Zacks Small-Cap Research

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CASI Pharma (CASI-NASDAQ)

CASI: Zacks Company Report

CASI: CASI exited fiscal 2016 with a strong balance sheet; Stage I of Phase II of ENMD-2076 for FLC completed and advanced to stage II, Zevalin launched in Hong Kong

Current Price (04/03/17)	$1.34
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	**$0.84**
One-Year Return (%)	**24.07**
Beta	**0.78**
Average Daily Volume (sh)	**35,355**
Shares Outstanding (mil)	**60**
Market Capitalization ($mil)	**$81**
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)
2014	0.00 A	0.00 A	0.00 A	0.00 A	0.00 A
2015	0.02 A	0.02 A	0.00 A	0.00 A	0.05 A
2016	0.00 A	0.00 A	0.00 A	0.00 A	0.00 A
2017					0.50 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-$0.05 A	-$0.06 A	-$0.07 A	-$0.05 A	-$0.23 A
2015	-$0.06 A	-$0.06 A	-$0.05 A	-$0.05 A	-$0.22 A
2016	-$0.04 A	-$0.08 A	-$0.03 A	-$0.05 A	-$0.17 A
2017					-$0.16 E

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

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WHAT'S NEW

CASI Exited Fiscal 2016 with a Strong Balance Sheet

CASI recently reported its financials for the quarter and year ended December 31, 2016.

For the fourth quarter ended December 31, 2016, the company reported a net loss of ($2.7 million), or ($0.05) per share. This compares with a net loss of ($1.7 million), or ($0.05) per share for the fourth quarter of 2015. The increase in net loss is due to non-cash stock compensation expense of $0.7 million related to stock option issuances associated with financings completed in the fourth quarter of 2016, as well as increased costs associated with the expansion of the company's China operations.

For the fiscal year ended December 31, 2016, net loss was ($9.5 million), or ($0.17) per share, compared with a net loss of ($7.2 million) or ($0.22) per share for 2015. The larger net loss for 2016 was mainly due to an increase in non-cash stock compensation expense of $2.1 million related to stock option issuances associated with completed financings and increased costs associated with the company's Phase II Trial for ENMD-2076 in fibrolamellar carcinoma.

As of December 31, 2016, CASI had cash and cash equivalents of $27.1 million.

On Sept. 21, 2015, CASI Pharmaceuticals (CASI) announced that it had entered into definitive agreements for a **$25.1** million financing led by a China investment fund manager affiliated with the same management team of the company's current largest shareholder, IDG-Accel China Growth Fund III, L.P.

Pursuant to the agreement, CASI agreed to sell a total of 20,658,434 shares of common stock, at $1.190 per share, based on the closing bid price of the Company's common stock on the Nasdaq Capital Market on September 18, 2015, and a total of 4,131,686 warrants, representing a 20% warrant coverage, with a purchase price of $0.125 per whole warrant share. The warrants will become exercisable three months after issuance at $1.69 per share exercise price, and will expire three years from the date the warrants become exercisable.

On July 5, 2016, the Company completed the Third Closing and received $1.0 million.

On October 3, 2016, the Company completed the Final Closing and received $7.8 million.

On October 24, 2016, the Company completed the October Offering and received $3.0 million.

We welcome this financing and believe it's necessary in order to accelerate the company's advancement of its pipeline.

We understand that investors are concerned about the dilution of the existing shareholder base. But we remind investors that not every financing is bad. In this case, we believe the financing is positive to the company.

First, this financing boosts the company's balance sheet immediately. With proceeds from the new financing, the company's cash balance should be able to fund the company's operations into 2019 according to our financial model. Investors do not need to worry about a new dilutive financing in more than two years.

Second, the deal further validates CASI's business model and its clinical programs. CASI also received investments from IDG ACCEL and Kleiner Perkins Caufield & Byers China, two major venture capital firms in China. These firms tend to have long-term investment strategies, have representatives on the company's Board of Directors and are in line with the company's mission.

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.

CASI Announces Positive Phase II Data on ENMD-2076 in Patients with OCCC at ASCO

The Poster Presentation

During the 2016 ASCO meeting held June 3-7 at Chicago, CASI made a poster presentation about its lead candidate ENMD-2076 for ovarian clear cell carcinoma (OCCC).

