Sesen Bio Reports First Quarter 2022 Financial Results and Business Update

May 9, 2022

Strong balance sheet of $170 million in cash and cash equivalents as of March 31, 2022, expected to fund current operating plan into the fourth quarter of 2024

CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 9, 2022-- **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, 2022. During the quarter, the Company continued to engage with the US Food and Drug Administration (FDA) to identify an anticipated regulatory path toward potential resubmission of a Biologics License Application (BLA) for Vicineum™ for the treatment of non-muscle invasive bladder cancer (NMIBC). The Company has also initiated a process to review strategic alternatives with the goal of maximizing shareholder value.

US Regulatory Update

- **On March 28, 2022, Sesen Bio participated in a Type C Meeting with the FDA**. During the meeting, the FDA agreed to a majority of the Company's proposed protocol and statistical analysis plan design elements for an additional Phase 3 clinical trial that it plans to conduct for potential resubmission of a BLA for Vicineum for the treatment of NMIBC. The Company plans to meet with the FDA in mid-2022 to align on the remaining outstanding items related to the additional Phase 3 clinical trial, and intends to request that meeting in the coming weeks.

In addition to working with the FDA to align on a study design, the Company has been addressing comments related to Chemistry, Manufacturing and Controls (CMC) that were included in the Complete Response Letter (CRL) for the BLA for Vicineum for the treatment of bacillus Calmette-Guérin (BCG)-unresponsive NMIBC. The Company has completed technical work on several of the key CMC comments and is continuing to make progress on the remaining items. The Company's responses to the CMC comments will ultimately be reviewed by the FDA upon a potential BLA resubmission.

Other Business Updates

- **On January 6, 2022, Sesen Bio disclosed that it achieved a $20 million milestone payment pursuant to the Company's exclusive license agreement (Roche License Agreement) with Roche for legacy Interleukin-6 (IL-6) antagonist antibody technology owned by Sesen Bio.** Following this milestone payment, Sesen Bio has cumulatively received $50 million in upfront and milestone payments, with an additional $220 million in potential future milestone payments, as well as royalty payment obligations on future sales, remaining under the Roche License Agreement. As part of the Roche License Agreement, Roche also maintains the right to fully acquire the IL-6 technology.
- **On May 3, 2022, Sesen Bio announced that it had initiated a process to review strategic alternatives with the goal of maximizing shareholder value.** Potential strategic alternatives to be explored and evaluated during the review process may include the sale of the Company, a merger, acquisition or other business combination, a strategic partnership with one or more parties, or the licensing, sale or divestiture of some of the Company's proprietary technologies. The Company is actively working with an investment bank in this process. Pending any decision to undertake any strategic alternative, the Company is continuing its development activities in accordance with its existing business strategy.
- **On June 22, 2022, Sesen Bio will hold its Annual Meeting of Stockholders, one of the primary purposes of which will be to approve a proposal for a reverse stock split, which includes a proportionate reduction in authorized shares of common stock.** The proposed reverse stock split, if approved, should allow the Company to remain listed on the Nasdaq Global Market, which should increase the range and attractiveness of strategic alternatives that the Company is able to consider to maximize shareholder value.

First Quarter 2022 Financial Results

- **Cash Position:** Cash, cash equivalents and restricted cash were $169.8 million as of March 31, 2022, compared to $110.0 million as of March 31, 2021.
- **R&D Expenses:** Research and development expenses for the first quarter of 2022 were $4.8 million compared to $6.1

million for the same period in 2021. The decrease of $1.3 million was primarily due to lower costs associated with technology transfer and manufacturing ($1.4 million), regulatory and clinical consulting fees ($0.6 million) and license milestone fees ($0.6 million), which were partially offset by increases in employee-related compensation, primarily driven by increased headcount and the retention program implemented in the fourth quarter of 2021 ($1.2 million), and other R&D expenses ($0.1 million).

