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EQUITY RESEARCH
Company Report

May 22, 2018

Sesen Bio (SESN - $2.31)

Healthcare/Biotechnology

Ticker:	**SESN**
Rating:	**Buy**
Price Target:	**$8.00**

Highly Encouraging VISTA Trial 3-Month Data Set Up a Good Foundation for the 12-Month Primary Endpoint Readout

Yesterday, SESN (formerly EBIO) presented the robust Vicinium in high-grade NMIBC Phase III (VISTA) trial 3-month results at the AUA meeting with 42% CR in CIS patients. We believe this outcome is setting up a solid foundation for potentially meeting the primary endpoint: the 12-month CR rate in cohort 1.

- **Details.** The study enrolled a total of 133 high-grade NMIBC patient relapsed from the prior BCG therapy. Patients are categorized into three cohorts: cohort 1 (n=87): is of CIS (with/without papillary disease) with cancer recurrence within 6 months after last BCG treatment; cohort 2 (n=6): is of CIS (with/without papillary disease) with cancer recurrence within 6 - 11 months after last BCG treatment; and cohort 3 (n=40) is of papillary disease without CIS with cancer recurrence within 6 months after last BCG treatment. The data cut-off date was April 20, 2018. The CR rates were 39% (cohort 1, n=72), 80% (cohort 2, n=5) and 42% (cohorts 1&2 combined). Although the results would not be included as primary endpoint for the study, the 3-month results from cohort 3 (n=34) showed a 68% recurrence-free rate. All papillary disease-only patients have undergone mandatory resection and deemed without visible evidence of disease prior to starting treatment. On the safety side, Vicinium therapy was well-tolerated with 72% having Grade 1 or 2 AEs and only 4% treatment-related SAEs. Treatment discontinued rate is <1% (n=4). 4 treatment-related SAEs were acute kidney injury or renal failure and cholestatic hepatitis.
- **Implications.** Together, we believe the 3-month clinical results are robust and likely build a solid foundation for a positive 12-month data readout, estimated in mid-2019. The cohort 1 patients are more difficult to treat (relapsed within 6 months post BCG) than cohort 2. We anticipate the FDA will review the totality of the data at 12-months given the agency's recent guideline indicating unmet need in 2nd-line NMIBC including all patients relapsed within 12 months. Further, we believe the design of the maintenance phase of the VISTA trial with double the Vicinium administration vs. that of the prior Phase II study would bode well for further improvements in greater durable CR rate at 12-months. SESN shares lost 23% yesterday, and we believe this represents a buying opportunity since the outcome is well within the expectation. The primary endpoint readout, in our opinion, would likely be more robust than that of the prior studies.
- **Action.** We are reiterating our Buy rating and $8 target price to reflect our bullish view as Vicinium is rapidly completing the Phase III study with a possible product launch in 2021, if approved. Our valuation is based on our DCF, NPV-driven sum-of-the-parts and peer comparable analyses.

Trading Data:

Last Price (5/21/2018)	$2.31
52–Week High (5/2/2018)	$3.50
52–Week Low (11/10/2017)	$0.62
Market Cap. (MM)	$112
Shares Out. (MM)	26.11

Earnings Estimates: (per share)

(**June**)	1Q	2Q	3Q	4Q	FY	P/E
FY-18E	-0.11A	-0.20	-0.19	-0.18	-0.68	NM
FY-17A	-0.25	-0.30	-0.37	-0.22	-1.11	NM
FY-16A	-0.39	-0.33	0.91	-0.15	0.09	25.7x
FY-15A	-0.36	-0.36	-0.50	-0.54	-1.76	NM

Source: Laidlaw & Company estimates

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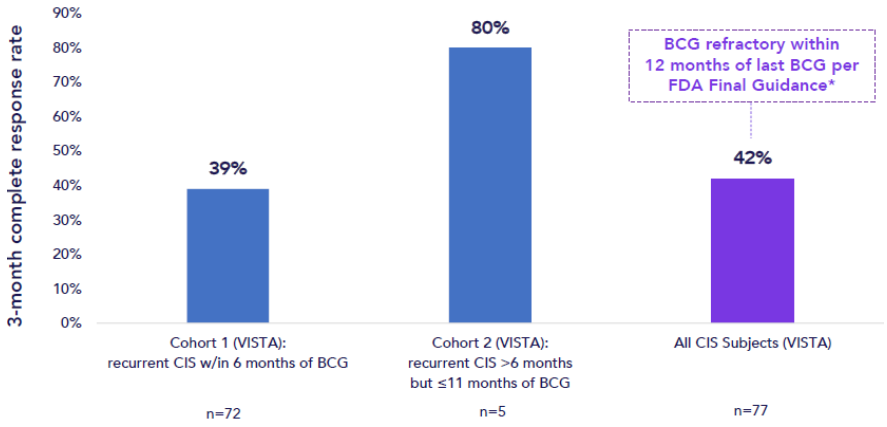
Figure 1: VISTA trial patient demographics

