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Zacks Small-Cap Research

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CASI Pharmaceuticals (CASI-NASDAQ)

CASI: Managing for the future

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. 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 $10 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.

Current Price (08/24/20)	$1.71
Valuation	**$2.89**

SUMMARY DATA

52-Week High	**$3.78**
52-Week Low	**$1.44**
One-Year Return (%)	**-41.25**
Beta	**0.91**
Average Daily Volume (sh)	**956,563**
Shares Outstanding (mil)	**124**
Market Capitalization ($mil)	**$233**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**22**
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	**N/A**
P/E using 2021 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Average,**
Type of Stock	**Small-Growth**
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
2019			2.7 A	1.4 A	4.1 A
2020	3.4 A	2.6 A			10.4 E
2021					28.2 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			-$0.21 E
2021					-$0.16 E

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

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COMPANY UPDATE

CASI Pharmaceuticals second quarter marked the start of a return to normalcy for Evomela sales, a new lower-cost supply contract for Evomela, continued progress in advancing several candidates in its hematology pipeline and completion of a $40 million equity financing.

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.

Six-month results

Evomela sales totaled $2.6 million in the quarter and $6.0 million for the first six months of 2020. For the year, the Company expects sales of at least $10 million. Cost of goods were $5.7 million, or 95% of revenues for 1H20. Cost of goods sold 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%.

Research and development for the quarter totaled $1.9 million down from just under $3.0 million in the year-earlier period, and $4.9 million in 1Q 20. The lower research costs primarily reflected reduced regulatory costs from the de-emphasized ANDA portfolio partially offset by expenses related to CID-103.

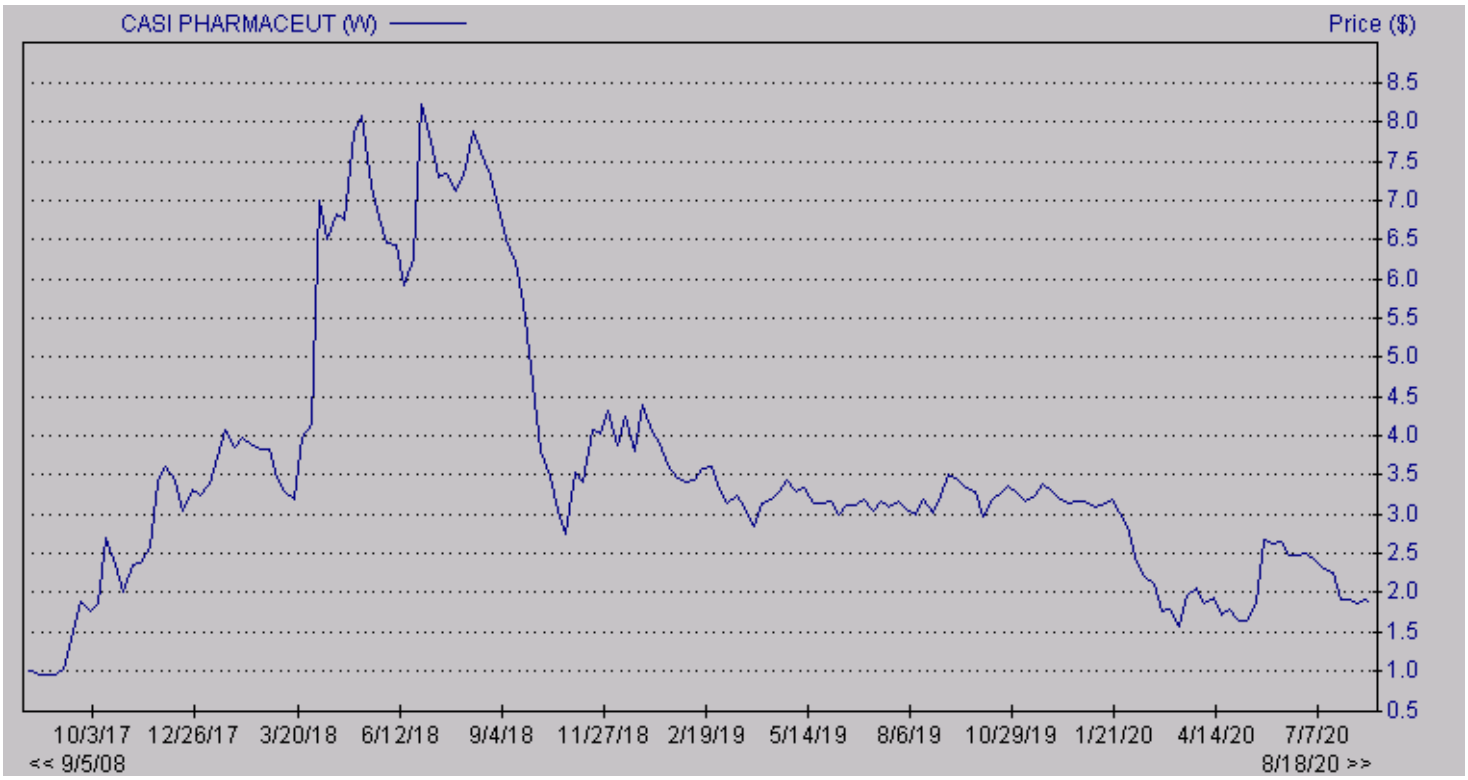
General and administrative was $4.1 million in the quarter and $8.1 million for the first half of 2020, down considerably from $7.0 million and $12.7 million for the second quarter and first half of 2019. In 2019, G&A included investments for the launch of Evomela. Costs related to Evomela sales are now in a separate sales and marketing expense line, totaling $1.6 million in 2Q20 and $2.8 million for the first half of 2020.

In total, CASI reported a net loss of ($0.09) per share, or ($8.7 million) in the second quarter, compared to ($0.17) per share, or ($15.5 million) in the year earlier period.

We are reducing our 2020 revenue estimate from $12.5 million to $10.4 million to account for continued economic impact from the pandemic. Our 2020 earnings expectation improves slightly from ($0.25) to ($0.21), based on lower R&D and G&A spending as well as a better sense of Evomela gross margins for the balance of the year.

Our valuation for CASI remains $2.89, 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.

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