- **G&A Expenses:** General and administrative expenses for the first quarter of 2022 were $9.0 million compared to $5.3 million for the same period in 2021. The increase of $3.7 million was due primarily to increases in legal expenses related, in part, to the independent internal review completed in February 2022 ($3.0 million), employee-related compensation, primarily driven by increased headcount and the retention program implemented in the fourth quarter of 2021 ($1.1 million), insurance expense ($0.1 million) and other general expenses ($0.2 million). This was partially offset by a decrease in consultant fees incurred in preparation for commercial launch as a result of the subsequent CRL received in August 2021 ($0.7 million).
- **Net Loss:** Net loss was $0.8 million, or $0.00 per basic and per diluted share, for the first quarter of 2022, compared to net loss of $55.5 million, or $0.35 per basic and diluted share, for the same period in 2021. The decrease of $54.7 million in net loss was primarily attributable to the non-cash decrease in fair value of contingent consideration ($61.1 million), partially offset by decreased license and related revenue recognized ($4.3 million).

About Vicineum™

Vicineum, a locally administered fusion protein, is Sesen Bio's lead product candidate being developed for the treatment of 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 to the antibody binding fragment until it is internalized by the cancer cell. This fusion protein design 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 clinical trial in the US for the treatment of BCG-unresponsive NMIBC. In February 2021, the FDA accepted the Company's Biologics License Application (BLA) file for Vicineum for the treatment of BCG-unresponsive NMIBC, granted Priority Review for the BLA and set a Prescription Drug User Fee Act (PDUFA) date of August 18, 2021. On August 13, 2021, the Company received a Complete Response Letter (CRL) from the FDA regarding its BLA for Vicineum. After meeting with the FDA, the Company plans to conduct an additional Phase 3 clinical trial for Vicineum for the treatment of NMIBC in connection with the potential resubmission of a BLA. The Company plans to request a meeting with the FDA in the coming weeks to align on the remaining outstanding items related to the additional Phase 3 clinical trial. 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 clinical trial for the treatment of BCG-unresponsive NMIBC. In February 2021, the FDA accepted the Company's BLA file for Vicineum for the treatment of BCG-unresponsive NMIBC, granted Priority Review for the BLA and set a PDUFA date of August 18, 2021. On August 13, 2021, the Company received a CRL from the FDA regarding its BLA for Vicineum. After meeting with the FDA, the Company plans to conduct an additional Phase 3 clinical trial for Vicineum for the treatment of NMIBC in connection with the potential resubmission of a BLA. The Company plans to request a meeting with the FDA in the coming weeks to align on the remaining outstanding items related to the additional Phase 3 clinical trial. Sesen Bio retains worldwide rights to Vicineum with the exception of Greater China, the Middle East and North Africa (MENA) and Turkey, for which the Company has partnered with Qilu Pharmaceutical, Hikma Pharmaceuticals and Eczacibasi Pharmaceuticals Marketing (EIP), 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, which is being developed for the treatment of 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 its operations as a result of COVID-19, however, the Company is not able to quantify or predict with certainty the overall scope of potential impacts to its business, including, but not limited to, its ability to conduct an additional Phase 3 clinical trial for Vicineum for the treatment of NMIBC, its ability to raise capital and, if approved, its ability to 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," "expect," "intend," "may," "plan," "predict," "target," "potential," "will," "would," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. For example, statements regarding the anticipated regulatory path forward for Vicineum for the treatment of NMIBC, the Company's plans to conduct an additional Phase 3 clinical trial for potential resubmission of a BLA for Vicineum for the treatment of NMIBC, the Company's plans to meet with the FDA in mid-2022 to align on the remaining outstanding items related to the additional Phase 3 clinical trial, the Company's intentions to request such meeting in the coming weeks, any future payments to the Company pursuant to the Roche License Agreement including any future milestone payments and royalty payments, the Company's plans to review strategic alternatives with the goal of maximizing shareholder value, the Company's plans to explore and evaluate potential strategic alternatives, which may include the sale of the Company, a merger, acquisition or other business combination, a strategic partnership with one or more parties, or the licensing, sale or divestiture of some of the Company's proprietary technologies, the Company's plans to continue its development activities in accordance with its existing business strategy pending any decision to undertake any strategic alternative, the Company's plans to hold its Annual Meeting of Stockholders on June 22, 2022 and request stockholder approval of a reverse stock split, the Company's expectations that such reverse stock split, if approved, should allow the Company to remain listed on the Nasdaq Global Market, which should increase the range and attractiveness of strategic alternatives that the Company is able to consider to maximize shareholder value, the impact of COVID-19 on the Company, including its ability to conduct an additional Phase 3 clinical trial for Vicineum for the treatment of NMIBC, its ability to raise capital, and, if approved, its ability to commercialize Vicineum. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the risk that the Company may not resume its plans to pursue regulatory approval for Vicineum, the risk that the Company may not be able to align with the FDA on the remaining outstanding items related to the additional Phase 3 clinical trial for Vicineum for the treatment of NMIBC, or other issues related to preparing for an additional Phase 3 clinical trial for Vicineum, including difficulties with clinical trial site selection and obtaining clinical trial materials and supplies, the risk that clinical trials of Vicineum for the treatment of NMIBC, including the additional clinical trial needed to address issues raised in the CRL, may fail to demonstrate safety and efficacy to the satisfaction of the FDA, or otherwise produce favorable results, the risk that the FDA may not approve a BLA for Vicineum for the treatment of NMIBC if the Company resubmits a BLA at a future time, the risk that Vicineum for the treatment of NMIBC may cause undesirable side effects, serious adverse events or have other properties that could delay or halt clinical trials, delay or prevent its regulatory approval by the FDA, limit the commercial profile of its labeling, if approved, or result in significant negative consequences following any marketing approval, the occurrence of any event, change or other circumstances that could give rise to the termination of the Roche License Agreement, the risk that the Company may not be successful in identifying one or more strategic alternatives or ultimately pursuing a strategic alternative that delivers the anticipated benefits or enhances shareholder value, the risk that the Company's exploration and evaluation of strategic alternatives or the public announcement thereof may be disruptive to the Company's business operations or cause the Company's stock price to fluctuate significantly, the risk that the Company's exploration and evaluation of strategic alternatives may be time consuming and involve the dedication of significant resources and may require the Company to incur significant costs and expenses, the risk that the Company's exploration and evaluation of strategic alternatives could divert the attention of the Company's management and its board of directors from the existing business operations, negatively impact the Company's ability to attract, retain and motivate key employees, and expose the Company to potential litigation in connection with the process of exploring strategic alternatives or any resulting transaction, 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 BALANCE SHEETS
(Unaudited; In thousands, except share and per share data)

