Zacks Small-Cap Research

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May 8, 2018
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CASI Pharma (CASI-NASDAQ)

CASI: The acquisition of FDA approved ANDAs from Sandoz greatly enhances CASI's import drug business and transforms the company from clinical stage to commercial stage.

Valuation: Our relative valuation metrics indicates a fair value of $15.00/share.

Current Price (02/01/18)	$4.27
Valuation	**$15.00**

OUTLOOK

CASI is a **commercial stage** biopharmaceutical company with a therapeutic focus on cancer and autoimmune diseases. Its lead global oncology drug candidate ENMD-2076 is in multiple Phase I/II clinical trials in both North America and China. CASI's 3 import drug registration programs are going well in China.

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	**$7.99**
52-Week Low	**$0.91**
One-Year Return (%)	**660.95**
Beta	**0.84**
Average Daily Volume (sh)	**800,588**
Shares Outstanding (mil)	**86**
Market Capitalization ($mil)	**$688**
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 A	0.00 A	0.00 E	0.00 A
2018					1.50 E
2019					7.50 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	-$0.04 A	-$0.03 A	-$0.08 A	-$0.17 A
2018					-$0.16 E
2019					-$0.13 E

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

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WHAT'S NEW

CASI Exited 2017 with A Strong Balance Sheet

There was no revenue recorded for the fourth quarter ended December 31, 2017.

R&D expenses for the fourth quarter 2017 were $3.8 million compared to $1.3 million in 2016, an increase of $2.5 million. The increase primarily reflected continued investment in CASI's development of approved drugs in-licensed from Spectrum Pharmaceuticals, Inc. in China.

G&A expenses for the fourth quarter 2017 were $1.2 million compared to $1.4 million in 2016. The decrease primarily reflected the decrease in non-cash stock compensation expense offset by increases due to additional personnel within the company's business development function and higher professional fees.

Net loss for the fourth quarter 2017 was $5.0 million ($0.08 per share), compared with a net loss of $2.7 million ($0.05 per share) for the fourth quarter 2016.

As of December 31, 2017, CASI had cash and cash equivalents of approximately $43.5 million.

In March 2018, CASI closed a **$50 million** private placement. The Company issued 15,432,091 shares of its common stock with accompanying warrants to purchase 6,172,832 shares of its common stock. The purchase price for each share of common stock and warrant was $3.24. The warrants will become exercisable 180 days after issuance at a $3.69 per share exercise price, and will expire five years from the date of issuance.

The company plans to use the proceeds to prepare for the anticipated launch of its first commercial product in China and also for working capital general corporate purposes.

With the current cash and proceeds from the private placement, the company's financial flexibility is greatly enhanced. We don't see any immediate need to raise capital for CASI.

CASI Acquires ANDA Portfolio From Sandoz

The Event

On Jan. 26, 2018, CASI announced that it has acquired a portfolio of 25 U.S. FDA-approved abbreviated new drug applications (ANDAs), one ANDA that FDA tentatively approved, and three ANDAs that are pending FDA approval. These products are listed below.

Product	Approved
Benazepril tablets	X
Bisoprolol fumarate tablets	X
Burprenorphine HCL Sublingual tablets	X
Cefprozil tablets	X
Cilostazol tablets – 50mg	X
Cilostazol tablets – 100mg	X
Desvenlafaxine ER tablets	X
Diclofenac potassium tablets	X
Diclofenac sodium DR tablets	X
Econazole nitrate cream	X
Entecavir tablets	X
Epinastine HCl Ophthalmic Solution	X
Heparin sodium for injection	X
Lisinopril tablets	X
Lisinopril BPP tablets	X
Methimazole tablets	X
Midodrine tablets	X
Nabumetone tablets	X
Naratriptan tablets	X
Ondansetron HCL tablets	X
Repaglinide tablets	X
Ribavirin capsules	X
Spironolactone tablets	X
Tizanidine tablets	X
Triamterene and hydrochlorothiazide combination tablets	X

Product	**Pending**
Aripiprazole tablets	X
Bepotastine Ophthalmic Solution	X
Bromfenac Ophthalmic Solution	X
Telmisartan and hydrochlorothiazide tablets	X

The Implications

The transaction is **transformative** for CASI in our opinion, which will **transition** the company from clinical stage to a commercial pharmaceutical company.