OCCC represents 6% of all epithelial ovarian carcinomas and is associated with chemotherapy resistance and worse prognosis with advanced disease. Approximately 50% of OCCC are characterized by inactivating mutations in *ARID1A* and upregulation of PIK3/AKT/mTOR pathway. ENMD-2076, is an oral anti-angiogenic/anti-proliferative kinase inhibitor against the mitotic kinase Aurora A.

The poster title is: Antitumor Activity, Safety and Predictive Biomarker Results of ENMD-2076 Administered to Patients (pts) with Recurrent Ovarian Clear Cell Carcinoma (OCCC): A Trail of the Princess Margaret **Phase II** Consortium.

This is a multi-center, open-label, Phase II study of single agent ENMD-2706 (275 mg daily, 28 day Cycle) in patients with recurrent OCCC.

The primary objectives include

- assessment of the anticancer activity of ENMD-2076 defined by the 6- month PFS rate,

- assessment of the objective response rate (ORR) using RECIST 1.1 criteria.

Secondary objectives include

- determination of duration of response

Exploratory objectives include

- correlation between somatic mutations in *PI3KCA*, *ARID1A* and *PTEN* and patient outcome.
- correlation between expression of *ARID1A* and *PTEN* by immunohistochemistry in archival samples and pretreatment tumor biopsies with patient outcome.

Data from 37 patients were presented. ENMD-2076 was generally well tolerated with a side effect profile typical of this class of agent.

6-month PFS rate was 0.16. 6-month PFS rate for ARID1A negative was 28% vs 0% for ARID1A positive. Overall response rate was 11%.

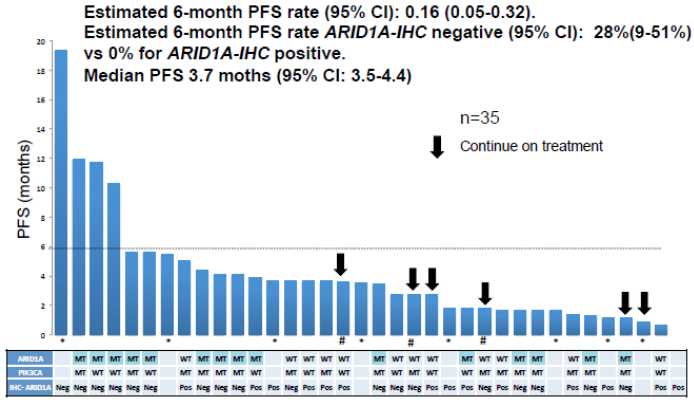


Figure 1. Mutational profile (*ARID1A* and *PIK3CA*) and *ARID1A-IHC* of patients according to PFS. * Profiling data not available. # Partial response by RECIST v.1.1

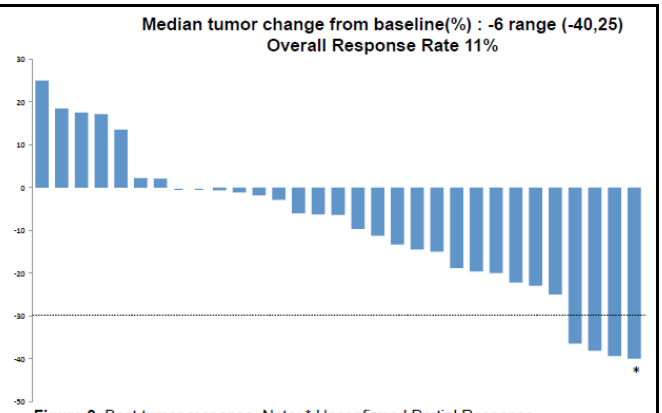


Figure 2. Best tumor response. Note: * Unconfirmed Partial Response

The correlation of PIK3CA status and PFS was significant. In wild type PIK3CA patients, median PFS was 5.7 months vs 3.7 months in PIK3CA mutant patients (p=0.07).

The correlation between ARID1A-IHC status and PFS was also significant. In ARID1A-IHC negative patients, median PFS was 4.1 months vs 3.7 months for ARID-IHC positive patients (p=0.026).

