

Sesen Bio (SESN - \$1.02)

4Q18: Additional Clinical Readouts of the Vicinium VISTA Study Provided More Comprehensive Picture of Efficacy

SESN reported 4Q18 financial results this morning with a net loss of (\$6.8MM), vs. (\$8.3MM) and (\$6.4MM) for Laidlaw and the Street. Net loss per share was (\$0.09) vs. (\$0.11) and (\$0.08) for Laidlaw and the Street, respectively. SESN ended 4Q18 with cash of ~\$50MM, enough to support its operations into 1Q20, in our opinion. Given the 10K was filed last Friday, most of call focused on the additional Phase III data from the ongoing VISTA trial.

- Details.** After the recently reported (1/3/2019) preliminary CRR results of 3-, 6-, 9- and 12-months from the VISTA study, SESN this morning provided more interim results from the trial. This included duration of response, time to disease recurrence, and time to cystectomy that had further enriched the available data package, in our opinion. The data cutoff date was December 3, 2018. Duration of response at 12-months in cohort 1 (n=86) is the co-primary endpoint of the VISTA trial. The interim median duration of complete response is 227 days based on the Kaplan-Meier method. A pooled data (cohorts 1+2, n=93) showed 69% who have achieved CR in 3 months maintained its status 6 months or longer. Projected cystectomy-free time is ~519 days (95% CI, 361-523), or 18 months (n=133). Although the treatment results from the high-grade Ta or T1 NMIBC patients are not part of BLA filing, the outcome in treating these patient cohorts could provide a more comprehensive picture of Vicinium's efficacy. Median time to disease recurrence in high-grade papillary-only (Ta and T1) NMIBC (n=40) is 270 days (95% CI, 169-452). Recurrence-free rates in the same patient cohort were 56% and 36% at 6 and 12 months, respectively. It is noted that preliminary Vicinium data showed promising response rate results comparing to Keytruda in NMIBC treatment (53% vs. 49% at 9 months) with Vicinium having a possibly more benign safety profile. SESN expects to report the 12-month follow-up data in mid-2019, a pre-BLA meeting with the FDA shortly afterward, and potential BLA filing in 2H19 or 2020.
- Implications.** We view the additional clinical interim data reported this morning having added additional dimensions of Vicinium treatment effect in NMIBC patients. We anticipate the 12-month data would afford more matured information as the potential final BLA package, and the readout of various survival related outcome (PFS or OS) could be very interesting.
- Action.** We are reiterating our Buy rating and reducing our target price to \$5 from \$8 to reflect our still bullish view on Vicinium but with an adjusted valuation. Our valuation is based on our DCF, NPV-driven sum-of-the-parts and peer comparable analyses.

Earnings Estimates: (per share)

(June)	1Q	2Q	3Q	4Q	FY	P/E
FY-19E	-0.10	-0.12	-0.11	-0.11	-0.45	NM
FY-18A	-0.11	-0.16	-0.18	-0.09	-0.55	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	NM

Source: Laidlaw & Company estimates

Healthcare/Biotechnology

Ticker:	SESN
Rating:	Buy
Price Target: ↓ lower	\$5.00

Trading Data:

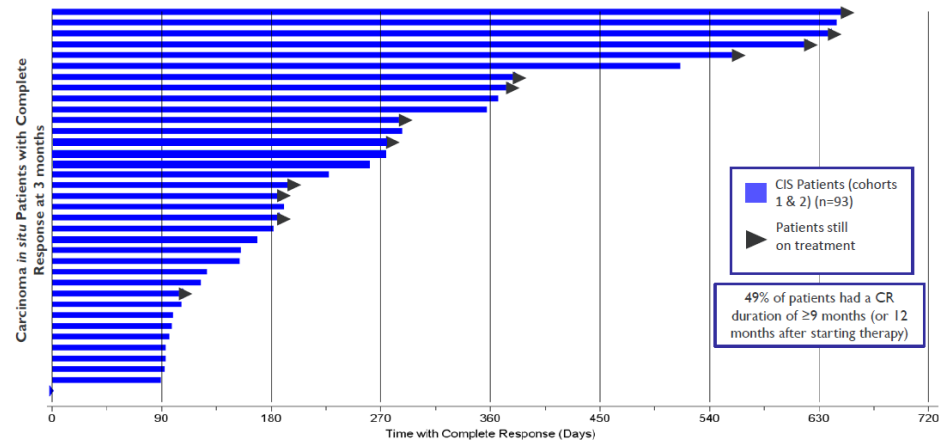
Last Price (3/1/2019)	\$1.02
52-Week High (5/2/2018)	\$3.50
52-Week Low (1/18/2019)	\$0.66
Market Cap. (MM)	\$71
Shares Out. (MM)	61.77