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 169,790	$ 162,636
Accounts receivable	1,011	21,011
Other receivables	1,041	3,482
Prepaid expenses and other current assets	8,795	18,476
Total current assets	180,637	205,605
Non-current assets:		

Restricted cash	20	20
Property and equipment, net	33	43
Intangible assets	14,700	14,700
Goodwill	13,064	13,064
Long term prepaid expenses	17,301	7,192
Other assets	85	123
Total non-current assets	45,203	35,142
Total Assets	$ 225,840	$ 240,747
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 666	$ 2,853
Accrued expenses	7,278	8,255
Other current liabilities	530	460
Total current liabilities	8,474	11,568
Non-current liabilities:		
Contingent consideration	39,100	52,000
Deferred tax liability	3,969	3,969
Deferred revenue	1,500	1,500
Total non-current liabilities	44,569	57,469
Total Liabilities	53,043	69,037
Stockholders' Equity:		
Preferred stock, $0.001 par value per share; 5,000,000 shares authorized at March 31, 2022 and December 31, 2021 ; no shares issued and outstanding at March 31, 2022 and December 31, 2021	-	-
Common stock, $0.001 par value per share; 400,000,000 shares authorized at March 31, 2022 and December 31, 2021; 199,463,645 shares issued and outstanding at March 31, 2022 and December 31, 2021	199	199
Additional paid-in capital	489,662	487,768
Accumulated deficit	(317,064)	(316,257)
Total Stockholders' Equity	172,797	171,710
Total Liabilities and Stockholders' Equity	$ 225,840	$ 240,747

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

	Three Months ended March 31,	
	2022	**2021**
Revenue:		
License and related revenue	$ -	$ 4,310
Total revenue	$ -	$ 4,310
Operating expenses:		
Research and development	$ 4,760	$ 6,078
General and administrative	8,975	5,293
Change in fair value of contingent consideration	(12,900)	48,160
Total operating expenses	$ 835	$ 59,531
Loss from Operations	$ (835)	$ (55,221)
Other income (expense), net	28	(3)
Loss Before Taxes	$ (807)	$ (55,224)
Provision for income taxes	-	(288)
Net Loss and Comprehensive Loss After Taxes	$ (807)	$ (55,512)
Net loss attributable to common stockholders - basic and diluted	$ (807)	$ (55,512)
Net loss per common share - basic and diluted	$ (0.00)	$ (0.35)
Weighted-average common shares outstanding - basic and diluted	199,464	157,033

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