UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15 (d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 10, 2021

SESEN BIO, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-36296**	**26-2025616**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

245 First Street, Suite 1800 **Cambridge, MA**	**02142**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 444-8550

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8–K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a–12 under the Exchange Act (17 CFR 240.14a–12)

☐ Pre–commencement communications pursuant to Rule 14d–2(b) under the Exchange Act (17 CFR 240.14d–2(b))

☐ Pre–commencement communications pursuant to Rule 13e–4(c) under the Exchange Act (17 CFR 240.13e–4(c))

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001	SESN	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 – Regulation FD Disclosure.

In June 2017, Sesen Bio, Inc. (the "Company") entered into a Cooperative Research and Development Agreement ("CRADA") with the National Cancer Institute ("NCI") for the development of Vicineum™ in combination with AstraZeneca's immune checkpoint inhibitor durvalumab for the treatment of bacillus Calmette-Guérin ("BCG")-unresponsive non-muscle invasive bladder cancer ("NMIBC"). Vicineum is believed to work via a dual mechanism of action to directly kill cancer cells and activate a local inflammatory process that stimulates T-cells, which then proliferate and destroy the cancer cells. Because of this second mechanism, there may be potential for a synergistic effect when given in combination with checkpoint inhibitors. This hypothesis is being tested by the NCI in a Phase 1 clinical trial in patients with BCG-unresponsive NMIBC to evaluate the safety, efficacy and biological correlates of Vicineum in combination with durvalumab ("NCI Trial").

On September 10, 2021, preliminary results from an interim analysis of 12 patients in the NCI Trial ("Interim Analysis") are being presented by Dr. Sandeep Gurram, a Urologic Oncology Fellow at the NCI and an investigator in the NCI Trial, at a conference hosted by the American Urological Association. Enrollment in the Phase 1 clinical trial is ongoing. A copy of such presentation is furnished herewith as Exhibit 99.1 and is incorporated herein by reference.

Based on the Interim Analysis, the combination of Vicineum and durvalumab has been generally well-tolerated with no new safety signals emerging (no Grade 4 or 5 treatment-related adverse events) and has a similar safety profile compared to both agents used individually. The Interim Analysis also indicated a 3-month complete response rate of 42% (5/12) and a 12-month complete response rate of 17% (2/12).

The information furnished in this Item 7.01, including the presentation attached as Exhibit 99.1, shall not be deemed to be "filed" for the purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of such section, nor shall such information be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS:

This Current Report on Form 8-K contains forward-looking statements, including, but not limited to, statements regarding the belief that Vicineum works via a dual mechanism of action that kills cancer cells, the safety, efficacy and tolerability of the combination of Vicineum and durvalumab based on the NCI's Interim Analysis, which are based on the Company's current expectations and inherently involve significant risks and uncertainties. The Company's actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, including the risk that the hypothesis regarding Vicineum's dual mechanism of action may fail after further investigation, the risk that the Interim Analysis may not be predictive of the success of later clinical trials, the Interim Analysis does not necessarily predict final results, clinical data and analyses are often susceptible to varying interpretations, the clinical trial process may fail to demonstrate that the combination of Vicineum and durvalumab is both safe and effective for their intended uses, the combination of Vicineum and durvalumab for the treatment of BCG-unresponsive NMIBC may cause undesirable side effects and serious adverse events or have other properties that could delay or halt clinical trials, among other risks and uncertainties. A further description of the risks and uncertainties relating to the business of the Company is contained in the Company's most recent annual report on Form 10-K and the Company's quarterly reports on Form 10-Q, as well as any amendments thereto reflected in subsequent filings with the Securities and Exchange Commission. The Company undertakes no duty or obligation to update any forward-looking statements contained in this report as a result of new information, future events or changes in its expectations.

Item 9.01 - **Financial Statements and Exhibits**.

(d) Exhibits.

Exhibit No.	Description
99.1	NCI Presentation Made at the 2021 American Urological Association Conference on September 10, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: September 10, 2021

Sesen Bio, Inc.