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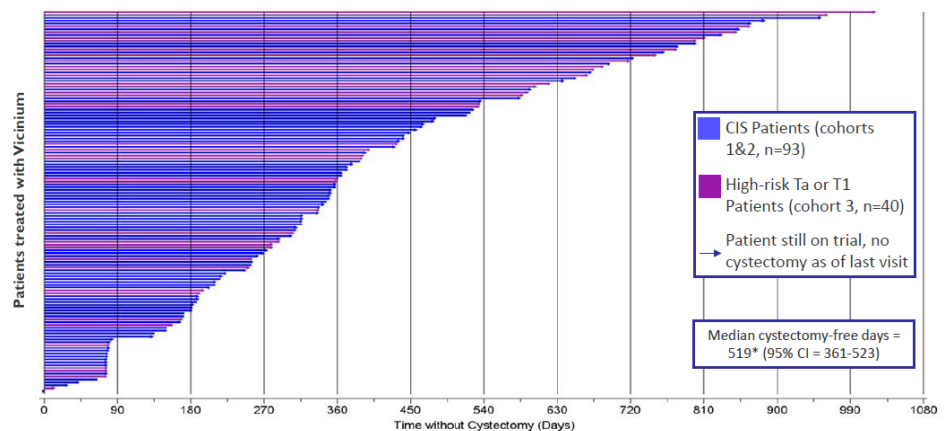
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Figure 1: Duration of response that achieved CR at 3 months



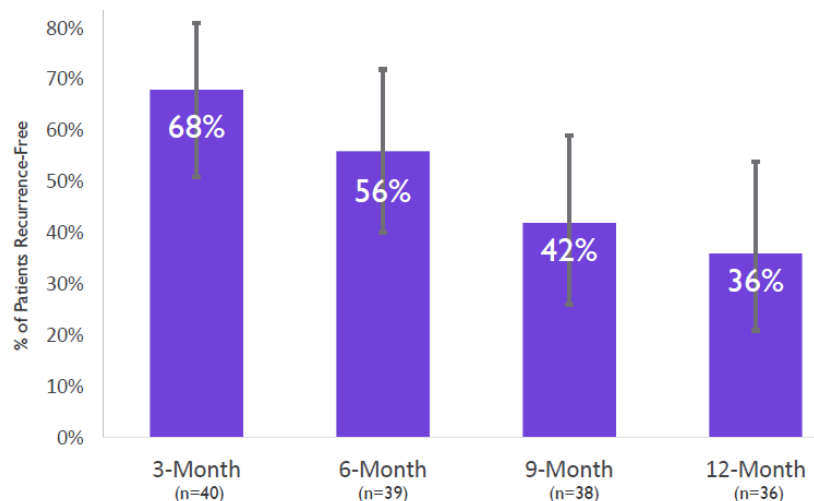
Source: The company report

Figure 2: Projected cystectomy free for ~18 months



Source: The company report

Figure 3: Recurrence free rate in high-risk Ta/T1 NMIBC



Source: The company report

Anticipated milestones in 2019 and beyond

Program	Indication	Event	Timing	Importance
Vicinium	Non-muscle invasive bladder cancer (NMIBC)	Potentially report Vicinium/durvalumab Phase I study biomarker results	2019	***
		Report Phase III (VISTA) study 12-month full results	Mid-2019	***
		Potentially file BLA	2H19/2020	***
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.

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 ended the recent quarter with ~\$50MM total cash. 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.

