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Zacks Small-Cap Research

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CASI Pharmaceuticals, Inc. (CASI-NASDAQ)

CASI: Initiating coverage – Leveraging pharmaceutical opportunities in China and beyond

Our initial 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 (05/10/19)	$3.36
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	**$2.77**
One-Year Return (%)	**-58.47**
Beta	**1.19**
Average Daily Volume (sh)	**160,529**
Shares Outstanding (mil)	**96**
Market Capitalization ($mil)	**$322**
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	**-8.6**
P/E using 2020 Estimate	**-36.0**
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
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	0.0 A	0.0 A	0.0 A	0.0 A	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					-$0.24 E
2020					-$0.14 E
2021					$0.18 E

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

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 $165 million. We expect CASI to move to GAAP profitability by 2021 and increase steadily from there. Our model shows $16.5 million in net profit ($0.18 per share) in 2021, growing to $41.8 million ($0.45 per share) by 2023.

CASI is well funded with c. $85 million in cash and marketable securities on its balance sheet and only $1.5 million in debt.

VALUATION: Our initial 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.

COMPANY DESCRIPTION

CASI Pharmaceuticals was founded in 1991 as Entremed, a pre-revenue player in the oncology market. The company changed its name to CASI Pharmaceuticals, Inc. in June 2014 as part of the restructuring that started in 2012 with the investment by IDG-Accel and later Kleiner Perkins Caufield China.

In the past few years the Company has purchased the rights to sell three US-approved oncology drugs in China and other parts of Asia from Spectrum Pharmaceuticals (SPPI- NASDAQ- $9.44), acquired a portfolio of 29 ANDA drugs from Sandoz (NVS-NYSE-$81.88), and an HBV ANDA from Laurus Labs, Ltd. CASI's proprietary portfolio includes its lead drug ENMD-2076, a small-molecule multi-kinase inhibitor currently in PhII studies, and two pre-clinical candidates in immuno-oncology. In mid-April, CAS purchased global rights to an investigational anti-CD38 monoclonal antibody drug, TAK011010.

In December 2018, CASI received NMPA (the Chinese regulatory authority formerly known as CFDA) approval to market Evomela, for bone marrow transplants in multiple myeloma. CASI will import Evomela from Spectrum and expects to launch in 2019. With $85M cash on its balance sheet, CASI is rapidly building out its commercial infrastructure in China, while seeking additional products for its pipeline.

On March 13, 2019, CASI signed an exclusive distribution agreement with China Resources Guokang Pharmaceuticals Co., Ltd. to distribute Evomela in China. With product on hand, we believe sales could commence as soon as 2Q19.

Exhibit 1: CASI product portfolio (selected)

Product	Indication	Comment
Licensed		
Evomela	Multiple myeloma	Approved - launching 2019
Marqibo	Acute lymphoblastic leukemia	Under NMPA review, bridging trial required
Zevalin	Non-Hodgkin's lymphoma	Under NMPA review, bridging trial required
ANDA Portfolio (selection)		
Entecavir tablet	Hepatitis B (cHBV)	2016 generic sales in China $1.5 billion (est)*
Bisoprolol fumarate tablet	Hypertension	2016 generic sales in China $205 million (est)*
Desvenlafaxine SR tablet	Depression	2016 generic sales in China $170 million (est)*
Aripoprazole tablet	Schizophrenia	2016 generic sales in China $108 million (est)*
Cilostazol tablet	Peripheral vascular disease	2016 generic sales in China $65 million (est)*
Tenofovir disoproxil fumarate (TDF)	Hepatitis B (cHBV)	
Ondansetron	CINV	
Repaglinide	Type 2 diabetes	
Proprietary		
ENMD-2076	Follicular carcinoma, triple negative breast cancer (TNC)	Phase II
CASI-001 and -002	Immuno-oncology	Preclinical
TSK011010	Immuno-oncology	IND/IMPD, Phase I expected to start 2019/2020

Source: Company filings

Setting the standard for innovation, quality, speed and cost-effectiveness in China

CASI seeks to lead commercialization for pharmaceuticals in China. Sees itself as understanding China better than larger global drug companies and using its know-how and resources to deliver quality product at a low-cost to consumers. Management plans to achieve this by acquiring a broad portfolio of products, moving them through the regulatory process and manufacturing locally. Longer-term, the Company will seek FDA approval to sell generics into the US market where it believes it leverage low-cost Chinese production costs.

The process starts with growing a pipeline of products addressing high-needs in China such as hepatitis B, cancer and heart disease. CASI's portfolio includes three in-licensed cancer drugs and 30 ANDA generics as well as several proprietary drugs still under development.