Correlation of sequencing status for *PIK3CA/ARID1A* with PFS

	Groups	median PFS (95% CI)	p value
Sequencing *PIK3CA*	MT group (n=17)	3.7 (1.6-4.4)	0.07
	WT group (n=10)	5.7 (3.6-11.7)	
Sequencing *ARID1A*	MT group (n=15)	4.1 (1.6-5.7)	0.88
	WT group (n=13)	3.7 (1.7-5.1)	

Correlation of *ARID1A-IHC* and PFS

Groups	median PFS (95% CI)	p value
Negative (n=18)	4.1(1.8-10.3)	0.026
Positive (n=13)	3.7(1.4-3.9)	

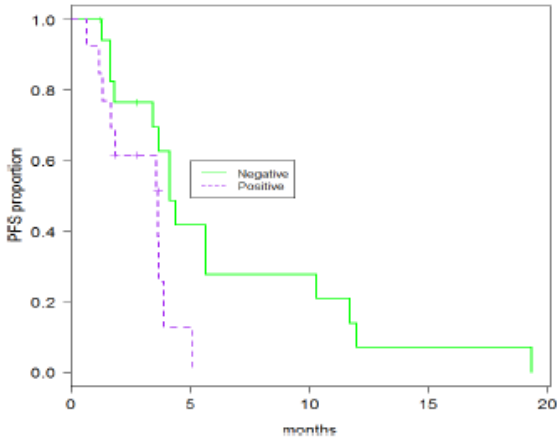


Figure 4. *ARID1A-IHC* and PFS correlation

Our Takeaways from the data presentation

These data showed that ENMD-2076 demonstrated antitumor activity in OCCC and was generally well tolerated. We are especially interested in the correlation between PIK3CA/ARID1A status and ENMD-2076 antitumor activity. The significant relationships between wild type PIK3CA and PFS and between negative ARID1A and PFS are worth further investigation and may become a criteria for choosing OCCC patients in new clinical trials.

Update on ENMD-2076 in Soft Tissue Sarcoma (STS)

On Nov. 5, 2015, CASI presented data from its Phase II study of ENMD-2076 (NCT01719744) in soft tissue sarcoma (STS) at the 2015 Connective Tissue Oncology Society (CTOS) annual meeting in Salt Lake City (poster presentation).

The Phase II trial is conducted at University of Toronto, Canada.

The primary endpoint is 6-month progression free survival. Secondary endpoints include:

- number of and severity of adverse events per participant
- number of participants with an objective response, including duration of response
- number of certain biomarkers in participants compared to progression free survival.

Data presented at the CTOS meeting are based on total of **23 evaluable patients**.
ENMD-2076 is generally safe and well tolerated in patients. High grade toxicities include hypertension (56%), ALT increase (35%) and diarrhea (17%).

ENMD-2076 has shown clinical activity in patients with advanced STS, with clinical benefits and side effects profile typical of this class of agent. 2 patients had partial response, and 8 patients had stable disease. Clinical benefit rate (PR+SD>6 months) was 17% (4/23). Median overall survival has not reached and median progress free survival was 2.1 months.

Clinical Efficacy

Total number of evaluable pts		23
Median number of cycles (range)		2 (1 – 10)
Best Response (n)	PR	2
	SD	8
	PD	11
	N/A	2
Clinical Benefit Rate	PR + SD > 6 mo	17%
Median OS		Not reached
Median PFS		2.1 mo (95%CI 1.7–4.3)

All 4 patients who derived clinical benefit (2 PR and 2 SD > 6months) received ENMD-2076 in the first-line setting.

Genetic variations in CCL11 and FLNB (FilaminB) are potentially associated with benefit from ENMD-2076 while gene variations in EGFR, and CYP4B1 polymorphism could be associated with lack of benefit.

The findings from the Phase II clinical trial confirms the rationale that ENMD-2076 may provide clinical benefit to a subset of STS patients, which may lead to the development of personalized target therapy. The identification of potential clinical correlative biomarkers provides valuable information for the next step in the continued development of ENMD-2076 in STS. The company is on track to initiate the **Phase II** trial for STS **in China**, which will be conducted under the same protocol and will allow the company to

investigate and further validate the drug's clinical activities and correlative biomarkers in an expanded patient population.

We believe the company will decide the next step in the development of ENMD-2706 after they gain more data from the China clinical trial.