Figure 1: Income Statement

Sesen Bio, Inc. – Income Statement

('000 \$)	2016	2017	1Q18	2Q18	3Q18	4Q18	2018	1Q19E	2Q19E	3Q19E	4Q19E	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	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																		
Research and development	13,479	12,510	3,255	2,779	3,372	4,671	14,077	4,718	5,727	5,441	5,550	21,435	24,436	24,681	25,668	26,694	27,762	28,873
General and administrative	14,736	8,070	1,952	2,351	3,825	3,495	11,623	3,530	3,565	3,601	3,637	14,333	15,050	15,652	16,184	16,734	17,303	17,891
Loss (gain) from change in fair value of contingent consideration	(1,100)	9,100	(1,200)	3,900	7,200	(1,100)	8,800	1,500	1,500	1,500	1,500	6,000	6,000	6,000	6,000	6,000	6,000	6,000
Marketing and sales	0	0	0	0	0	0	0	0	-	-	-	0	0	18,000	21,600	22,248	22,915	23,603
Operating expense	27,115	29,680	4,007	9,030	14,397	7,066	34,500	8,248	9,292	9,042	9,187	35,768	45,486	64,332	69,452	71,677	73,981	76,367
Operating incomes (losses)	2,866	(29,255)	(4,007)	(9,030)	(14,397)	(7,066)	(34,500)	(8,248)	(9,292)	(9,042)	(9,187)	(35,768)	(45,486)	(53,927)	(4,197)	45,785	112,015	161,240
Other income (expense), net	(970)	226	44	72	382	309	807	47	45	41	38	171	140	161	169	178	186	196
Income (loss) before taxes	1,896	(29,029)	(3,963)	(8,958)	(14,015)	(6,757)	(33,693)	(8,201)	(9,247)	(9,001)	(9,149)	(35,597)	(45,346)	(53,766)	(4,028)	45,963	112,201	161,436
Income tax expense	5	-	-	-	-	-	0	-	-	-	-	-	-	-	0	(16,087)	(39,270)	(56,503)
Net income	1,891	(29,029)	(3,963)	(8,958)	(14,015)	(6,757)	(33,693)	(8,201)	(9,247)	(9,001)	(9,149)	(35,597)	(45,346)	(53,766)	(4,028)	29,876	72,931	104,933
Net income attributable to common shareholders	\$1,891	(\$29,029)	(\$3,963)	(\$8,958)	(\$14,015)	(\$6,757)	(\$33,693)	(\$8,201)	(\$9,247)	(\$9,001)	(\$9,149)	(\$35,597)	(\$45,346)	(\$53,766)	(\$4,028)	\$29,876	\$72,931	\$104,933
Net Earnings (Losses) Per Share—Basic	\$0.09	(\$1.11)	(\$0.11)	(\$0.16)	(\$0.18)	(\$0.09)	(\$0.55)	(\$0.10)	(\$0.12)	(\$0.11)	(\$0.11)	(\$0.45)	(\$0.54)	(\$0.61)	(\$0.05)	\$0.34	\$0.82	\$1.17
Net Earnings (Losses) Per Share—Diluted	\$0.09	(\$1.11)	(\$0.11)	(\$0.16)	(\$0.18)	(\$0.09)	(\$0.55)	(\$0.10)	(\$0.12)	(\$0.11)	(\$0.11)	(\$0.45)	(\$0.54)	(\$0.61)	(\$0.05)	\$0.34	\$0.82	\$1.17
Shares outstanding—basic	21,083	26,105	35,674	56,421	77,030	77,971	61,774	78,371	78,771	79,171	79,571	78,971	83,971	87,971	88,471	88,971	89,471	89,971
Shares outstanding—diluted	21,083	26,105	35,674	56,421	77,030	77,971	61,774	78,371	78,771	79,171	79,571	78,971	83,971	87,971	88,471	88,971	89,471	89,971
Margin Analysis (% of Sales/Revenue)																		
COGS															15%	15%	15%	15%
R&D	45%	2944%	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	202%	33%	19%	13%	10%
G&A	49%	1899%	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	128%	21%	12%	8%	6%
Operating Income (loss)	10%	-6884%	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-441%	-5%	33%	51%	58%
Pretax	6%	-6830%	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-439%	-5%	33%	51%	58%
Tax Rate	70152%	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	35%	35%	35%	35%
Net Income	6%	-6830%	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-439%	-5%	22%	33%	38%
Financial Indicator Growth Analysis (YoY%)																		
Total Revenue	2928%	-99%	-100%	N.A.	N.A.	N.A.	-100%	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	527%	80%	58%	28%
R&D expenses	-49%	-7%	13%	-4%	-7%	50%	13%	45%	106%	61%	19%	52%	14%	1%	4%	4%	4%	4%
General and administrative	50%	-45%	-12%	5%	135%	76%	44%	81%	52%	-6%	4%	23%	5%	4%	3%	3%	3%	3%
Sales and marketing															20%	3%	3%	3%
Operating expense	-25%	9%	-39%	23%	57%	7%	16%	106%	3%	-37%	30%	4%	27%	41%	8%	3%	3%	3%
Operating Incomes (Losses)	-108%	-1121%	-35%	23%	57%	7%	18%	106%	3%	-37%	30%	4%	27%	19%	-92%	-1191%	145%	44%
Pretax Income	-106%	-1631%	-35%	22%	54%	3%	16%	107%	3%	-36%	35%	6%	27%	19%	-93%	-1241%	144%	44%
Net Income	-106%	-1635%	-35%	22%	54%	3%	16%	107%	3%	-36%	35%	6%	27%	19%	-93%	-842%	144%	44%
EPS - Basic	-105%	-1340%	-55%	-46%	-51%	-60%	-51%	-6%	-26%	-38%	33%	-17%	20%	13%	-93%	-837%	143%	43%
EPS - Diluted	-105%	-1340%	-55%	-46%	-51%	-60%	-51%	-6%	-26%	-38%	33%	-17%	20%	13%	-93%	-837%	143%	43%

