August 15, 2019

Zacks Small-Cap Research

Sponsored – Impartial - Comprehensive

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

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

CASI Pharmaceuticals (CASI-NASDAQ)

CASI: Evomela launched in China

Our valuation is $8.17 per basic share, based on sum-of-the-parts risk-adjusted NPV for each of its products less corporate overhead. The ANDA portfolio comprises the vast majority of our NPV valuation at $748 million. We expect the Company to continue to make deals in this space and have modeled for $500 million in annual generics sales by 2045. We value the licensed drugs at $90 million.

OUTLOOK

CASI announced the launch of Evomela, the only approved and commercially available form of melphalan available in China. Our model includes $0.8 million in Evomela sales for 2019 growing to $3.8 million by the end of 2021.

Current Price (08/14/19)	$3.08
Valuation	**$8.17**

SUMMARY DATA

52-Week High	**$8.08**
52-Week Low	**$2.77**
One-Year Return (%)	**-60.81**
Beta	**1.08**
Average Daily Volume (sh)	**113,873**
Shares Outstanding (mil)	**96**
Market Capitalization ($mil)	**$295**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**12**
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 2019 Estimate	**-8.3**
P/E using 2020 Estimate	**-18.7**
Zacks Rank	**N/A**

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

ZACKS ESTIMATES

Revenue
(millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018					0 A
2019					6 E
2020					21 E
2021					68 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			-$0.34 E
2020					-$0.21 E
2021					$0.11 E

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

© Copyright 2019, Zacks Investment Research. All Rights Reserved.

COMPANY UPDATE

On August 12, CASI announced the commercial launch of Evomela, the only approved and commercially available form of melphalan available in China. This is the Company's first commercialized product and we are encouraged to see that volatile trade tensions between the US and China do not appear to be hampering CASI's progress towards establishing its footprint as a leading provider of high quality proprietary, licensed and ANDA pharmaceuticals to the rapidly evolving Chinese market.

Evomela is an encapsulated form of the generic melphalan, a drug commonly used to prepare patients with multiple myeloma (MM) for stem-cell transplants. Generic melphalan preparations include propylene glycol, which can cause lactic acidosis, hemolysis and kidney dysfunction in certain patients. Evomela reduces or eliminates these risks. The drug is also used for patients with MM who can't tolerate oral preparatory treatments. The estimated incidence of multiple myeloma in China is ~2.0 cases per 100,000 persons, for an estimated annual incidence of approximately 27,800 with approximately 16,900/year eligible candidates for autologous stem cell transplantation. Stem cell transplantation is less frequent in China vs. Western countries both for reasons of access and cost but has grown rapidly in recent years. In 2014, the number of transplants in China was estimated at 3,500, compared with 800 in 2011.

Management notes the supply chain is queued up, with hospitals and physicians educated on the product and its availability. We assume launch at a price of $6,400 per treatment. Our model includes $0.8 million in Evomela sales for 2019 growing to $3.8 million by the end of 2021. We estimate peak sales of $34 million in 2045, based on 55% market penetration and a price that falls to c. $3,800 per treatment. Sharp price decreases often go hand-in-hand with inclusion on various "approved" drug lists in China, and we believe that CASI will opt for the lower-price/higher market share route in part to suppress potential competition.

Second quarter results

CASI Pharmaceutical reported Q219 results on August 9. Results showed continued investment towards launching its recently approved in-licensed drug, Evomela in China, progress towards gaining regulatory approvals for Marqibo and Zevalin and expansion of its robust product portfolio with its investment in CID-103 (also known as TSK011010), an anti-CD38 monoclonal antibody, which expands the Company's hematology product pipeline.

Research and development for Q219 rose $1.2 million (+76%) to $3.0 million compared to $1.7 million in the year-earlier period, reflecting regulatory, consulting and manufacturing related services, additional personnel and facilities costs. General and administrative spending climbed to $7.0 million in the quarter, including $1.9 million in stock compensation paid to senior management. The balance of the increase stemmed from higher personnel costs in preparation for the marketing launch of Evomela and professional service fees.

In total, CASI reported a net loss of ($0.16) per share, or ($15.3 million) compared with a loss of ($0.07) per share or ($5.9 million) in the first quarter of 2019.

We are adjusting our estimates to reflect higher spending for research and development in 2019 from $7.8 million to $11.9 million, but holding our G&A expense steady at $23.7 million. This change reduces our 2019 EPS estimate from ($0.29) to ($0.34). We are also raising our R&D spending expectations for 2020-2022, reducing our EPS estimates by c. $0.03-0.05 each year.