CHARACTERISTICS	COHORT 1	COHORT 2	COHORT 3
	CIS that recurred within 6 months of BCG	CIS that recurred >6 months but ≤11 months of BCG	Papillary (without CIS) that recurred within 6 months of BCG
Total subjects enrolled	87	6	40
Evaluable subjects at 3-months	72	5	34
Median age (current)	75	71	77
Males/Females	54/18	4/1	29/5
Median prior treatment for NMIBC BCG cycles Intravesical chemotherapy TURBT	4 (range 2-14) 1 (range 0-23) 4 (range 0-11)		

Source: Company report

Figure 2: Vicinum showed efficacy in 3-month analysis



Source: Company report

Figure 3: Safety profile of Vicinum is satisfactory

Treatment-Emergent Adverse Event[2]	Subjects (n=129) with: All TEAEs		Treatment-Related TEAEs	
	All Grades	Grade ≥3	All Grades	Grade ≥3[3]
Any TEAE	104 (81%)	36 (28%)	52 (41%)	5 (4%)
Urinary tract infection	37 (29%)	5 (4%)	13 (10%)	2 (%)
Dysuria	25 (19%)	0 (0%)	14 (11%)	0 (0%)
Hematuria	21 (16%)	2 (2%)	11 (9%)	0 (0%)
Pollakiuria (frequency of urination)	16 (12%)	0 (0%)	12 (9%)	0 (0%)
Diarrhea	13 (10%)	0 (0%)	2 (2%)	0 (0%)
Fatigue	13 (10%)	0 (0%)	8 (6%)	0 (0%)
Micturition urgency	11 (9%)	0 (0%)	8 (6%)	0 (0%)
Nausea	10 (8%)	1 (1%)	3 (2%)	0 (0%)
Lipase increased (all asymptomatic)	10 (8%)	4 (3%)	2 (2%)	1 (0%)

Subjects (n=129)	Treatment-Emergent SAEs[4]	Treatment-Related SAEs
Any Serious AE	17 (13%)	4 (3%)
Acute kidney injury or renal failure	4	3
Hematuria	3	0
Cholestatic hepatitis	0	1

Source: Company report

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Anticipated milestones in 2018 and beyond

Program	Indication	Event	Timing	Importance
Vicinium	Non-muscle invasive bladder cancer (NMIBC)	Potentially report Vicinium/durvalumab Phase I study biomarker results	**3Q18**	***
		Report Phase III (VISTA) study 12-month interim results	**Mid-2019**	****
		Potentially file BLA	**2H19**	***
VB6-845d	Solid tumors	Potentially start Phase I study	**2019**	***

**** / ***** *Major catalyst event that could impact share price very significantly while *** event is more informative*

Source: Laidlaw & Company estimates and company presentation.

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Major risks

Clinical study failure could have a major impact on SESN share value. Despite the robust Phase II study results of Vicinium in BCG unresponsive NMIBC, it remains difficult to fully handicap the outcome of the Phase III study, both of the 3-month interim analysis and the full 12-month readout, given the differences in study design. Should the study fail to successfully meet the primary endpoint, SESN share value could be substantially impacted. Failures in clinical development of other pipeline products could have similar negative impact on share price as well.

Failure or substantial delay of regulatory approval could have a major negative impact on SESN share value. Even if SESN's leading and future follow-up pipeline products complete clinical studies successfully, risks remain as whether the regulatory agencies could approve the regulatory filing. If unsuccessful or with substantial delays due to various factors, such as requirement for additional studies, the SESN shareholder value could also be significantly impaired.