By: /s/ Thomas R. Cannell, D.V.M.
Thomas R. Cannell, D.V.M.
President and Chief Executive Officer

Interim Analysis of a Phase I Single-Arm Study of the Combination of Durvalumab and Vicineum (oportuzumab monatox, VB4-845) in Subjects with High-Grade Non-Muscle-Invasive Bladder Cancer Previously Treated with BCG

NCT03258593

Sandeep Gurram, Sonia Bellfield, Rebecca Dolan, Beatriz Walter, Maria Merino, Scot Niglio, Andrea Apolo, Piyush Agarwal, Vladimir Valera

AUA-2021

NIH NATIONAL CANCER INSTITUTE

@SandeepGurramMD

Disclosures

- No disclosures to present
- Study drugs were provided by Sesen Bio (Vicineum) and AstraZeneca (Durvalumab)

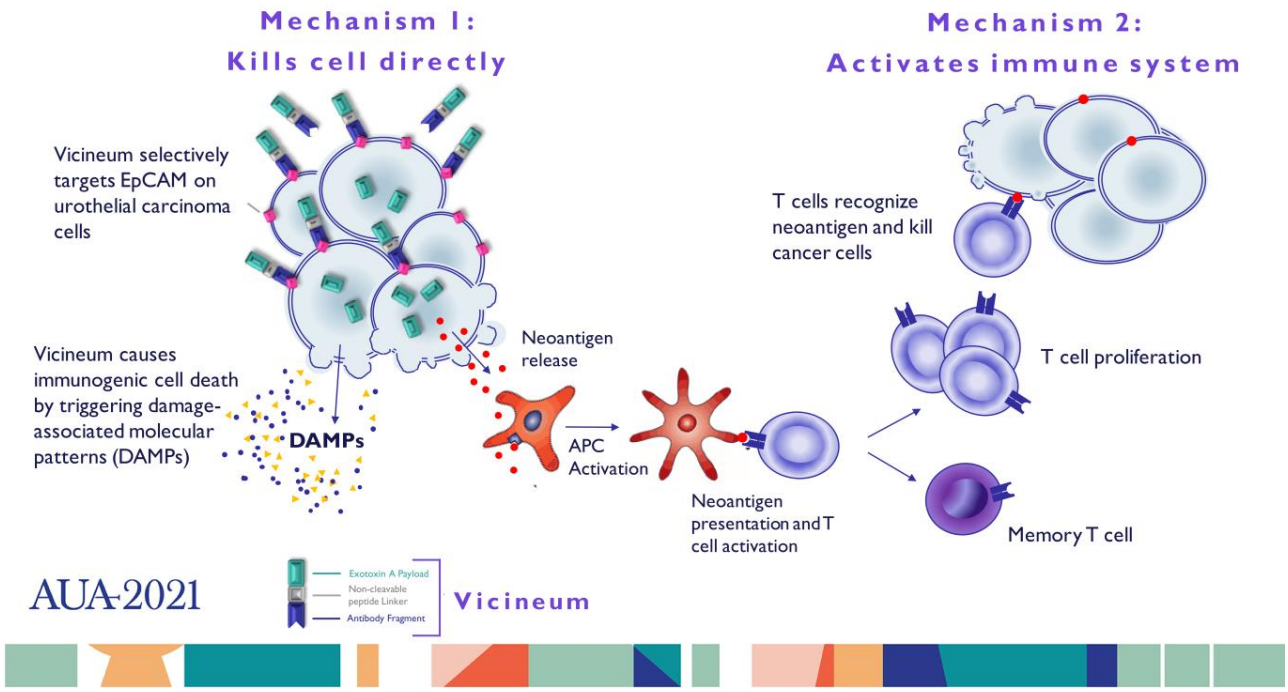
AUA 2021

Background

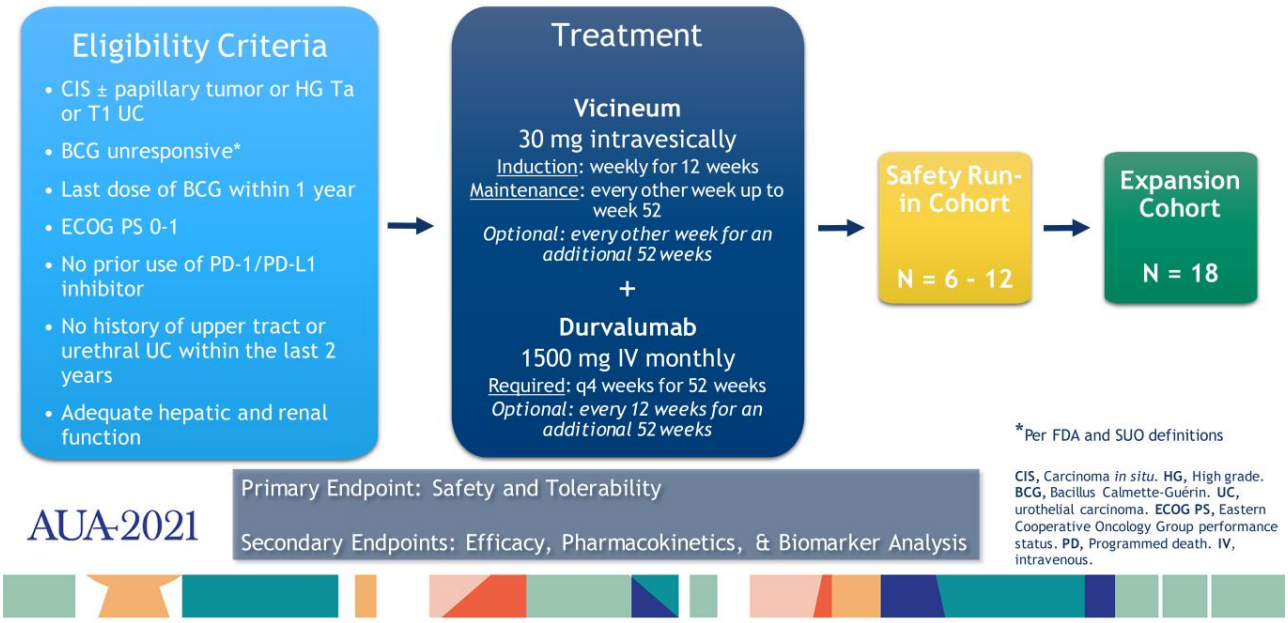
- Vicineum is a recombinant fusion protein comprised of an anti-EpCAM linked to a truncated form of Pseudomonas exotoxin A
  - 98% of BCG-refractory pts with EpCAM overexpression
- Phase III VISTA trial has demonstrated efficacy
  - Duration of response in CR subjects: 287 days
- PD-1/PD-L1 inhibitor activity in BCG-unresponsive population was demonstrated in Keynote 057

VISTA Phase III Results

Timepoints	**Cohort 1** Recurrent CIS ± papillary within 6 mo of BCG n = 82	**Cohort 2** Recurrent CIS ± papillary within >6 but <12 mo of BCG n = 7	**Combined Cohort 1 and 2** All CIS subjects n= 89
3-mo CR rate	39%	57%	40%
