode of administration that would allow physicians to easily integrate Vicinium into their practices. We believe these data support the potential for a successful launch characterized by rapid uptake and growth of Vicinium.

First Quarter 2020 Financial Results

- **Cash Position:** Cash and cash equivalents were $42.5 million as of March 31, 2020, compared to $48.1 million as of December 31, 2019.

- **R&D Expenses:** Research and development expenses for the first quarter of 2020 were $8.9 million compared to $4.7 million for the same period in 2019. The first quarter increase was due primarily to costs related to the ongoing technology transfer process as we scale-up for commercial manufacturing, in addition to increased regulatory costs partially offset by lower employee compensation and lower clinical expenses related to the Phase 3 VISTA trial for Vicinium.
- **G&A Expenses:** General and administrative expenses for the first quarter of 2020 were $3.4 million compared to $3.1 million for the same period in 2019. The first quarter increase was due primarily to increases in professional fees and employee compensation, offset by reduced market research costs.
- **Net Income (Loss):** Net income was $41.6 million, or $0.31 per basic share and $0.31 per diluted share, for the three months ended March 31, 2020, compared to a net loss of $6.5 million, or $0.08 per basic and diluted share, for the same period in 2019. The change was primarily the result of the non-cash change in fair value of contingent consideration due to significantly higher discount rates associated with current market conditions related to the COVID-19 pandemic.

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 3780957. 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 Vicinium® 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 Vicinium 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 Vicinium®

Vicinium, 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). Vicinium 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. Vicinium 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 Vicinium 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 Vicinium promote an anti-tumor immune response that may potentially combine well with immuno-oncology drugs, such as checkpoint inhibitors. The activity of Vicinium 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, Vicinium ®, also known as VB4-845, is currently in 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 Vicinium to the FDA under Rolling Review. Vicinium 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 Vicinium. 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: our ability to successfully develop our product candidates and complete our planned clinical programs, expectations regarding the impact of the COVID-19 pandemic, expectations regarding our PPQ manufacturing runs, expectations regarding the timing of completion of our BLA submission for Vicinium, expectations regarding the timing of potential approval of our BLA submission by the FDA, expectations regarding the timing of the submission of our MAA for Vicinium to the EMA, expectations regarding the timing of potential approval of our MAA submission by the EMA, expectations regarding the potential successful launch of Vicinium, if approved, our ability to obtain marketing approvals for our product candidates, 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 INCOME (LOSS)
(In thousands, except per share data)
(Unaudited)

	Three Months ended March 31,	
	2020	**2019**
Operating expenses:		
Research and development	$ 8,867	$ 4,686
General and administrative	3,448	3,055
Change in change in fair value of contingent consideration	(53,700)	(1,000)
Total operating expenses	(41,385)	6,741
Income (Loss) from Operations	41,385	(6,741)
Other income (expense):		
Other income, net	179	261
Net Income (Loss) and Comprehensive Income (Loss)	**$ 41,564**	**$ (6,480)**
Net income (loss) attributable to common stockholders - basic	$ 34,407	$ (6,480)
Net income (loss) attributable to common stockholders - diluted	$ 34,408	$ (6,480)
Net income (loss) per common share - basic	$ 0.31	$ (0.08)
Weighted-average common shares outstanding - basic	109,808	77,458
Net income (loss) per common share - diluted	$ 0.31	$ (0.08)
Weighted-average common shares outstanding - diluted	109,823	77,458

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

	March 31, 2020	**December 31, 2019**
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 42,463	$ 48,121
Prepaid expense and other current assets	2,420	6,326

Total current assets	44,883	54,447
Restricted cash	20	20
Property and equipment, net	207	238
Intangibles	46,400	46,400
Goodwill	13,064	13,064
Other assets	91	196
Total Assets	**$ 104,665**	**$ 114,365**
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 2,068	$ 1,902
Accrued expenses	4,893	6,169
Other current liabilities	405	446
Total current liabilities	7,366	8,517
Contingent consideration	66,320	120,020
Deferred tax liability	12,528	12,528
Total Liabilities	86,214	141,065
Commitments and contingencies		
Stockholders' Equity (Deficit):		
Preferred stock, $0.001 par value per share; 5,000,000 shares authorized at March 31, 2020 and December 31, 2019; no shares issued and outstanding at March 31, 2020 and December 31, 2019		
Common stock. $0.001 par value per share; 200,000,000 shares authorized at March 31, 2020 and December 31, 2019; 109,991,553 and 106,801,409 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	110	107
Additional paid-in capital	270,301	266,717
Accumulated deficit	(251,960)	(293,524)
Total Stockholders' Equity (Deficit)	18,451	(26,700)
Total Liabilities and Stockholders' Equity (Deficit)	**$ 104,665**	**$ 114,365**

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