Zacks Small-Cap Research

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CASI Pharma (CASI-NASDAQ)

CASI: Zacks Company Report

CASI: Phase II of ENMD-2076 for TNBC completed; Stage I of Phase II of ENMD-2076 for FLC completed and advanced to stage II, Zevalin launched in Hong Kong

Current Price (07/11/17)	$1.05
Valuation	**$4.50**

OUTLOOK

CASI is a **commercial stage** biopharmaceutical company with a therapeutic focus on cancer and autoimmune diseases. Its lead oncology drug candidate ENMD-2076 is in multiple Phase II clinical trials in both North America and China. CASI's import drug business is going well in China. The company is also developing 2ME2 for autoimmune disorders.

CASI's unique dual development approach leverages its expertise and resources in both North America and greater China, which differentiates itself from local competitors in each of the territory.

We are optimistic about CASI's prospect.

SUMMARY DATA

52-Week High	**$1.72**
52-Week Low	**$0.84**
One-Year Return (%)	**6.82**
Beta	**0.77**
Average Daily Volume (sh)	**16,675**
Shares Outstanding (mil)	**60**
Market Capitalization ($mil)	**$63**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**N/A**
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 2015 Estimate	**N/A**
P/E using 2016 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
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)
2016	0.00 A	0.00 A	0.00 A	0.00 A	0.00 A
2017	0.00 A	0.00 E	0.00 E	0.05 E	0.50 E
2018					1.50 E
2019					10.0 E

Earnings per Share
(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	-$0.04 A	-$0.08 A	-$0.03 A	-$0.05 A	-$0.17 A
2017	-$0.03 A	-$0.03 E	-$0.04 E	-$0.04 E	-$0.13 E
2018					-$0.19 E
2019					-$0.13 E

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

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WHAT'S NEW

Update on First Quarter 2017 Financials

There were no revenues reported for the first quarter ended March 31, 2017.

R&D expenses for 1Q17 were $1.05 million, compared to $1.02 million for the same period last year.

S&GA expenses for 1Q17 were $0.64 million, compared to $0.77 million for the first quarter 2016.

CASI reported a net loss for the first quarter of 2017 of ($1.7 million), or ($0.03) per share, compared with a net loss of ($1.8 million), or ($0.04) per share, for the same period last year.

As of March 31, 2017, CASI had cash and cash equivalents of $25.5 million.

Update on Phase II ENMD-2076 in Triple Negative Breast Cancer (TNBC)

On April 14, 2017, CASI reported that along with the investigators a decision has been reached to stop further patient enrollment in its **Phase II,** open-label study of ENMD-2076 in previously treated locally advanced or metastatic triple-negative breast cancer (TNBC) conducted at the University of Colorado, Denver and the Indiana University Melvin and Bren Simon Cancer Center.

The study was a 2-stage design which targeted an accrual of **35 patients**. The patient number was expanded to take into consideration those patients which may not be evaluable for efficacy analysis as per the protocol. In this uncommon tumor type and challenging setting to recruit, a total of **41 patients** have been enrolled which has been determined to be sufficient to assess the potential efficacy of ENMD-2076 in this patient population and for ongoing biomarker analysis.

The Company continues to collect and evaluate data in those patients enrolled in the study, and the biomarker program which evaluates potential markers that could be predictive of a response to ENMD-2076 is ongoing. In addition, the ongoing **Phase IIa study in China** in patients with TNBC continues to enroll patients in the dose escalation phase, the primary objective of which is to determine the recommended Phase II dose in Chinese study subjects. This dose escalation phase is expected to reach the full accrual target in **Q3 2017.**

Along with the investigators, the Company plans to present the study results at the next available opportunity.

CASI's goal is to reach a clinical inflection point with the identification of clinically correlative biomarker(s) in order to support a **Phase III** trial in a well-defined subset of a TNBC patient population.

Update on ENMD-2076 in FLC

The Phase II Trial

On Nov. 4, 2015, CASI announced the dosing of the first patient in the **Phase II** clinical trial at Memorial Sloan-Kettering Cancer Center. The trial will enroll **up to 30 patients**. The primary endpoint is to determine the 6-month progression free survival (PFS6) rate when patients with advanced fibrolamellar carcinoma (FLC) are treated with daily oral ENMD 2076. Secondary Objectives include the overall response rate using RECIST v 1.1 criteria, the median progression free survival (PFS), time to progression (TTP), and overall survival (OS).

- This is a **single arm trial** to evaluate the objective response rate (ORR) of ENMD-2076 in FLC patients as the primary endpoint.

- The trial will be conducted as a Simon **2-stage study** with interim futility analysis released after **16 patients** reach a clinical event. Futility would be declared if none of the patients experience an objective response and would result in the termination of the study.

- If, however, one or more patients experience an objective response, the study would continue with additional patients. At that time, the company would expect to meet with the FDA to discuss what clinical efficacy endpoint would be considered reasonably likely to provide clinical benefit and support an accelerated approval based on the surrogate endpoint of tumor response.

