Sesen Bio Reports Second Quarter 2018 Financial Results and Pipeline Updates

August 14, 2018

FDA Grants Fast Track Designation for Vicinium in NMIBC

Company Focused on Defining Registration Pathway for Vicinium and Preparing for BLA Submission in 2019

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Aug. 14, 2018-- Sesen Bio, Inc. (NASDAQ: SESN), a late-stage clinical company developing next-generation antibody-drug conjugate (ADC) therapies for the treatment of cancer, today reported pipeline updates and operating results for the second quarter ended June 30, 2018.

"The first half of 2018 was full of successful milestones for Sesen Bio, and I am excited to have joined the company at such an important time in its evolution," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio, who was recently appointed on August 7, 2018. "The three-month data from the Phase 3 VISTA Trial demonstrate a strong complete response rate and favorable safety with Vicinium for high-grade non-muscle invasive bladder cancer, and we look forward to assessing twelve-month efficacy data in less than a year's time. Now, with Fast Track designation for Vicinium, we are focused on advancing our engagement with the FDA, kicking off critical manufacturing readiness activities, initiating pre-commercial efforts and preparing for our very first BLA submission for Vicinium for this highly deserving patient population. I am very confident in what the future holds for Sesen Bio and look forward to delivering on the important milestones we have ahead."

Business Update

- In June 2018, Sesen Bio completed an underwritten public offering of its common stock raising gross proceeds of approximately $46 million. The company believes this financing extends the company's cash runway into 2020 based on its current operating plan.

Vicinium Program Updates

- In August 2018, the U.S. Food and Drug Administration (FDA) granted Fast Track designation to Vicinium™ for the treatment of BCG-unresponsive, high-grade non-muscle invasive bladder cancer (NMIBC). Fast Track designation is intended to expedite the development and review process of therapeutics that address unmet medical needs, including opportunities for more frequent interactions with the FDA.
- In June 2018, the National Cancer Institute (NCI) initiated patient dosing in the Phase 1 trial of Vicinium in combination with AstraZeneca's PD-L1 checkpoint inhibitor, Imfinzi™ (durvalumab). The NCI is evaluating the combination under a Cooperative Research and Development Agreement, which was executed in June 2017.
- In May 2018, Sesen Bio presented positive, three-month data from its ongoing Phase 3 VISTA Trial of Vicinium for the treatment of patients with high-grade NMIBC who have been previously treated with bacillus Calmette-Guérin (BCG), during a plenary session at the American Urological Association Annual Meeting.
    - In the cohort of patients with carcinoma in situ (CIS) with or without papillary disease whose cancer recurred within six months of their last course of BCG treatment, treatment with Vicinium demonstrated a complete response rate of 39 percent. In evaluable patients in the cohort of patients with CIS with or without papillary disease whose cancer recurred after six months, but before 11 months, after their last course of BCG treatment, treatment with Vicinium demonstrated a complete response rate of 80 percent. This translates into a 42 percent complete response rate for the combined cohorts of CIS patients who were BCG-unresponsive within 12 months of their last BCG treatment.
    - In patients with papillary disease without CIS whose cancer recurred within six months of their last course of BCG treatment, treatment with Vicinium demonstrated a 68 percent recurrence-free rate at three months.
    - To date, Vicinium has been well-tolerated by patients in the VISTA Trial. Sesen Bio anticipates reporting twelve-month data from its Phase 3 VISTA Trial in mid-2019.

Second Quarter 2018 Financial Results

- **Cash Position:** Cash and cash equivalents were $62.9 million as of June 30, 2018, compared to $15.8 for the same period in 2017.
- **R&D Expenses:** Research and development expenses were $2.8 million for the quarter ended June 30, 2018, compared to $2.9 million for the same period in 2017. This decrease was due primarily to a reduction in Vicinium-related development expenses.

- **G&A Expenses:** General and administrative expenses were $2.4 million for the quarter ended June 30, 2018, compared to $2.2 million for the same period in 2017. This increase was due primarily to an increase in professional fees.
- **Net Loss:** Net loss was $9.0 million, or $0.16 per share, for the quarter ended June 30, 2018, compared to net loss of $7.3 million, or $0.30 per share, for the same period in 2017.
- **Financial Guidance:** Following the company's public offering in June 2018, Sesen Bio believes it will have capital sufficient to fund its current operating plans into 2020.