In-licensed products: In 2014, CASI purchased the rights to three oncology drugs from Spectrum Pharmaceuticals for 5.4m shares of stock (c.18% of shares outstanding) and a $1.5m promissory note. CASI received marketing approval for Evomela from the NMPA in late 2018; the other two are undergoing bridging trials for local approval.

- ***Evomela:*** 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. Moreover, melphalan is not approved in China and will help expand the rate of stem-cell transplants in China for patients with MM. 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. Spectrum Pharmaceuticals sold $48 million of Evomela in 2018.

- ***Marqibo:*** Marqibo is a liposomal form of vincristine used to treat blood and solid tumors. The dug is approved in the US as third line treatment for Philadelphia chromosome negative (Ph-) acute lymphoblastic leukemia (ALL). We estimate c. 3,000 eligible patients per year in China for Marqibo out of a reported incidence of 80-100,000 annual cases of relapsed/refractory Ph- ALL. Spectrum sold $7.0 million of Marqibo in 2018.

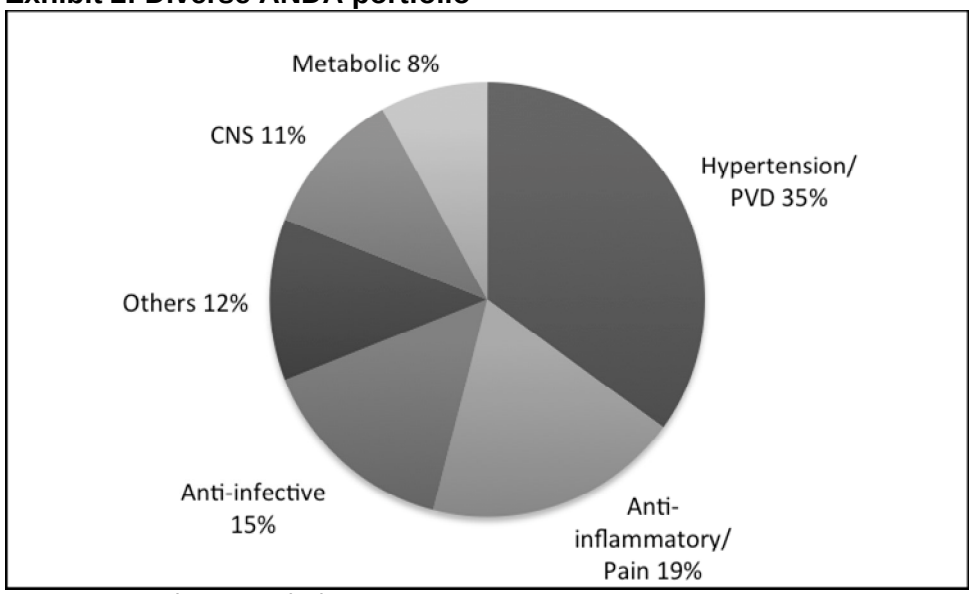
- ***Zevalin:*** Zevalin is an yttrium-90 radio labeled CD20 targeting antibody used in combination therapy with rituximab primarily in second-line and higher follicular non-Hodgkin lymphoma (NHL). The drug has been on the US market since 2002 with 2018 sales of $12.3 million. The annual incidence of NHL in China is 4.2 per 100,000, of which 3% is follicular NHL.

ANDA portfolio:

In January 2018, CASI acquired a portfolio of 29 approved and pending ANDAs from Sandoz for $18 million. The value of these products is very minor relative to Sandoz's size (particularly as a part of Novartis) so we view the sale as simple portfolio realignment for Sandoz. In October 2018, CASI added purchased an additional ANDA for hepatitis B from Laurus Labs Ltd. for $0.7 million in upfront cash plus an additional $2.3 million in milestones. With ANDA approval and products that address areas of high therapeutic need, we expect CASI to be able to quickly commercialize these assets beginning in 2019. In a February 2019 presentation, CASI management estimates generic sales for its top five ANDA products (Entecavir, Bisoprolol fumarate, Desvenlafaxine SR, Aripiprazole and Cilostazol) totaled $2.0 billion in 2016.

Liver disease is a significant issue in China with a reported incidence of 84.3 per 100,000 in China between 2005 and 2010. Childhood vaccination programs appear to be highly successful, however, there are still some 28 million people living with chronic hepatitis B, of which 7 million have advanced disease. A 2018 article in the Lancet notes that affordability is a key barrier to treatment, with only one of six approved treatments, lamivudine, on China's National Drug List A (NRDL A), which provides 100% reimbursement. Entecavir is on China's National Drug List B (NRDL B), making it eligible for 10-90% reimbursement (c. $800), depending on the patient's insurance and local province; however, we believe that as reforms in China continue, Entecavir and other Hepatitis B drugs may be added to the NRDL A.