- Assuming that the results of the proposed study show that ENMD-2076 improves objective tumor response, CASI would expect to propose a confirmatory clinical trial and, in parallel, submit an **NDA for accelerated approval** based on objective tumor response rates.

- CASI will submit to the FDA a request for **breakthrough therapy** designation whenever clinical data meets the appropriate criteria.

The Phase II trial of ENMD-2076 in FLC is enrolling patients at five sites – Memorial Sloan Kettering Cancer Center, Dana Farber Cancer Center, University of California at San Francisco, University of Colorado-Denver, and University of Texas Southwestern Medical Center. The recruitment is going very well and top line data will be available **in late 2016**.

The Update

On Aug. 16, 2016, CASI announced that its **Phase II** trial of ENMD-2076 in fibrolamellar carcinoma (FLC) has met its **Stage I** endpoint of objective response for non-futility based on the pre-specified interim analysis criteria and will advance to **Stage II** development.

Meanwhile, the Stage I remains ongoing with approximately one-third of the patients still under treatment. A full interim analysis will be conducted and reported after all 16 patients have reached study endpoint of responses.

FLC is a **rare form** of liver cancer that usually occurs in young adults who have no history of liver disease. FLC patients typically present with a palpable abdominal mass but no symptoms, although pain, weight loss and jaundice may occur. The typical treatment is surgical removal of the tumor. When the tumor cannot be removed surgically or when there is distant spread, systemic treatment is used. Currently, there is **no standard systemic therapy regimen** for FLC**.**

Studies have shown that FLC appears to have a **better prognosis** than typical HCC. The population-based relative survival of patients with FLC in the US is 73% at 1 year and 32% at 5 years. In contrast, HCC relative survival is 26% at 1 year and 7% at 5 years.

FLC comprises approximately 5% of all hepatocellular carcinomas (HCC). The total incidence of HCC is estimated to be 780,000 each year worldwide according to the World Health Organization. Therefore, each year, approximately 39,000 people are diagnosed with FLC worldwide.

Peak sales of ENMD-2076 for FLC alone could be in the neighborhood of $200 million worldwide if we assume a reasonable cost of $50,000 for each patient and about 10% market share of new incidence when ENMD-2076 is approved for FLC.

The Phase II Trial of ENMD-2076 for FLC will Expanded into China

On May 12, 2016, CASI announced that China's Food and Drug Administration (CFDA) has approved the Company's application to conduct a **Phase II** clinical trial in FLC patients in China for ENMD-2076.

We are pleased with CFDA's approval of this Phase II trial which is an expansion of the ongoing Phase II trial for FLC in the US. This is also the company's fourth approval from CFDA to conduct Phase II trials with the company's novel and orally-active Aurora A/angiogenic kinase inhibitor, and confirms CASI's core competency to navigate and obtain CFDA approvals to conduct trials in China as part of a global clinical program.

The Orphan Drug designation (ODD) for ENMD-2706

In October, 2015, ENMD-2076 received Orphan Drug designation (ODD) from the European Medicines Agency (EMA) for the treatment of hepatocellular carcinoma (HCC), including fibrolamellar carcinoma (FLC), a rare type of HCC.

The designation provides CASI with **10 years** of market exclusivity in EU if ENMD-2076 is approved there. ENMD was also granted ODD for the treatment of HCC by the US FDA in 2014, which provides CASI with a **7-year** market exclusivity in the US after its New Drug Application approval.

We welcome the announcement and believe it represents an important regulatory milestone in the course of development of ENMD-2076. The ODD from both the US and EU will enhance the commercial value of ENMD-2076 for global market.

Attractive Valuation

We continue to be optimistic about the prospect of CASI and our fair valuation remains at **$4.50** per share.

CASI is a commercial stage biopharmaceutical company focusing on the development and commercialization of therapeutics for cancer and autoimmune disease and is competitively positioned with an integrated U.S./China drug development model. In addition to China as a strategic clinical location, CASI is also focused on the China commercial opportunity. China is projected to be the 2nd largest pharmaceutical market by 2016 and the largest oncology market by 2019.

CASI currently has three products in various stages of the import drug registration process with CFDA in China, with one product (Zevalin) officially launched in Hong Kong. All three products are approved in the U.S. and marketed by its collaborator Spectrum Pharmaceuticals, Inc. When all three products are approved in China (we estimate the approval in 2019 or 2020), CASI will become a key player in China's oncology market and revenue could increase dramatically due to rapid market penetration.

In addition to imported drugs from the US, CASI is also developing its proprietary pipeline with two lead candidates ENMD-2076 for cancers and 2ME2 for autoimmune disease using its **unique dual drug development strategy.** This dual drug development approach leverages the company's expertise and resources in both the U.S. and China**,** which has many advantages over traditional drug development approaches. These advantages include low cost, high productivity due to large talent pool in China, and large patient pool for clinical trials.

ENMD-2076 is already in multiple **Phase II** clinical trials targeting breast cancer, soft tissue sarcoma, and ovarian clear cell carcinoma. A new Phase II trial was initiated in November 2015 to target fibrolamellar carcinoma (FLC).

