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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)

Focusing on hematology

Our valuation is $2.89 per basic share, based on sum-of-the-parts risk-adjusted NPV for each of its products less corporate overhead. We lowered our sales expectations for the ANDA portfolio to $185 million by 2045 and our valuation to $163 million. While this change is significant, we believe that there is room for upside as the company moves its licensed and proprietary hematology portfolio closer to commercialization.

Current Price (05/07/20)	$1.70
Valuation	**$2.89**

OUTLOOK

CASI reported full-year 2019 results of $4.1 million for 2019, in line with our expectations. On its first investor conference call, management noted that while its business was disrupted by COVID-19 in January and February, the main hospitals in China are returning to normal and the Company believes that the impact on Evomela sales will be short-lived. We are pushing out our 2020 estimates to allow for the slowdown for the pandemic. Separately, the Company has opted to discontinue development of its ANDA product portfolio, citing reimbursement changes in China for generic drugs.

SUMMARY DATA

52-Week High	**$3.78**
52-Week Low	**$1.44**
One-Year Return (%)	**-51.18**
Beta	**0.81**
Average Daily Volume (sh)	**119,136**
Shares Outstanding (mil)	**101**
Market Capitalization ($mil)	**$168**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**21**
Insider Ownership (%)	**24**
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	**-3.8**
P/E using 2021 Estimate	**-7.4**
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					12.5 E
2021					30.5 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					-$0.25 E
2021					-$0.19 E

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

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COMPANY UPDATE

CASI Pharmaceuticals signaled a shift in its business strategy in March – focusing its efforts on its hematology franchise and deemphasizing its ANDA portfolio. This change scales back CASI's initial broad-reaching goal to be the leading provider of high quality proprietary, licensed and ANDA pharmaceuticals to the rapidly evolving Chinese market.

CASI's decision was made in response to a change by the Chinese government to further narrow its list of key non-proprietary drug suppliers. CASI is unique in its understanding of how to pursue opportunities in China while minimizing the pitfalls that often plague US-listed China-focused companies. CASI's management sees its opportunity as long-term. We agree with CASI's decision as it will likely result in the best combination of revenue growth and solid profitability while moderating capital needs over the intermediate term.

CASI's ANDA portfolio was a significant driver in our valuation. We expected the Company to continue to make deals in this space and have modeled for $500 million in annual sales by 2045. The generics market in China is highly competitive, but quality of locally manufactured products is often a concern. We are lowering our sales expectations for the ANDA portfolio to $185 million by 2045 and our valuation to $163 million. Our new valuation for CASI is $2.89. While this change is significant, we believe that there is room for upside as the company moves its licensed and proprietary hematology portfolio closer to commercialization.

2019 Results

2019 marked the successful launch of Evomela in China, progress towards gaining regulatory approvals for Marqibo and 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.

Revenues for the year totaled $4.1 million, all from the sale of Evomela. The majority of these sales were in Q319 ($2.7m) following the August launch. Cost of goods were $3.9 million, or 95% of revenues. Cost of goods sold were impacted by a transitional supply agreement and certain non-recurring charges associated with the startup production. We are targeting gross margins of 55-60% over the long-term.

Research and development for 2019 rose $1.2 million (15%) to $9.8 million compared to $8.5 million in the year-earlier period, reflecting higher regulatory costs associated with our ANDAs in 2019, costs incurred with the development of CID-103 and higher consulting and manufacturing related services. Acquired IPRD added another $7 million in 2019.

Selling, general and administrative spending climbed to $30.4 million in 2019 from $18 million in 2018. 2019 SG&A included $3.1 million in selling expense for Evomela, $7.3 million in stock compensation paid to senior management and other expenses primarily related to the Company's growth in China.

In total, CASI reported a net loss of ($0.48) per share, or ($45.4 million), compared to ($0.32) per share, or ($27.5 million), in 2018.

We are reducing our 2020 revenue estimate from $20.8 million to $12.5 million to account for the move away from the ANDA portfolio. We forecast $7.1m in Evomela sales for 2020 and total sales of $12.5 million assuming approval and commercialization for Marqibo and Zevalin. Our 2020 earnings expectation goes from ($0.21) to ($0.25).

HISTORICAL STOCK PRICE



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