Exhibit 2: Diverse ANDA portfolio



Source: CASI Pharmaceuticals, Inc.

Initially, CASI will work with a contract manufacturer to produce its ANDA products; however, in several years, the Company expects to be manufacture product in a new certified GMP facility jointly owned with Wuxi Jintou Huicun Investment Enterprise, LP. The new facility will enable CASI to lower its manufacturing costs while maintaining strict quality controls.

ENMD-2076: is CASI's only on-going clinical development program for a proprietary drug; however, results to date have been disappointing. The Company recently discontinued phase II studies in the US and China for ENMD-2076 as a single agent after the drug failed to show sufficient activity. The Company may pursue approval for the drug as a combination therapy going forward.

TSK011010: In April 2019, CASI in-licensed exclusive worldwide rights from Black Belt Therapeutics Limited for TSK011010, an investigational anti-CD-38 monoclonal antibody, for €5 million (c. US$5.6 million) upfront and a €2 million equity investment (c. US$2.2 million) in a newly-established company associated with Black Belt Therapeutics focusing on immuno-oncology targets. GLP IND-enabling studies are complete and IND/IMPD submissions are planned for 2019.

Exhibit 3: ANDA portfolio

Indication class	Product
Hypertension/PVD	
	Benazepril tablets
	Bisoprolol fumarate tablets
	Lisonopril tablets and BPP tablets
	Spironolactone tablets
	Triamterene/hydrochlorothiazide combination tablets
	Midodrine tablets
	Cliostazol tablets 50mg, 100mg tablets
	Telmisartan/hydrochlorohiazide*
Anti-inflammatory/pain	
	Diclofenac potassium 50mg tablet
	Didofenac sodium DR 25mg, 50mg, 75mg tablet
	Nabumeone tablets
	Tizanidine tablets
	Buprenorphine HCL sublingual tablets
	Bromfenac ophthalmic solution*
Anti-infective/antiviral	
	Entecavir tablet
	Tenofovir disoproxil fumarate (TDF)
	Cefprozil tablet
	Epinastine HCL ophthalmic solution
	Ribavirin tablets
	Epinastine HCL ophthalmic solution
CNS	
	Desvenlafaxine ER tablet
	Naratriptan tablets
	Aripiprazole*
Metabolic	
	Methimazole tablets
	Repaglinide tablets
Others	
	Ondasetron HCL tablets
	Heparin sodium for injection
	Bepotastine ophthalmic solution*

*Source: Company filings, * ANDA pending*

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, management has outlined opportunities and steps it believes will help navigate uncertainty. To us, CASI's main risk is 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.

Regulatory environment: 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. CASI's first product, Evomela, seems to have moved smoothly through the regulatory system as anticipated. It is important to note that change and implementation happen slowly in China. Therefore, while Evomela received marketing authorization relatively quickly, it is probably premature to bank on a smooth path to approvals for each application. This could affect our revenue expectations particularly in the 2019-2021 timeframe as the Company ramps up its product applications.

- ***New drug approvals:*** In 2017, the NMPA reduced some of the approval and marketing authorization hurdles for new drugs. These changes include acceptance of clinical data obtained in foreign clinical trials as well as streamlined approval paperwork for drugs that will be tested in China.

- ***Generic drugs:*** In 2013, China launched an initiative (GQCE) to ensure that domestically manufactured generic drugs meet quality (bio-equivalency) standards. In 2016, China took an additional step that imposes these requirements on imported generics as well. The GQCE will also reduce generic competition by limiting the number of manufacturers on the approved reimbursement list for public hospitals (which covers 90% of the pharmaceutical market) to the first three manufacturers to receive GQCE approval.

Reimbursement and commercial success: Chinese citizens are covered by one of three government-run insurance plans. Coverage (such as reimbursement) varies by plan, geographic location and type of service. Coverage most closely resembles indemnity insurance plans in the US, where patients pay upfront for services and are then reimbursed by the health plan. There are private plans that supplement government insurance, but they are relatively nascent.

Drugs must be on one of three lists in China to be approved for reimbursement: the EDL (essential drug list), NRDL A (National Reimbursement Drug List A) and the NRDL B. The EDL covers many traditional Chinese medications as well as some basic generic drugs. The NRDL covers more western-style medicines, with higher-cost drugs eligible for partial reimbursement on the B list, while lower-cost drugs on the NRDL A receive full reimbursement. Drugs are added to the NRDL periodically (it was last updated in 2017) and an update is expected, but not assured for 2019. Provinces have some discretion to add drugs to their local NRDL. Drugs not on one of the three lists can be marketed in China, but access will be limited to wealthy citizens who can pay out of pocket.