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

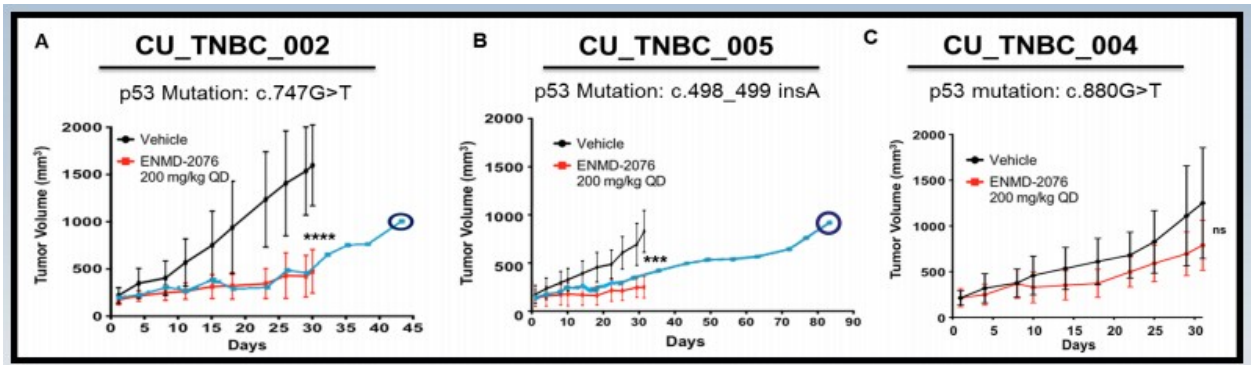
On November 8, 2015, CASI announced a poster presentation by investigators of the University of Colorado, on a study of ENMD-2076 in p53 mutated triple negative breast cancer (TNBC) **animal models** at the AACR-NCI-EORTC International Conference, November 5-9 in Boston, Massachusetts.

Three TNBC patient derived tumor xenografts (PDTX) models harboring different p53 mutations were used for ENMD-2076 treatment studies.

ENMD-2076 had robust anti-tumor activity against the CU_002 and CU_005 TNBC PDTX models. Tumor growth inhibition (TGI) compared to vehicle at day 30 for models CU_TNBC_002, CU_TNBC_005, and CU_TNBC_004 were 71.3%, 66.1% and 37.0%, respectively. The growth curves for individual tumors that developed acquired resistance to treatment are depicted in blue with the dark blue circle indicating the time of tumor collection. **** $p < 0.0001$, ***$p < 0.001$.

The CU_004 TNBC PDTX model was intrinsically resistant to ENMD-2076 treatment (TGI 37%, p value 0.07). In the two sensitive PDTX models, an increase in p53, p73, BAX and the apoptotic marker CC3 and a decrease in the anti-apoptotic protein BCL2 and Ki67 following treatment at Day 30 were observed.

Consistent with Aurora kinase A inhibition, a decrease in pAA and an increase in pHH3 expression in both sensitive and resistant PDTX models following treatment at Day 4 and Day 30 was detected. At the time of acquired resistance, defined by at least doubling of tumor volumes from the maximal response, the loss of p73, p53, and BAX expression and an increase in p16 staining and SA β-gal activity were observed. These findings were also observed in the intrinsically resistant CU_004 model.



The conclusion is that ENMD-2076 has pro-apoptotic anti-cancer activity in a subset of p53 mutated TNBC PDTX models. Sensitivity is associated with the induction of p73 which may mediate the response in the absence of functional p53. Intrinsic and acquired resistance to ENMD-2076 in TNBC PTDX models is associated with loss of p73 expression and an increase in markers associated with senescence including p16 expression and SA β-gal activity. These data support the role of senescence as a potential mechanism of resistance to Aurora kinase inhibitors in p53 mutated TNBC and support the continued development of combination therapies including with inhibitors of pathways

The TNBC **Phase II** trial in the U.S. has completed patient recruitment and study treatment. Efficacy activities were observed in a subset of patients while correlative biomarker analysis with clinical benefit is currently underway at the University of Colorado.

As part of the US Phase II trial and under the same protocol, the company has begun patient recruitment and treatment at multi-center sites in **China**, where the company is studying efficacy and safety as well as correlative biomarkers of ENMD-2076 in an expanded patient population.

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

Update on Evomela

In December 2016, China's Food and Drug Administration (CFDA) has accepted for review the Company's import drug registration application for Evomela® (melphalan) for Injection.

CASI licensed **Evomela** from its partner Spectrum Pharmaceuticals along with two other commercial-stage Spectrum drugs, Marqibo® and Zevalin®. Evomela received U.S. FDA approval in March 2016 for **multiple myeloma** patients as a high-dose conditioning treatment prior to autologous stem cell transplantation (ASCT) and as palliative treatment for patients who are not candidates for oral therapy.

