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Zacks Small-Cap Research

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Elizabeth Senko, CFA
312-265-9484
esenko@zacks.com

scr.zacks.com

10 S. Riverside Plaza, Chicago, IL 60606

CASI Pharmaceuticals (CASI-NASDAQ)

CASI: Forging ahead on new candidates

Our valuation of $3.50 per basic share is based on sum-of-the-parts risk-adjusted NPV for each of its products less corporate overhead. Our valuation includes proceeds from the recent equity offering along with the adjusted share count. We continue to believe that there is room for upside as the company moves its licensed and proprietary hematology portfolio closer to commercialization.

OUTLOOK

After some disruption to business in the first quarter from the pandemic, CASI noted the main hospitals in China are returning to normal particularly in the north, and Evomela sales are likely meet or exceed $14 million in 2020. In addition, the Company completed its planned move to a lower-cost supplier for Evomela and expects its COGS for Evomela to be less than 30%, compared with 95% for the first half of 2020. We are fine-tuning our estimates for 2020-21 and raising our target price from $2.89 to $3.50.

Current Price (11/27/20)	$2.42
Valuation	**$3.50**

SUMMARY DATA

52-Week High	**$3.32**
52-Week Low	**$1.44**
One-Year Return (%)	**-26.89**
Beta	**0.44**
Average Daily Volume (sh)	**413,762**
Shares Outstanding (mil)	**124**
Market Capitalization ($mil)	**$300**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**18**
Insider Ownership (%)	**25**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2020 Estimate	**-6.7**
P/E using 2021 Estimate	**-10.4**
Zacks Rank	**N/A**

Risk Level	**Average,**
Type of Stock	**Small-Blend**
Industry	**Med-Drugs**
Zacks Rank in Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	0.0 A	0.0 A	0.0 A	0.0 A	0.0 A
2019	0.0 A	0.0 A	2.7 A	1.4 A	4.1 A
2020	3.4 A	2.6 A	4.2 A		14.1 E
2021					32.2 E

Earnings per share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	-$0.05 A	-$0.07 A	-$0.10 A	-$0.10 A	-$0.32 A
2019	-$0.09 A	-$0.16 A	-$0.10 A	-$0.13 A	-$0.48 A
2020	-$0.09 A	-$0.07 A	-$0.14 A		-$0.38 E
2021					-$0.18 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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COMPANY UPDATE

CASI Pharmaceuticals' third quarter continued the return to normalcy for Evomela sales, a new lower-cost supply contract for Evomela, continued progress in advancing several candidates in its hematology pipeline.

2019 was a year of firsts for CASI: the successful launch of Evomela in China, progress towards gaining regulatory approval for Zevalin and expansion of CASI's robust product portfolio with the licensing rights to Juventas Cell Therapy's anti-CD19 CAR-T therapy, CNCT19; its investment in CID-103 (also known as TSK011010), an anti-CD38 monoclonal antibody; and an agreement with Pharmathen to develop and distribute octreotide LAI in China.

The Company expects to complete Phase I trials for CNCT19, its in-licensed anti-CD19 CAR-T therapy in early 2021, followed by a pivotal phase II trial to be completed by the end of 2021 and NDA filing in early 2022. If this timeline holds and the drug is approved, CASI believes its product will perform comparably to other anti-CD19 CAR-T therapies at a much more affordable cost because it will be manufactured locally. CASI estimates that the annual patient pool for this therapy in China is 30,000-50,000.

Financial Results

Evomela sales totaled $4.2 million in the quarter and $10.2 million for the first nine months of 2020. For the year, the Company now expects sales of at least $14 million, up from previous guidance of $10 million. Cost of goods were $1.8 million, or 43% of revenues in the quarter, down from 95% of sales for 1H20. Cost of goods sold earlier in the year were impacted by a transitional supply agreement and certain non-recurring charges associated with the startup production. We have been targeting gross margins of 55-60% over the long-term; however, on its 2Q call, management said it expects COGS under the new contract to be about 30% - implying a gross margin of 70%. While the Company did not achieve that margin for the full third quarter, we expect Evomela gross margins will continue to improve with higher volumes.

Research and development for the quarter totaled $2.8 million up from $1.8 million in the year-earlier period. Higher research costs reflect start-up costs associated with new hematology candidates. In addition, the Company made milestone payments to Juventas of $10.3 million and $0.6 million to Parmathen.

General and administrative was $5.3 million in the quarter down considerably from $8.1 million in the year-earlier period. In 2019, G&A included investments for the launch of Evomela. Costs related to Evomela sales are now in a separate sales and marketing expense line, totaling $2.0 million in 3Q20 and $4.8 million for nine-months ended September 30.

In total, CASI reported a net loss of ($0.14) per share, or ($16.7 million) in the third quarter, compared to ($0.10) per share, or ($9.8 million) in the year earlier period.

We are raising our 2020 revenue estimate from $10.4 million to $14.1 million to account for renewed strength in Evomela sales. At the same time, we are lowering our EPS expectations to reflect the milestone payments. Our estimate for 2020 is now ($0.38). Our estimate for 2021 drops slightly to ($0.18) from ($0.16). Despite these small changes, we are raising our valuation for CASI from $2.89 to $3.50 reflecting both more shares outstanding from the recent equity offering and the cash raised. We continue to believe that there is meaningful upside to our estimates and valuation as we get closer to 2022.

HISTORICAL STOCK PRICE



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