Commercial risks remain difficult to handicap. Despite SESN's drugs, like Vicinium could be approved, it may be difficult to more precisely forecast the commercial value of the drug due to various reasons. Multiple factors that could affect the future sales of a drug include: 1) change of competitive landscape, possibly due to entrance of new and better drugs especially given the larger number of products or therapies (such as gene therapy) in development; 2) the pace of physician adoption for the drug use or surgical procedure, like radical cystectomy could continue to be the favorable treatment option by physicians; 3) pricing flexibility; 4) level or acceptance of reimbursement by third party insurers, and 5) potential change of the treatment paradigm and render some drug obsolete. In short, if the company's sales substantially fall short, we believe shareholder disappointment could negatively impact the company's valuation.

Additional financings could dilute shareholder value. The company currently has ~$19.7MM total cash (proforma). As such, SESN would most likely need more financial resources going forward if they want to complete the current and other upcoming clinical studies and potentially participate in the commercialization of approved drug. Unless the company can successfully explore non-dilutive financial sources, the value to current shareholders might be reduced with additional equity offerings, unless the share price increase if the upside created due to greater financial resources could offset the dilution of current shareholders.

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Figure 1: Income Statement

Sesen Bio, Inc. – Income Statement

('000 $)	2016	2017	1Q18	2Q18	3Q18E	4Q18E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Revenues														
Product revenues	0	0	-	-	-	-	0	0	0	12,241	76,770	138,190	218,818	279,538
Vicinum revenue	0	0	-	-	-	-	0	0	0	12,241	76,770	138,190	218,818	279,538
Collaboration revenue	1,331	0	-	-	-	-	0	0	0	0	0	0	0	0
License revenue	28,650	425	-	-	-	-	0	0	0	0	0	0	0	0
Total Revenue	29,981	425	-	-	-	-	0	0	0	12,241	76,770	138,190	218,818	279,538
COGS										1,836	11,515	20,729	32,823	41,931
Research and development	13,479	12,510	3,255	3,444	3,004	3,100	12,803	18,853	21,493	21,707	22,576	23,479	24,418	25,395
General and administrative	14,736	8,070	1,952	2,358	2,405	2,477	9,192	10,159	10,667	11,094	11,471	11,861	12,265	12,682
Loss (gain) from change in fair value of contingent consideration	(1,100)	9,100	(1,200)	1,500	1,500	1,500	3,300	6,000	6,000	6,000	6,000	6,000	6,000	6,000
Marketing and sales	0	0	0	0	-	-	0	0		18,000	21,600	22,248	22,915	23,603
Operaing expense	27,115	29,680	4,007	7,302	6,909	7,077	25,295	29,013	38,160	56,802	61,647	63,588	65,598	67,679
Operating incomes (losses)	2,866	(29,255)	(4,007)	(7,302)	(6,909)	(7,077)	(25,295)	(29,013)	(38,160)	(46,397)	3,607	53,874	120,398	169,928
Other income (expense), net	(970)	226	44	43	45	49	181	171	140	161	169	178	186	196
Income (loss) before taxes	1,896	(29,029)	(3,963)	(7,259)	(6,864)	(7,028)	(25,114)	(28,842)	(38,020)	(46,236)	3,776	54,051	120,584	170,124
Income tax expense	5	-	-	-	-	-	0	-	-	-	(1,322)	(18,918)	(42,204)	(59,543)
Net income	1,891	(29,029)	(3,963)	(7,259)	(6,864)	(7,028)	(25,114)	(28,842)	(38,020)	(46,236)	2,454	35,133	78,380	110,580
Net income attributable to common shareholders	$1,891	($29,029)	($3,963)	($7,259)	($6,864)	($7,028)	($25,114)	($28,842)	($38,020)	($46,236)	$2,454	$35,133	$78,380	$110,580
Net Earnings (Losses) Per Share—Basic	$0.09	($1.11)	($0.11)	($0.20)	($0.19)	($0.18)	($0.68)	($0.71)	($0.84)	($0.93)	$0.05	$0.70	$1.54	$2.15
Net Earnings (Losses) Per Share—Diluted	$0.09	($1.11)	($0.11)	($0.20)	($0.19)	($0.18)	($0.68)	($0.71)	($0.84)	($0.93)	$0.05	$0.70	$1.54	$2.15
Shares outstanding—basic	21,083	26,105	35,674	36,074	36,474	39,474	36,924	40,474	45,474	49,474	49,974	50,474	50,974	51,474
Shares outstanding—diluted	21,083	26,105	35,674	36,074	36,474	39,474	36,924	40,474	45,474	49,474	49,974	50,474	50,974	51,474
Margin Analysis (% of Sales/Revenue)														
COGS										15%	15%	15%	15%	15%
R&D	45%	2944%	NA	NA	NA	NA	NA	NA	NA	177%	29%	17%	11%	9%
G&A	49%	1899%	NA	NA	NA	NA	NA	NA	NA	91%	15%	9%	6%	5%
Operating Income (loss)	10%	-6884%	NA	NA	NA	NA	NA	NA	NA	-379%	5%	39%	55%	61%
Pretax	6%	-6830%	NA	NA	NA	NA	NA	NA	NA	-378%	5%	39%	55%	61%
Tax Rate	70152%	NA	NA	NA	NA	NA	NA	NA	NA	NA	35%	35%	35%	35%
Net Income	6%	-6830%	NA	NA	NA	NA	NA	NA	NA	-378%	3%	25%	36%	40%
Financial Indicator Growth Analysis (YoY%)														
Total Revenue	2928%	-99%	-100%	N.A.	N.A.	N.A.	-100%	N.A.	N.A.	N.A.	527%	80%	58%	28%
R&D expenses	-49%	-7%	13%	18%	-17%	0%	2%	47%	14%	1%	4%	4%	4%	4%
General and administrative	50%	-45%	-12%	5%	47%	25%	14%	11%	5%	4%	3%	3%	3%	3%
Sales and marketing											20%	3%	3%	3%
Operaing expense	-25%	9%	-39%	-1%	-24%	7%	-15%	15%	32%	49%	9%	3%	3%	3%
Operating Incomes (Losses)	-108%	-1121%	-35%	-1%	-24%	7%	-14%	15%	32%	22%	-108%	1394%	123%	41%
Pretax Income	-106%	-1631%	-35%	-1%	-25%	7%	-13%	15%	32%	22%	-108%	1331%	123%	41%
Net Income	-106%	-1635%	-35%	-1%	-25%	7%	-13%	15%	32%	22%	-105%	1331%	123%	41%
EPS - Basic	-105%	-1340%	-55%	-32%	-49%	-17%	-39%	5%	17%	12%	-105%	1317%	121%	40%
EPS - Diluted	-105%	-1340%	-55%	-32%	-49%	-17%	-39%	5%	17%	12%	-105%	1317%	121%	40%