Melphalan inhibits DNA replication and transcription causing cytotoxicity in dividing and non-dividing cells including multiple myeloma. Evomela is a new propylene glycol (PG)-free IV formulation of melphalan developed for a high-dose conditioning treatment prior to hematopoietic stem cell transplantation (HSCT) in patients suffering from multiple myeloma (MM) and for the palliative treatment of multiple myeloma patients for whom oral therapy is not appropriate. Evomela completely avoids the use of PG, which is used as a co-solvent in the current formulation of melphalan and has been reported to cause renal and cardiac side-effects that limit the ability to deliver higher quantities of intended therapeutic compounds. The use of captisol technology to reformulate melphalan is anticipated to allow for longer administration durations and slower infusion rates, potentially enabling clinicians to avoid reductions and safely achieve a higher dose intensity of pre-transplant chemotherapy.

We estimate Evomela will be approved in China in 2020.

IARC estimates that approximately 12,197 new MM patients will be diagnosed with a mortality of 9,038 cases in China in 2015. The five-year prevalence of MM in China is estimated at 14,100 cases. **Branded or generic melphalan is currently not available in China**. This gives CASI a great opportunity to promote and expand Evomela in China once it is approved by the CFDA.

Update on MARQIBO®

On Jan. 12, 2016, CASI announced that CFDA has accepted for review its import drug registration application for MARQIBO® (vinCRIStine sulfate LIPOSOME injection).

CASI's China rights to MARQIBO was licensed from its US partner **Spectrum Pharmaceuticals**, Inc. MARQIBO is the first and only liposome-encapsulated vincristine approved and currently marketed in the U.S. for second line treatment of adult Philadelphia chromosome-negative (Ph-) acute lymphoblastic leukemia (ALL). CASI's filing with the CFDA is an important milestone step to expand the availability of the treatment to patients in China.

Since Marqibo is already approved in the US, it falls into the imported drug registration process category, which takes a shorter timeframe for gaining marketing approval in China than clinical stage candidates.

According to IARC, annual incidence of leukemia is estimated at 70,240 cases with a mortality of 58,746 cases in China in 2015. The five-year prevalence of leukemia is estimated at 73,694 cases including approximately 10,000 Ph(-) adult ALL. The retail cost of Marqibo in the US is approximately $11,700 per dose, and treatment cycle is 28 days, 4 doses per cycle, multiple cycle regimen.

We assume 10% market penetration, the peak sales of Marqibo will be about **$40 million for one cycle** treatment in China. When treatment cycles increase and new indications are added, the sales will increase accordingly.

Update on Zevalin

On July 20, 2015, CASI officially launched ZEVALIN® in Hong Kong for patients with indicated non-Hodgkin's lymphoma (NHL). The drug will be supplied by CASI and its local partner, Global Medical Solutions Hong Kong Limited.

As a reminder, CASI acquired exclusive rights **for greater China** to **Zevalin** ® (ibritumomab tiuxetan) from **Spectrum Pharmaceuticals, Inc.** in September 2014. Zevalin IV injection is a CD20-directed radiotherapeutic antibody. It is approved in the US for the treatment of relapsed or refractory, low-grade or follicular B-cell non-Hodgkin's lymphoma **(FNHL).** Zevalin is also indicated for the treatment of patients with previously untreated follicular non-Hodgkin's Lymphoma who achieve a partial or complete response to first-line chemotherapy.

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Zevalin therapeutic regimen consists of two components: **rituximab**, and Yttrium-90 **(Y-90)** radiolabeled Zevalin for therapy. Zevalin builds on the combined effect of a targeted biologic monoclonal antibody augmented with the therapeutic effects of a beta-emitting radioisotope. Zevalin builds on the combined therapeutic effects of a targeted biologic monoclonal antibody augmented with a beta-emitting radioisotope.

We are pleased that CASI is launching Zevalin in Hong Kong on schedule.

Since Hong Kong is a relatively small market for oncology, we don't expect meaningful sales in Hong Kong. However, we think the launch of Zevalin in Hong Kong is strategically important to CASI in a few aspects. ***First*****,** since Hong Kong is close to mainland China, which has a much larger cancer patient population, launching Zevalin in Hong Kong will raise the drug's visibility in both Hong Kong and mainland China, which could help penetrate the China market when Zevalin gets final approval in China. ***Second***, CASI will also gain marketing experience from Zevalin launch in Hong Kong, which is important for the future products launch in China. ***Third****,* we believe it is the first step of the company's building up its commercialization capabilities, a record breaking in the company's history.