During our conversation with management, they told us that CASI intends to select and commercialize certain products from the portfolio that have unique market opportunity and cost-effective manufacturing in China and/or in the U.S. The initial focus will be on hepatitis B virus infection (entecavir), diabetes and hypertension drugs.

With the acquisition of FDA approved ANDAs, CASI does not need to do any bioequivalent tests for any of the acquired ANDAs according to the new rules established by the CFDA. In order to commercialize these FDA approved ANDAs in China, CASI only needs to transfer the manufacturing technologies from Sandoz to manufacturers in China, which will save tremendously in terms of costs and time. Based on our understanding of the current rules set by CFDA, we estimate CASI could introduce some of the ANDAs into China market in about one and a half year.

We believe, with the acquisition of FDA approved ANDAs and the high-quality standards of Sandoz, CASI will leverage CFDA's most recent regulations to accept western pharmaceutical and clinical data for rapid entry into China's market while maintaining the **first mover** advantages.

With the soaring demand in China for high quality import pharmaceuticals, we are confident that CASI will be able to achieve commercial success with the high-quality Sandoz ANDAs in the China pharmaceutical market down the road.

We will update investors once we have detailed development and commercialization plan from the company. Please remain tuned.

Update on Import Drug Pipeline

EVOMELA®:

In early April 2018, CASI received a letter from the Center for Drug Evaluation (CDE) (group within the China FDA in charge of technical review) indicating that EVOMELA® (melphalan) for injection has been scheduled for review by the Expert Advisory Anti-Tumor Drugs Committee, which is scheduled to take place between April 25-26, 2018.

The Advisory Committee Meeting is a closed meeting. No additional information on the EVOMELA® application has been requested by the CDE in advance of the Advisory Committee Meeting, however, CASI will submit a Clinical Data Briefing Package which will summarize the various components contained in the previously submitted application.

CFDA has granted priority review for CASI's import drug registration clinical trial application (CTA) for EVOMELA (melphalan) for Injection. The CFDA cited the following three reasons for granting the priority review:

- EVOMELA is indicated for the treatment of multiple myeloma, which is classified as a rare disease in China;
- There is no melphalan in any formulation available in China to address this unmet medical need;
- EVOMELA has clear therapeutic advantages to currently available therapeutics.

MARQIBO®

The CFDA review of MARQIBO import drug clinical trial application (CTA) is in process. CASI anticipates that the CFDA will complete its review of the CTA in the next **four to six months**, and expects to initiate the confirmatory trial within six months after CTA approval. The confirmatory trial is required as part of the registration process for the import drug registration.

ZEVALIN®

The CFDA filing and review of ZEVALIN import drug clinical trial application (CTA) is in process. The ZEVALIN antibody kit and the radioactive Yttrium-90 component of the clinical trial application require separate submissions to the CFDA, which the first part is currently under review and the latter part is in the submission process. The Company expects to initiate the confirmatory trial within **six months** after the CFDA's approval of both the ZEVALIN kit and the Yttrium-90 submissions.

Update on ENMD-2076 for STS and CCOC

The data from the investigator-sponsored **Phase II** study in patients with CCOC was presented at the 2017 ASCO. The data from the investigator-sponsored **Phase II** study in patients with STS was presented at the 2015 Annual Meeting of the Connective Tissue Oncology Society. The correlative genomics testing has been completed and a publication is expected to be submitted in 2017.

Although anticancer activity was observed in the CCOC and STS studies, as per CASI management, the level of single agent activity does not support the development of ENMD-2076 in these two tumor types as a monotherapy. Therefore, based on the clinical data, CASI has determined it will not pursue company sponsored development of ENMD-2076 in CCOC and STS.