12-mo CR rate	17%	14%	17%


Mechanism 1:
Kills cell directly
Vicineum selectively targets EpCAM on urothelial carcinoma cells
Vicineum causes immunogenic cell death by triggering damage-associated molecular patterns (DAMPs)
DAMPs
Neoantigen release
APC Activation
Neoantigen presentation and T cell activation
Mechanism 2:
Activates immune system
T cells recognize neoantigen and kill cancer cells
T cell proliferation
Memory T cell
AUA-2021
Exotoxin A Payload
Non-cleavable peptide Linker
Antibody Fragment
Vicineum

Study Design



AUA 2021

Primary Endpoint: Safety and Tolerability

Secondary Endpoints: Efficacy, Pharmacokinetics, & Biomarker Analysis

*Per FDA and SUO definitions

CIS, Carcinoma *in situ*. **HG**, High grade. **BCG**, Bacillus Calmette-Guérin. **UC**, urothelial carcinoma. **ECOG PS**, Eastern Cooperative Oncology Group performance status. **PD**, Programmed death. **IV**, intravenous.

Baseline Characteristics	
Characteristic	**Vicineum + Durvalumab** *n = 12*
Median age – yr. (range)	69.5 (57 - 82)
Sex – no. (%)	
Male	11 (92)
Female	1 (8)
Race – no. (%)	
White, non-Hispanic	12 (100)
ECOG performance status – no. (%)	
0	10 (83)
1	2 (17)
Smoking History	
Never Smoker	3 (25)
Former Smoker	8 (67)
Current Smoker	1 (8)
Median number of BCG induction courses – no. (range)	2 (1-4)
Pathology at screening – no. (%)	
CIS ± papillary	4 (33)
Ta	6 (50)
T1	2 (17)