CASI is currently **registering Zevalin in China** and will file for marketing application in Taiwan later this year. Since Zevalin is already approved in the US, we believe that gaining approval from local regulatory authorities for commercialization in greater China will require a shorter timeframe compared to clinical-stage drugs. It usually takes about 3 to 4 years to get approval of an imported drug in China. We expect Zevalin to be approved by CFDA in 2019.

According to International Agency for Research on Cancer (IARC), annual incidence of NHL is estimated at 46,563 cases with a mortality of 29,201cases in China in 2015. The five-year prevalence is estimated at 69,200 cases, including 13% of cases in FNHL and 30% of cases in DLBCL.

The retail price of Zevalin per dose in the US is approximately $50,000 and the treatment cycle is one dose. The price tag in China for imported drugs is similar to its overseas price, but usually will be 100% out of pocket cost to patients. We assume 10% penetration of the NHL market by Zevalin, which means peak sales will be approximately **$150 million or more** in China.

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 $1.40 per share which values the company at $82.0 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

	2015 (Dec)					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	FYA	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	$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	$0.00
Product revenue	$0.02	$0.02	$0.00	($0.00)	$0.05	$0.00	$0.00	$0.00	$0.00	$0.00	$0.50	$1.50	$10.00	$25.00	$65.00
Total Revenues	**$0.02**	**$0.02**	**$0.00**	**$0.00**	**$0.05**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.50**	**$1.50**	**$10.00**	**$25.00**	**$65.00**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
CoGS	0.01	0.00	0.00	0.00	0.01	0.00	0.00	0.00	0.00	0.00	0.13	0.38	2.00	5.00	13.00
Gross Income	**$0.02**	**$0.02**	**$0.00**	**$0.00**	**$0.04**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.38**	**$1.13**	**$8.00**	**$20.00**	**$52.00**
Gross Margin	73.6%	88.6%	-	-	75.0%	-	-	-	-	-	75.0%	75.0%	80.0%	80.0%	80.0%
R&D	$0.87	$1.22	$0.94	$1.04	$4.08	$1.02	$1.36	$1.01	$1.25	$4.65	$5.00	$6.00	$7.50	$9.00	$10.50
% R&D	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
SG&A	$0.92	$0.86	$0.67	$0.66	$3.12	$0.77	$1.91	$0.68	$1.42	$4.78	$5.50	$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	$0.00
Operating Income	**($1.8)**	**($2.1)**	**($1.6)**	**($1.7)**	**($7.2)**	**($1.8)**	**($3.3)**	**($1.7)**	**($2.7)**	**($9.4)**	**($10.1)**	**($12.4)**	**($9.0)**	**$0.5**	**$29.0**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-	44.62%
Other Net	($0.0)	$0.0	$0.0	($0.1)	($0.1)	($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)**	**($2.0)**	**($1.6)**	**($1.8)**	**($7.2)**	**($1.8)**	**($3.3)**	**($1.7)**	**($2.7)**	**($9.4)**	**($10.1)**	**($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	$0.0
Tax Rate	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Reported Net Income	**($1.8)**	**($2.0)**	**($1.6)**	**($1.8)**	**($7.2)**	**($1.8)**	**($3.3)**	**($1.7)**	**($2.7)**	**($9.4)**	**($10.1)**	**($12.4)**	**($9.1)**	**$0.4**	**$28.9**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Net Margin	-	-	-	-	-	-	-	-	-	-					
Diluted Shares Out	32.4	32.4	32.4	32.4	32.4	40.2	42.9	49.2	58.8	55.9	62.0	65.0	68.0	70.0	75.0
Reported EPS	**($0.06)**	**($0.06)**	**($0.05)**	**($0.05)**	**($0.22)**	**($0.04)**	**($0.08)**	**($0.03)**	**($0.05)**	**($0.17)**	**($0.16)**	**($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*	*$0.00*
Non GAAP Net Income	**($1.8)**	**($2.0)**	**($1.6)**	**($1.8)**	**($7.2)**	**($1.8)**	**($3.3)**	**($1.7)**	**($2.7)**	**($9.4)**	**($10.1)**	**($12.4)**	**($9.1)**	**$0.4**	**$28.9**
Non GAAP EPS	**($0.06)**	**($0.06)**	**($0.05)**	**($0.05)**	**($0.22)**	**($0.04)**	**($0.08)**	**($0.03)**	**($0.05)**	**($0.17)**	**($0.16)**	**($0.19)**	**($0.13)**	**$0.01**	**$0.39**

Source: Company filings and Zacks estimates

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