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Source: Bloomberg LP; Company reports; Laidlaw & Company estimates.

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Additional information available upon request.

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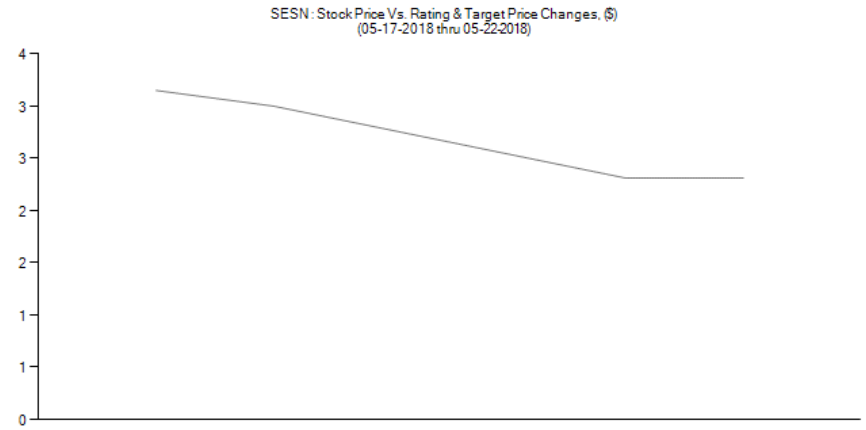
RATINGS INFORMATION

Rating and Price Target Change History



Source: Laidlaw & Company Created by: Blue-Compass.net

3 Year Rating Change History

Date	Rating	Closing Price ($)
05/10/...	Buy (B)	2.62

3 Year Price Change History

Date	Target Price ($)	Closing Price, ($)
05/10/...	8.00	2.62

3 Year Rating Change History

Date	Rating	Closing Price ($)

3 Year Price Change History

Date	Target Price ($)	Closing Price, ($)

Source: Laidlaw & Company Created by: Blue-Compass.net

Note the company changed its name to Sesen Bio from Eleven Biotherapeutics effective May 17, 2018.

Laidlaw & Company Rating System*		% of Companies Under Coverage With This Rating	% of Companies for which Laidlaw & Company has performed services for in the last 12 months	
			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%

Buy (B)	Expected to outperform the sector average over 12 months.	66.67%	25.93%	3.70%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	0.00%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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