Getting on the NRDL is a negotiation and price is often the key point. It is not unusual to see price cuts of 50% or more as part of an NRDL agreement; the upside is a significant increase in potential sales. However, the government also considers physician endorsement/adoption, cost efficacy and overall budget impact. We account for this by including pricing discounts of 40-60% for CASI's licensed products starting roughly three-to-four years after initial regulatory approval.

Once a drug is on the NRDL, it becomes a preferred drug for public hospitals. As noted above, generic drug manufacturers must be one of the first three to receive GQCE approval in order to be included on the NRDL for public hospitals to be allowed to purchase from a particular manufacturer.

Hospitals are responsible for determining their individual formularies, creating an additional marketing step for manufacturers. Unfortunately, hospitals are not required to update their formularies with any particular frequency, so the sales cycle from NRDL listing to purchase is often more than a year. We see this as the least predictable part of our revenue expectations.

Portfolio additions: Our valuation leans heavily on CASI's ability to expand its product portfolio, particularly for generics. The Company is focused on conditions such as oncology and hepatitis that the government is targeting for improved public health. In our view, the current ANDA portfolio has built a pipeline for higher sales over the next several years as well as an important calling card for drug makers seeking partnerships in China.

VALUATION

We are initiating on CASI Pharmaceutical with a valuation of $8.17 per basic share, based on a sum-of-the-parts NPV for each of its products less corporate overhead.

Exhibit 4: Valuation

Valuation by NPV sum-of-the-parts						
Product	**Indication**	**Launch**	**NPV ($mil)**	**Probability**	**rNPV ($mil)**	**NPV/Share ($)**
Evomela	Conditioning in MM	2019	37	***100%***	37	0.39
Marqibo	Ph- ALL	2020	26	***90%***	24	0.25
Zevalin	R/R NHL	2020	29	***90%***	29	0.31
ANDA Portfolio	Multiple	2019	904	***90%***	748	8.00
Corporate overhead			(158.2)	***100%***	(158.2)	(1.69)
Net Cash			85	***100%***	85	0.91
Valuation			**922**		**763**	**8.17**

Source: Company filings, Zacks Investment Research estimates.

Our model includes assumptions for all three licensed products, the ANDA portfolio and CASI's proprietary cancer drug candidate, ENMD-2076. We use a 12.5% discount rate across all of our assumptions, with probability risk adjustments ranging from 15%-100% depending on the product.

For Evomela (which has local approval and a distribution agreement), we assume a 2019 launch at a price of $6,400 per treatment. 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.

We model for Marqibo peak sales of $11-12 million, a 6% market share on an average treatment price of $108,000. Our price drops to c. $49,000 by 2045, reflecting potential competition. We've used a 90% probability adjustment for Marqibo to reflect the need for further clinical tests to get local approval. Zevalin is modeled with a 90% probability rate and peak sales of $18 million for 8% market share, based on a launch price of $12,000 per treatment, dropping to c. $7,500 by 2045. As with Marqibo, our 90% probability rate reflects the need for further clinical tests to get local approval.

The ANDA portfolio comprises the vast majority of our NPV valuation. We expect the Company to continue to make deals in this space and have modeled for $500 million in annual sales by 2045. The generics market in China is highly competitive, but quality of locally manufactured products is often a concern. CASI is investing heavily to become the high-quality local provider of generic products in high-value niches, which we believe will allow the Company to outperform local competition. Our model is based on 45% operating margins (20% COGS, 30% marketing and 5% R&D spend). Our model includes upfront cash of $0.7 million and milestone payments of $2.3 million for the hepatitis B treatment, tenofovir disoproxil fumarate (TDF) licensed from Laurus Labs in late 2018.

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. Progress on new product acquisitions and approvals along with quarterly updates are likely to be the primary catalysts for the share price.

Profit and loss

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 to $18.0 million, to support a $5 million increase in non-cash compensation primarily associated with stock option awards for the Chairman, increases in salaries, benefits and recruitment expense of $2.6 million and $1.8 million in professional services, investor and public relations expense. Increased G&A also includes business development and closing expenses of $4.0 million.

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; however, the Company has committed to purchase over $12 million of Evomela, suggesting that our revenue estimate may be conservative.