CASI also has a strong balance sheet and an experienced management team, who, we believe, is able to lead the company to the next level.

When it comes to the valuation, we believe CASI's shares are undervalued at the current market price based on the company's strong fundamentals. Currently, shares of the company are trading at around $1.08 per share which values the company at $65.0 million in market cap based on approximately 60

million outstanding shares. We believe this undervalues the company based on what we have discussed above.

Based on our long term financial model, we expect CASI to become profitable in 2020 with an EPS of $0.01 based on total revenue of $25 million. EPS will grow to $0.39 while revenue will reach $65 million in fiscal 2021. If we use the average biotech P/E ratio of 30x, using 25% discount rate for 4 years, we come up with a fair value of $4.50 per share. This price target values the company at $270 million in market cap, which is still conservative in our view.

However, there are some **risks** associated with our price target.

Our price target assumes the final approval of the three imported drugs in 2019 or 2020 in China and the final approval of ENMD-2076 and 2ME2. Although risks associated with imported drug registration are relatively low in China, we can't completely rule out the possibility of disapproval, or delay of the approval.

Further, ENMD-2076 and 2ME2 are still in the development stage. The risks associated with drug development are high, especially for early stage candidates. Both ENMD-2076 and 2ME2 have a high hurdle to overcome both clinically and regulatorily. Any delay or failure in clinical development or regulatory approval will cause the share price to decline dramatically.

PROJECTED INCOME STATEMENT

	2016 (Dec)					2017 (Dec)					2018 (Dec)	2019 (Dec)	2020 (Dec)	2021 (Dec)
$ in million except per share data	Q1	Q2	Q3	Q4	FYA	Q1	Q2	Q3	Q4	FYE	FYE	FYE	FYE	FYE
Grant revenue	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Royalties	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Product revenue	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.50	$0.50	$1.50	$10.00	$25.00	$65.00
Total Revenues	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.50**	**$0.50**	**$1.50**	**$10.00**	**$25.00**	**$65.00**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
CoGS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.13	0.13	0.38	2.00	5.00	13.00
Gross Income	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.37**	**$0.37**	**$1.13**	**$8.00**	**$20.00**	**$52.00**
Gross Margin	-	-	-	-	-	-	-	-	74.0%	74.0%	75.0%	80.0%	80.0%	80.0%
R&D	$1.02	$1.36	$1.01	$1.25	$4.65	$1.05	$1.10	$1.25	$1.50	$4.90	$6.00	$7.50	$9.00	$10.50
% R&D	-	-	-	-	-	-	-	-	-	-	-	-	-	-
SG&A	$0.77	$1.91	$0.68	$1.42	$4.78	$0.64	$0.70	$1.00	$1.20	$3.54	$7.50	$9.50	$10.50	$12.50
%SG&A	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Expenses	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Operating Income	**($1.8)**	**($3.3)**	**($1.7)**	**($2.7)**	**($9.4)**	**($1.7)**	**($1.8)**	**($2.3)**	**($2.3)**	**($8.1)**	**($12.4)**	**($9.0)**	**$0.5**	**$29.0**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	44.62%
Other Net	($0.0)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	($0.1)	($0.1)	($0.1)
Pre-Tax Income	**($1.8)**	**($3.3)**	**($1.7)**	**($2.7)**	**($9.4)**	**($1.7)**	**($1.8)**	**($2.3)**	**($2.3)**	**($8.1)**	**($12.4)**	**($9.1)**	**$0.4**	**$28.9**
Income taxes(benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Reported Net Income	**($1.8)**	**($3.3)**	**($1.7)**	**($2.7)**	**($9.4)**	**($1.7)**	**($1.8)**	**($2.3)**	**($2.3)**	**($8.1)**	**($12.4)**	**($9.1)**	**$0.4**	**$28.9**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	
Net Margin	-	-	-	-	-	-	-	-	-	-				
Diluted Shares Out	40.2	42.9	49.2	58.8	55.9	60.2	62.0	63.0	65.0	62.5	65.0	68.0	70.0	75.0
Reported EPS	**($0.04)**	**($0.08)**	**($0.03)**	**($0.05)**	**($0.17)**	**($0.03)**	**($0.03)**	**($0.04)**	**($0.04)**	**($0.13)**	**($0.19)**	**($0.13)**	**$0.01**	**$0.39**
One time charge	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*
Non GAAP Net Income	**($1.8)**	**($3.3)**	**($1.7)**	**($2.7)**	**($9.4)**	**($1.7)**	**($1.8)**	**($2.3)**	**($2.3)**	**($8.1)**	**($12.4)**	**($9.1)**	**$0.4**	**$28.9**
Non GAAP EPS	**($0.04)**	**($0.08)**	**($0.03)**	**($0.05)**	**($0.17)**	**($0.03)**	**($0.03)**	**($0.04)**	**($0.04)**	**($0.13)**	**($0.19)**	**($0.13)**	**$0.01**	**$0.39**

Source: Company filings and Zacks estimates

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HISTORICAL STOCK PRICE



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