Sesen Bio Reports Fourth Quarter and Full-Year 2019 Financial Results

March 16, 2020

Company on track to complete Vicinium® BLA submission in the second half of 2020 with potential approval in first half of 2021

New market research supports large commercial opportunity

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- **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, 2019. The Company also provided an update highlighting regulatory progress and the commercial opportunity of Vicinium for the treatment of patients with high-risk non-muscle invasive bladder cancer (NMIBC).

"2019 was a year of tremendous progress for Sesen Bio in every way, but especially in terms of our regulatory progress," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "After four pivotal meetings with the FDA and the initiation of our BLA submission in 2019, we now turn our focus to finalizing the BLA for Vicinium and transforming into a commercial-ready organization in 2020. We believe Vicinium is a highly differentiated product candidate with a unique mechanism of action and clinical profile. We look forward to continuing our collaborative relationship with the FDA as we work to bring this important product to patients."

Regulatory Update

- **Initiation of Vicinium BLA Submission of clinical and non-clinical data**
  - **On December 6, 2019, the Company initiated the BLA submission for Vicinium under Rolling Review to the FDA.** The initial submission included the completed non-clinical and clinical modules, and a partially completed Module 3 which details Chemistry, Manufacturing and Controls (CMC).
  - **Anticipated completion of BLA submission in second half of 2020 with potential approval in first half of 2021.** As part of finalizing Module 3, the Company anticipates completing three commercial-scale process performance qualification manufacturing runs for both bulk drug substance and drug product in the summer of 2020. The associated quality release testing results and master validation report will then be incorporated into Module 3, along with additional characterization testing and stability data to support the demonstration of analytical comparability between clinical and commercial drug supply. The Company anticipates submitting this information to the FDA in the second half of 2020 to complete the BLA submission. If the FDA accepts the BLA filing, the Company plans to request a Priority Review.

Commercial Opportunity

- **Early commercial launch planning underway**
  - **New market research supports large commercial opportunity.** In the first quarter of 2020, the Company conducted 30-minute interviews with 34 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). Overall, these urologists indicated that Vicinium would be the preferred treatment modality in the majority of their patients in comparison to Keytruda and radical cystectomy. We believe this favorable response from urologists is due not only to the distinct mechanism of action and strong efficacy and safety profile of Vicinium, but also to its mode of administration and ease of adoption into clinical practice, which may provide continuity of care for patients and urologists.

Fourth Quarter and Full-Year 2019 Financial Results

- **Cash Position:** Cash and cash equivalents were $48.1 million as of December 31, 2019, compared to $50.4 million as of December 31, 2018.
- **R&D Expenses:** Research and development expenses for the fourth quarter of 2019 were $5.4 million compared to $4.7 million for the same period in 2018. For the year ended December 31, 2019, research and development expenses were $24.7 million compared to $14.1 million for the same period in 2018. The fourth quarter and annual increases were due primarily to costs related to the ongoing technology transfer process as we scale-up for commercial manufacturing and increased regulatory, internal and external staffing costs, partially offset by reduced expenses related to the Phase 3 VISTA trial for Vicinium.

- **G&A Expenses:** General and administrative expenses for the fourth quarter of 2019 were $3.3 million compared to $3.5 million for the same period in 2018. For the year ended December 31, 2019, general and administrative expenses were $12.2 million compared to $11.6 million for the same period in 2018. The fourth quarter decrease was due primarily to decreases in market research expense, public relations expense and external legal fees, partially offset by increases in internal staffing costs and professional and audit fees. The annual increase was due primarily to increases in internal staffing costs, professional and audit fees, partially offset by lower external legal fees and commercial expenses.
- **Net Loss:** Net loss was $33.6 million, or $0.32 per share, for the fourth quarter of 2019, compared to $6.8 million, or $0.09 per share, for the same period in 2018. For the year ended December 31, 2019, net loss was $107.5 million, or $1.18 per share, compared to $33.7 million, or $0.55 per share, for the same period in 2018. The fourth quarter and annual increases were due primarily to a higher non-cash change in the fair value of contingent consideration and the higher research and development expenses described above.

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.

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 timing of our process performance qualification manufacturing runs, expectations regarding the timing of completion of our BLA submission for Vicinium, our expectation to request a Priority Review in the event our BLA submission is accepted by the FDA, expectations regarding the timing of potential approval of our BLA submission by the FDA, 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.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except per share data)

	(unaudited)		(unaudited)	
	Three Months ended December 31,		Twelve Months ended December 31,	
	2019	2018	2019	2018
Operating expenses:				

Research and development	$ 5,420	$ 4,671	$ 24,663	$ 14,077
General and administrative	3,298	3,495	12,208	11,623
Change in fair value of contingent consideration	25,020	(1,100)	71,620	8,800
Total operating expenses	33,738	7,066	108,491	34,500
Loss from Operations	(33,738)	(7,066)	(108,491)	(34,500)
Other income (expense):				
Other income, net	185	309	991	807
Net Loss and Comprehensive Loss	**$ (33,553)**	**$ (6,757)**	**$ (107,500)**	**$ (33,693)**
Net loss per common share - basic and diluted	$ (0.32)	$ (0.09)	$ (1.18)	$ (0.55)
Weighted-average common shares outstanding - basic and diluted	103,848	77,345	90,929	61,774

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

	(unaudited) December 31, 2019	**December 31, 2018**
Assets		
Current assets:		
Cash and cash equivalents	$ 48,121	$ 50,422
Prepaid expense and other current assets	6,326	1,334
Total current assets	54,447	51,756
Restricted cash	20	20
Property and equipment, net	238	321
Intangibles	46,400	46,400
Goodwill	13,064	13,064
Other assets	196	-
Total Assets	**$ 114,365**	**$ 111,561**
Liabilities and Stockholders' (Deficit) Equity		
Current liabilities:		
Accounts payable	$ 1,902	$ 1,367
Accrued expenses	6,169	4,746

Other current liabilities	446	-
Total current liabilities	8,517	6,113
Contingent consideration	120,020	48,400
Deferred tax liability	12,528	12,528
Other liabilities	-	313
Total Liabilities	141,065	67,354
Commitments and contingencies		
Stockholders' (Deficit) Equity:		
Preferred stock, $0.001 par value per share; 5,000,000 shares authorized at December 31, 2019 and 2018; no shares issued and outstanding at December 31, 2019 and 2018	-	-
Common stock. $0.001 par value per share; 200,000,000 shares authorized at December 31, 2019 and 2018; 106,801,409 and 77,456,180 shares issued and outstanding at December 31, 2019 and 2018, respectively	107	77
Additional paid-in capital	266,717	230,154
Accumulated deficit	(293,524)	(186,024)
Total Stockholders' (Deficit) Equity	(26,700)	44,207
Total Liabilities and Stockholders' (Deficit) Equity	**$ 114,365**	**$ 111,561**

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