

Zacks Small-Cap Research

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CASI Pharmaceuticals (CASI-NASDAQ)

CASI: Moving towards additional regulatory approvals 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.

Current Price (05/17/19) **\$3.15**
Valuation \$8.17

OUTLOOK

CASI is establishing its footprint as a leading provider of high quality proprietary, licensed and ANDA pharmaceuticals to the rapidly evolving Chinese market. 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. With a robust, diverse pipeline, commitment to investing in new opportunities and ample cash, we believe that CASI Pharmaceuticals will move rapidly over the next several years to be a leading player in China.

SUMMARY DATA

52-Week High **\$8.23**
 52-Week Low **\$2.77**
 One-Year Return (%) **-56.13**
 Beta **1.19**
 Average Daily Volume (sh) **158,295**

Shares Outstanding (mil) **96**
 Market Capitalization (\$mil) **\$302**
 Short Interest Ratio (days) **N/A**
 Institutional Ownership (%) **12**
 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 2019 Estimate **N/A**
 P/E using 2020 Estimate **N/A**

Zacks Rank **N/A**

Risk Level **Above Avg.,**
 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	0.0 A				
2019					5.8 E
2020					20.8 E
2021					68.1 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				-\$0.29 E
2019					-\$0.16 E
2020					\$0.14 E

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

COMPANY UPDATE

CASI Pharmaceutical reported Q119 results on May 15. 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 Q119 rose \$0.9 million (+52%) to \$2.6 million compared \$1.7 million in the year-earlier period, reflecting costs associated with regulatory, consulting and manufacturing related services, additional personnel and facilities costs. General and administrative spending climbed to \$5.7 million in the quarter, including \$1.6 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 (\$0.09) per share, or (\$8.2 million) compared with a loss of (\$0.05) per share or (\$3.6 million) in the first quarter of 2018.

We are adjusting our estimates to reflect higher spending for research and development in 2019 from \$2.6 million to \$7.8 million, but holding our G&A expense steady at \$23.7 million. This change reduces our 2019 EPS estimate from (\$0.24) to (\$0.29). We are also raising our R&D spending expectations for 2020-2022, reducing our EPS estimates by c. \$0.03-0.04 each year.

INVESTMENT SUMMARY

COMPANY DESCRIPTION: CASI is establishing its footprint as a leading provider of high-quality proprietary, licensed and ANDA pharmaceuticals to the rapidly evolving Chinese market. We believe that 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 China as a sustainable opportunity and is investing with this in mind. With a robust, diverse pipeline, commitment to investing in new opportunities and ample cash, we believe that CASI Pharmaceuticals will firmly establish itself over the next several years as a leading player in China. Longer-term the Company aspires to expand sales outside of China and neighboring countries to the US and other markets.

FINANCIALS: The opportunity for CASI is significant; the Company is well funded with a solid business strategy, growing product portfolio and strong experience management team. We expect that the Company will invest and manage with the long-term in mind, which may keep a lid on potential margins, but will result in consistent and sustainable results for investors.

On March 29, 2018, CASI reported full-year 2018 results and filed its 10-k. The Company's net loss grew to \$27.2 million from \$10.8 million in 2017. The key factor was a significant increase in G&A. 2019 is likely to be a transitional year as the Company begins its commercial rollout. As a result, we expect costs as a percent of revenues to be higher than long-term estimates. Our model calls for 2019 revenues of \$5.8 million, which we expect to come from both Evomela and ANDA portfolio sales. In 2020, we forecast revenues of \$20.8 million, driven by growth in Evomela and ANDA portfolio sales as well as the likely introductions of Marqibo and Zevalin. By 2023, we look for sales to exceed \$161 million. We expect CASI to move to GAAP profitability by 2021 and increase steadily from there. Our model shows \$13.0 million in net profit (\$0.14 per share) in 2021, growing to \$48.2 million (\$0.50 per share) by 2023.

VALUATION: 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 sales by 2045. We value the licensed drugs at \$90 million. Our corporate overhead assumption is \$158 million on a discounted basis through 2045.

SENSITIVITIES: Our valuation and model are closely tied to successful execution in a market that is highly competitive and has been long-plagued by an unpredictable bureaucracy. However, China has taken a number of steps in the past few years to reclassify and clarify regulatory pathways for drugs in addition to increasing staffing and lowering outstanding applications, and, so far, CASI's first product, Evomela, seems to have moved smoothly through the regulatory system. China is also working to improve reimbursement for high-need drugs so that they are more affordable to citizens. To us, CASI's main risk is successfully gaining meaningful market share – particularly for its generic drugs. The Company intends to compete by focusing on high-need drugs (such as those for hepatitis B) and building a reputation for reliable high-quality products at a reasonable cost.

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)	(7,860)	(4,760)	(7,813)	(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)	(27,935)	(15,361)	13,074	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)	(28,010)	(15,436)	12,999	30,712	50,711
Taxes	0	0	0	0	0	0	0	(2,536)
Net income	(9,453)	(10,770)	(27,472)	(28,010)	(15,436)	12,999	30,712	48,176
Basic shares outstanding	55,869	61,514	84,752	93,480	93,480	93,480	93,480	93,480
Impact of dilutive securities	0	0	0	0	0	0	0	0
Diluted shares outstanding	55,869	61,514	84,752	93,480	93,480	93,480	93,480	93,480
Basic EPS	(\$0.17)	(\$0.18)	(\$0.32)	(\$0.30)	(\$0.17)	\$0.14	\$0.33	\$0.52
Diluted EPS	(\$0.17)	(\$0.18)	(\$0.32)	(\$0.30)	(\$0.17)	\$0.14	\$0.33	\$0.52
<u>Growth rates & margins</u>								
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	135%	23%	11%	6%	4%
SG&A margin	NA	NA	NA	400%	124%	45%	44%	41%
Tax rate	0%	0%	0%	0%	0%	0%	0%	5%
<u>EBITDA reconciliation</u>								
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	6,750	5,787	4,403	4,213	(5,520)
EBITDA	(6,359)	(9,983)	(20,708)	(17,886)	(6,274)	20,777	41,300	51,567
BALANCE SHEET								
Fiscal year	2017A	2018A	2019E	2020E	2021E	2022E	2023E	
Cash & equivalents	43,490	85,117	47,322	39,506	58,008	69,794	129,867	
Total current assets	43,812	92,565	49,438	43,000	66,952	84,073	148,778	
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	94,485	83,903	103,709	142,686	200,246	
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)	(8,448)	(6,816)	19,503	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	(38,048)	(7,816)	18,503	11,785	60,073	

Source: Company filings. Zacks Investment Research estimates.

HISTORICAL STOCK PRICE



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