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 I/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 data at the **2017 San Antonio Breast Cancer Symposium.**

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** multi-center US clinical trial. The trial will enroll **at least 30 patients**. The primary objective is to determine the objective response rate using RECIST v 1.1 criteria when patients with advanced fibrolamellar carcinoma (FLC) are treated with daily oral ENMD 2076. Secondary objectives include the determination of the 6-month progression free survival (PFS6), 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.
- Assuming that the results of the proposed study show that ENMD-2076 has an acceptable 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 accrual to this ongoing **Phase II** study is complete and is in the follow up phase. It is anticipated that the data from this study will be submitted to a medical conference for presentation **in 2018**.

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 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.

Fair Value Raised to $15.00/Share

We continue to be optimistic about the prospect of CASI and raise our fair valuation for CASI to **$15.00**/share from previous **$9.00/**share due to recent positive development within the company.

CASI is focused 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.

The acquisition of the FDA approved ADNAs greatly enhances CASI's import drug business in China. Together with three products in various stages of the import drug registration process with CFDA in China, CASI will become a key player in China's generic drug 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 **Phase II** clinical trials targeting breast cancer and 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 $8.0 per share which values the company at $694 million in market cap based on approximately 86 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 $0.05 based on total revenue of $28.5 million. EPS will grow to $0.49 while revenue will reach $75 million in fiscal 2021. If we use the average biotech P/E ratio of 35x, using 20% discount rate for 3 years, we come up with a fair value of $10.00 per share for the import drug business. We assign a $5 value to the company's clinical programs with total value at $15.00 per share. This price target values the company at $1.29 billion in market cap, which is fair 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 is still in the development stage. The risks associated with drug development are high, especially for early stage candidates. ENMD-2076 has 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	FY	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	$0.00	$0.00	$1.50	$7.50	$28.50	$75.00
Total Revenues	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$1.50**	**$7.50**	**$28.50**	**$75.00**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
CoGS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.38	1.50	5.70	15.00
Gross Income	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$1.13**	**$6.00**	**$22.80**	**$60.00**
Gross Margin	-	-	-	-	-	-	-	-	-	-	75.0%	80.0%	80.0%	80.0%
R&D	$1.02	$1.36	$1.01	$1.25	$4.65	$1.05	$1.73	$0.97	$3.85	$7.60	$7.00	$7.50	$9.00	$10.50
% R&D	-	-	-	-	-	-	-	-	-	-	-	-	-	-
SG&A	$0.77	$1.91	$0.68	$1.42	$4.78	$0.64	$0.69	$0.63	$1.19	$3.16	$4.50	$7.50	$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)**	**($2.4)**	**($1.6)**	**($5.0)**	**($10.8)**	**($10.4)**	**($9.0)**	**$3.3**	**$37.0**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	49.33%
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)**	**($2.4)**	**($1.6)**	**($5.0)**	**($10.8)**	**($10.4)**	**($9.1)**	**$3.2**	**$36.9**
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)**	**($2.4)**	**($1.6)**	**($5.0)**	**($10.8)**	**($10.4)**	**($9.1)**	**$3.2**	**$36.9**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	
Net Margin	-	-	-	-	-	-	-	-	-	-				
Diluted Shares Out	40.2	42.9	49.2	58.8	55.9	60.2	60.2	60.2	65.4	61.5	65.0	68.0	70.0	75.0
Reported EPS	**($0.04)**	**($0.08)**	**($0.03)**	**($0.05)**	**($0.17)**	**($0.03)**	**($0.04)**	**($0.03)**	**($0.08)**	**($0.17)**	**($0.16)**	**($0.13)**	**$0.05**	**$0.49**
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)**	**($2.4)**	**($1.6)**	**($5.0)**	**($10.8)**	**($10.4)**	**($9.1)**	**$3.2**	**$36.9**
Non GAAP EPS	**($0.04)**	**($0.08)**	**($0.03)**	**($0.05)**	**($0.17)**	**($0.03)**	**($0.04)**	**($0.03)**	**($0.08)**	**($0.17)**	**($0.16)**	**($0.13)**	**$0.05**	**$0.49**

Source: Company filings and Zacks estimates

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