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Primary Outcome

- Safety cohort: 3+3 design
  - All 6 subjects enrolled without any DLTs
  - MTD was determined to be 30 mg Vicineum in 50 mL saline

Tolerability

- No dose reductions or discontinuation of any agent
- No subjects were taken off study due to treatment related adverse events
- Two subjects were taken off study due to unrelated medical issues
  - Worsening of baseline peripheral vascular disease
  - Cognitive decline secondary to worsening vascular dementia

Treatment Related Adverse Events

- Number of patients experiencing any TrAE: 12 (100%)
- Number of patients experiencing grade ≥3 TrAE*: 3 (25%)
- 1 subject required systemic corticosteroids for a persistent grade 2 diarrhea due to checkpoint associated colitis

*No grade 4 or 5 TrAE's were noted

Treatment Related Adverse Events of Any Grade in ≥10% of Patients

CTCAE Term	All Grades (%)	Grade ≥3 (%)
Hematuria	5 (41.7)	1 (8.3)
Renal and urinary disorders - Other	5 (41.7)	0 (0)
Urinary tract infection	5 (41.7)	0 (0)
Urinary frequency	5 (41.7)	0 (0)
Pruritus	4 (33.3)	0 (0)
Diarrhea	3 (25)	0 (0)
Rash maculo-papular	3 (25)	0 (0)
Dry skin	2 (16.7)	0 (0)
Bladder spasm	2 (16.7)	0 (0)
Hypotension	2 (16.7)	0 (0)
Fatigue	2 (16.7)	0 (0)
Hyperthyroidism	2 (16.7)	0 (0)
Creatinine increased	2 (16.7)	0 (0)
Bladder infection	2 (16.7)	1 (8.3)
Insomnia	2 (16.7)	0 (0)
Serum amylase increased	2 (16.7)	0 (0)
Headache	2 (16.7)	0 (0)
Dysuria	2 (16.7)	0 (0)
Proteinuria	2 (16.7)	0 (0)
Urinary urgency	2 (16.7)	0 (0)
Chills	2 (16.7)	0 (0)
Thromboembolic event	1 (8.3)	1 (8.3)
Hyponatremia	1 (8.3)	1 (8.3)

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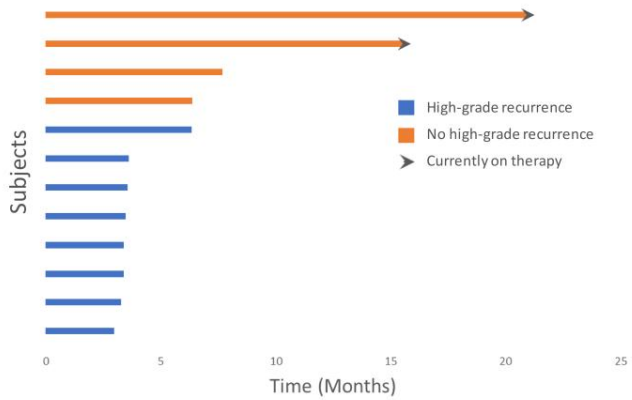
Hyponatremia	1 (8.3)	1 (8.3)

Secondary Outcomes

- Complete Responses
  - 3 month: 5/12 (42%)
  - 12 month: 2/12 (17%)
- Two subjects who came off study for unrelated medical reasons were 3-month responders



Efficacy Outcomes	Number of Patients (%)
Progression/recurrence of high grade NMIBC	8 (67)
Progression to MIBC†	1 (8.3)
12-month cystectomy-free survival	9 (75)
Death from bladder cancer	0 (0)

† includes at final on-study TUR or occult disease on cystectomy pathology

Conclusions

- The combination of Vicineum and Durvalumab in BCG unresponsive NMIBC is tolerated well with no new safety signals
- The doublet has a similar safety profile compared to both agents used individually
- Interim analysis shows a 3-month CR rate of 42% (5/12)
- Further biomarker analysis may help predict responders

Acknowledgements

Patients and their Families

Investigators

Vladimir Valera Romero MD PhD – PI

Sandeep Gurram MD

Piyush Agarwal MD

Andrea Apolo MD

Scot Niglio MD

Collaborators

Rebecca Dolan PA

Sonia Bellfield RN

Jacqueline Cadena NP

Liang Cao PhD

Beatriz Walter MD PhD

Maria Merino MD

Antoun Toubaji MD

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