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™ in patients with high-grade non-muscle invasive bladder cancer (NMIBC) that is carcinoma in situ (CIS), which is cancer found on the inner lining of the bladder that has not spread into muscle or other tissue) and/or papillary, which is cancer that has grown from the bladder lining out into the bladder but has not spread into muscle or other tissue, who have been previously treated with bacillus Calmette-Guérin (BCG). The primary endpoint of the trial is the complete response rate in patients with CIS with or without papillary disease. Patients in the trial receive 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. Twelve-month data are anticipated in mid-2019. To learn more about the Phase 3 VISTA Trial, please visit www.clinicaltrials.gov and search the identifier NCT02449239.

About Vicinium™
Vicinium™, also known as VB4-845, is Sesen Bio's lead product candidate and is a next-generation antibody-drug conjugate (ADC), developed using the company's proprietary Targeted Protein Therapeutics platform, for the treatment of high-grade 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 (ETA). Vicinium is constructed with a stable, genetically engineered peptide linker 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-grade NMIBC in patients who have previously received two courses of bacillus Calmette-Guérin (BCG) and whose disease is now BCG-unresponsive. Twelve-month data from the trial are anticipated in mid-2019. Additionally, Sesen Bio believes that Vicinium's cancer cell-killing properties 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 next-generation antibody-drug conjugate therapies for the treatment of cancer based on the company's Targeted Protein Therapeutics platform. The company's lead program, Vicinium™, also known as VB4-845, is currently in a Phase 3 registration trial, the VISTA Trial, for the treatment of high-grade non-muscle invasive bladder cancer. Twelve-month data from the trial are anticipated in mid-2019. Vicinium incorporates a tumor-targeting antibody fragment and a protein cytotoxic payload into a single protein molecule designed to selectively and effectively kill cancer cells while sparing healthy cells. 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: the uncertainties inherent in the initiation and conduct of clinical trials, the possibility that the three-month data of the Phase 3 VISTA Trial are not indicative of final clinical results and final clinical trial results may not be positive with regard to the safety or efficacy of Vicinium, our ability to successfully develop our product candidates and complete our planned clinical programs, our ability to obtain marketing approvals for our product candidates, expectations regarding our ongoing clinical trials, availability and timing of data from clinical trials, whether interim results from a clinical trial will be predictive of the final results of the trial or results of early clinical studies will be indicative of the results of future studies, the adequacy of any clinical models, expectations regarding regulatory approvals, expectations regarding the adequacy of our existing capital resources to fund our operations into 2020 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)

	June 30, 2018	December 31, 2017
Assets		
Current assets:		

Cash and cash equivalents	$ 62,961	$ 14,680
Prepaid expenses and other current assets	806	301
Total current assets	63,767	14,981
Property and equipment, net	421	522
Restricted cash	20	10
Intangible assets	46,400	46,400
Goodwill	13,064	13,064
Other assets	41	120
Total assets	$ 123,713	$ 75,097
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,310	$ 907
Accrued expenses	3,223	3,813
Total current liabilities	4,533	4,720
Other liabilities	288	215
Deferred tax liability	12,528	12,528
Contingent consideration	42,300	39,600
Stockholders' equity:		
Common stock	77	35
Additional paid-in capital	229,239	170,330
Accumulated deficit	(165,252)	(152,331)
Total stockholders' equity	64,064	18,034
Total liabilities and stockholders' equity	$ 123,713	$ 75,097

SESEN BIO, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(unaudited)
(in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	**2017**	**2018**	**2017**
Total revenue	$ -	$ -	$ -	$ 425
Operating expenses:				
Research and development	2,779	2,909	6,034	5,783
General and administrative	2,351	2,241	4,303	4,454
Loss from change in fair value of contingent consideration	3,900	2,200	2,700	3,700
Total operating expenses	9,030	7,350	13,037	13,937
Loss from operations	(9,030)	(7,350)	(13,037)	(13,512)
Other income, net	72	34	116	135
Net loss and comprehensive loss	$ (8,958)	$ (7,316)	$ (12,921)	$ (13,377)
Net loss per share —basic and diluted	$ (0.16)	$ (0.30)	$ (0.28)	$ (0.54)
Weighted-average number of common shares used in net				

loss per share —basic and diluted	56,421	24,685	46,105	24,648

View source version on businesswire.com: https://www.businesswire.com/news/home/20180814005161/en/

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