Exhibit 1: Financial Summary

INCOME STATEMENT								
Fiscal year	2016A	2017A	2018A	2019E	2020E	2021E	2022E	2023E
Revenue	0	0	0	5,813	20,807	68,111	115,050	161,180
Cost of sales including payaways	0	0	0	(2,650)	(5,654)	(16,702)	(27,206)	(36,960)
Gross Profit	0	0	0	3,163	15,153	51,408	87,843	124,219
Research & development	(4,646)	(7,595)	(8,507)	(11,860)	(9,360)	(9,813)	(6,925)	(6,775)
Acquired IPRD	0	0	(687)	0	0	0	0	0
Selling, general & administrative	(4,775)	(3,156)	(17,997)	(23,238)	(25,754)	(30,522)	(50,131)	(66,658)
Operating profit (EBIT)	(9,421)	(10,751)	(27,191)	(31,935)	(19,961)	11,074	30,787	50,786
Interest income	0	16	48	0	0	0	0	0
Interest expense	(26)	(15)	(8)	(8)	(8)	(8)	(8)	(8)
Other expense	(7)	(20)	(320)	(67)	(67)	(67)	(67)	(67)
Pretax profit	(9,453)	(10,770)	(27,472)	(32,010)	(20,036)	10,999	30,712	50,711
Taxes	0	0	0	0	0	0	0	(2,536)
Net income	(9,453)	(10,770)	(27,472)	(32,010)	(20,036)	10,999	30,712	48,176
Basic shares outstanding	55,869	61,514	84,752	95,502	95,717	95,717	95,717	95,717
Impact of dilutive securities	0	0	0	0	0	0	0	0
Diluted shares outstanding	55,869	61,514	84,752	95,502	95,717	95,717	95,717	95,717
Basic EPS	**($0.17)**	**($0.18)**	**($0.32)**	**($0.34)**	**($0.21)**	**$0.11**	**$0.32**	**$0.50**
Diluted EPS	**($0.17)**	**($0.18)**	**($0.32)**	**($0.34)**	**($0.21)**	**$0.11**	**$0.32**	**$0.50**
Growth rates & margins								
Revenue growth	NA	NA	NA	NA	358%	327%	169%	140%
Gross profit as % of sales	NA	NA	NA	54%	73%	75%	76%	77%
R&D margin	NA	NA	NA	204%	45%	14%	6%	4%
SG&A margin	NA	NA	NA	400%	124%	45%	44%	41%
Tax rate	0%	0%	0%	0%	0%	0%	0%	5%
EBITDA reconciliation								
Depreciation & amortization	66	118	366	3,300	3,300	3,300	6,300	6,300
Amortization of intangibles	0	0	1,305	1,845	1,845	1,845	1,845	1,845
Stock based compensation	2,995	650	6,118	7,550	6,523	4,563	4,213	(5,520)
EBITDA	(6,359)	(9,983)	(20,708)	(21,086)	(10,138)	18,937	41,300	51,567

BALANCE SHEET							
Fiscal year	2017A	2018A	2019E	2020E	2021E	2022E	2023E
Cash & equivalents	43,490	85,117	44,122	32,442	49,104	60,890	120,963
Total current assets	**43,812**	**92,565**	**46,238**	**35,936**	**58,048**	**75,169**	**139,874**
Property plant and equipment	1,047	1,751	20,451	18,151	15,851	39,551	34,251
Intangibles	0	18,785	24,530	22,685	20,840	18,995	17,151
Total Assets	**45,101**	**113,410**	**91,285**	**76,839**	**94,805**	**133,782**	**191,342**
Accounts payable	2,088	968	2,385	1,696	3,457	5,632	7,651
Accrued liabilities	2,974	1,406	2,325	2,081	2,724	4,602	6,447
Total current liabilities	**5,062**	**2,374**	**4,711**	**3,777**	**6,182**	**10,234**	**14,098**
Long-term debt	1,499	1,499	1,499	1,499	1,499	1,499	1,499
Total liabilities	6,561	3,948	6,284	5,350	7,755	11,807	15,671
Common stock / additional paid in capital	499,276	499,276	499,276	499,276	499,276	499,276	499,276
Treasury stock	(8,034)	(8,034)	(8,034)	(8,034)	(8,034)	(8,034)	(8,034)
Retained earnings / accumulated deficit	(452,702)	(452,702)	(452,702)	(452,702)	(452,702)	(452,702)	(452,702)
Other comprehensive income / (loss)	0	0	0	0	0	0	0
Total equity	**38,540**	**38,540**	**38,540**	**38,540**	**38,540**	**38,540**	**38,540**
Total liabilities and equity	**45,101**	**42,488**	**44,824**	**43,890**	**46,295**	**50,347**	**54,211**

CASH FLOW STATEMENT							
Fiscal year	2017A	2018A	2019E	2020E	2021E	2022E	2023E
Cash from operating activities		**(28,584)**	**(11,648)**	**(10,680)**	**17,663**	**41,785**	**61,073**
Capital expenditures		(1,131)	(22,000)	(1,000)	(1,000)	(30,000)	(1,000)
Purchases of intangible assets		(20,643)	(7,600)	0	0	0	0
Cash from investing activities		**(21,773)**	**(29,600)**	**(1,000)**	**(1,000)**	**(30,000)**	**(1,000)**
Cash from financing activities		**91,072**	**0**	**0**	**0**	**0**	**0**
Net change in cash during period		**40,715**	**(41,248)**	**(11,680)**	**16,663**	**11,785**	**60,073**

Source: Company filings, Zacks Investment Research estimates.

HISTORICAL STOCK PRICE



DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

Zacks SCR Analysts hereby certify that the view expressed in this research report or blog article accurately reflect the personal views of the analyst about the subject securities and issuers. Zacks SCR also certifies that no part of any analysts' compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report or blog article. Zacks SCR believes the information used for the creation of this report or blog article has been obtained from sources considered to be reliable, but we can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice. The Zacks SCR Twitter is covered herein by this disclosure.

INVESTMENT BANKING AND FEES FOR SERVICE

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.

Zacks SCR has received compensation from the issuer directly, from an investment manager, or an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer.

The non-investment banking services provided to the issuer include the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR.

Each issuer has entered into an agreement with Zacks to provide continuous independent research for a period of no less than one year in consideration of quarterly payments totaling a maximum fee of $40,000 annually.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.

SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the Valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover.

SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances , this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or Tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

CANADIAN COVERAGE

This research report is a product of Zacks SCR and prepared by a research analyst who is employed by or is a consultant to Zacks SCR. The research analyst preparing the research report is resident outside of Canada, and is not an associated person of any Canadian registered adviser and/or dealer and, therefore, the analyst is not subject to supervision by a Canadian registered adviser and/or dealer, and is not required to satisfy the regulatory licensing requirements of any Canadian provincial securities regulators, the Investment Industry Regulatory Organization of Canada and is not required to otherwise comply with Canadian rules or regulations.