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

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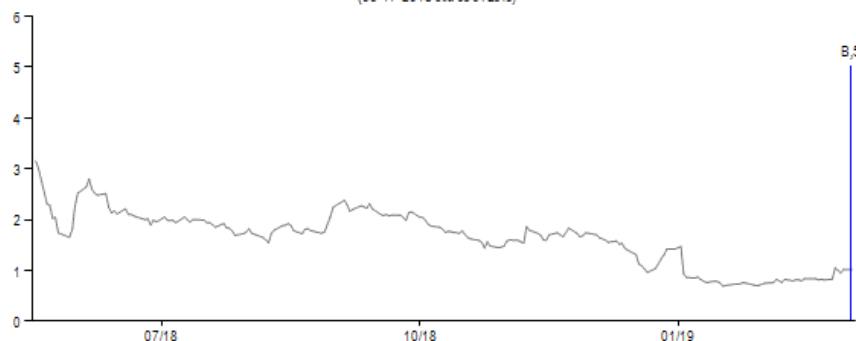
Additional information available upon request.

#Laidlaw & Company has received compensation from the subject company for investment banking services in the past 12 months and expects to receive or intends to seek compensation for investment banking services from the company in the next three months.

RATINGS INFORMATION

Rating and Price Target Change History

SESN: Stock Price Vs. Rating & Target Price Changes (\$) (05-17-2018 thru 03-04-2019)



3 Year Rating Change History

Date	Rating	Closing Price (\$)
03/04/2019	Buy (B)	1.02*

3 Year Price Change History

Date	Target Price (\$)	Closing Price, (\$)
03/04/2019	5.00	1.02*

* Previous Close 3/1/2019

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

EBIO: Stock Price Vs. Rating & Target Price Changes (\$) (05-18-2015 thru 05-17-2018)



Source: Laidlaw & Company Created by: Blue-Compass.net
Note the company changed its name to Sesen Bio from Eleven Biotherapeutics effective May 17, 2018

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			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.	64.52%	25.81%	3.23%

Hold (H)	Expected returns to be in line with the sector average over 12 months.	4.84%	1.61%	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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