COGS are forecast to come in around 54%, including Evomela upstream royalties of 20%. We expect R&D expense to total $2.6 million, primarily for bridging trials to support Marqibo and Zevalin approval, as well as modest amounts allocated to the ANDA portfolio and ENMD-2076.

CASI has invested in its sales and marketing infrastructure over the past year, and we expect investment will continue to establish market awareness both for its licensed products in 2019. We've modeled for SG&A of $23.4 million in 2019, of which $5 million is product-related marketing and sales expense; however, with its strong cash position, it is possible that the Company will invest more heavily in this area. Overall, we look for a loss of $22.8 million in 2019, a c. $5 million improvement from 2018's loss.

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 $165 million.

We model gross margins in the mid-to-high 70s beginning in 2020; however, costs could be much lower as a percentage of sales as the Company moves to its own manufacturing facility. We expect the Company to invest c. 20-30% of revenues towards sales and marketing for both its licensed and ANDA drugs. Over the long-term we look for corporate overhead at 10% of sales.

We expect CASI to move to GAAP profitability by 2021 and increase steadily from there. Our model shows $16.5 million in net profit ($0.18 per share) in 2021, growing to $41.8 million ($0.45 per share) by 2023.

Cash flow

CASI is not currently cash flow positive, consistent with its pre-revenue status and its stepped up investment towards commercialization in 2019. In 2018, CASI posted had cash flow from operations of ($28.6) million, compared with ($6.4) million in 2017. Investing cash flows totaled $21.8 million, reflecting the ANDA product acquisitions from Sandoz and Laurus. These uses of cash were offset financing cash flows of $93.3 million.

In March, CASI made its first payment of $21 million cash to Casi-Wuxi, its manufacturing joint venture with Wuxi et al LLP. CASI also transferred $30 million of selected ANDAs to the JV and will contribute another $29 million cash to the partnership in about three years. CASI will also make an upfront payment of €5 million ($5.6 million) and an equity investment of €2 million (c. US$2.2 million) to Black Belt Therapeutics to license TSK011010.Our capex forecasts for 2019 and 2022 reflect these investments.

Our model has sales sensitive working investment of $5.7 million for 2019. Over the longer-term we expect working investment to settle out around 20% of sales. On this basis, we expect the Company to be operationally cash flow positive sometime during 2021.

Balance Sheet

At December 31, 2018, CASI had $85 million in cash and equivalents on its balance sheet – up sharply as a result of two financings in 2018 – one for $50 million and the other for $37 million. Approximately $15 million of the balance is held by its Chinese subsidiary.

Separately, CASI paid $4.8 million as a deposit towards its $9.2 million purchase commitment for Evomela in 2019. In March, Company signed an additional commitment to purchase Evomela of $3.9 million.

Management indicates it has enough cash on hand at least through March 2020; however, we think that another financing is possible before then, particularly if an attractive asset becomes available. CASI has a strong core group of investors, which we believe would limit any significant price pressure from an additional financing. The Company has a c. $1.5 million promissory note on its balance sheet, at a 0.5% interest rate. The note is due September 19, 2019; however its due date has been extended in the past.

Exhibit 5: 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)	(2,600)	(2,600)	(4,217)	1,701	2,476
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)	(22,675)	(13,201)	16,669	39,413	60,037
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)	(22,750)	(13,276)	16,594	39,338	59,962
Taxes	0	0	0	0	0	0	0	(2,998)
Net income	(9,453)	(10,770)	(27,472)	(22,750)	(13,276)	16,594	39,338	56,964
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)**	**($0.24)**	**($0.14)**	**$0.18**	**$0.42**	**$0.61**
Diluted EPS	**($0.17)**	**($0.18)**	**($0.32)**	**($0.24)**	**($0.14)**	**$0.18**	**$0.42**	**$0.61**
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	45%	12%	6%	-1%	-2%
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	2,909	2,909	2,909	2,909	2,909
Stock based compensation	2,995	650	6,118	5,698	5,441	4,115	3,782	(5,057)
EBITDA	(6,359)	(9,983)	(20,708)	(13,678)	(4,460)	24,085	49,495	61,280

BALANCE SHEET							
Fiscal year	2017A	2018A	2019E	2020E	2021E	2022E	2023E
Cash & equivalents	43,490	85,117	52,594	47,656	70,530	91,575	161,038
Total current assets	**43,812**	**92,565**	**54,710**	**51,150**	**79,474**	**105,854**	**179,948**
Property plant and equipment	1,047	1,751	20,451	18,151	15,851	39,551	34,251
Intangibles	0	18,785	23,466	20,557	17,648	14,739	11,831
Total Assets	**45,101**	**113,410**	**98,693**	**89,925**	**113,040**	**160,211**	**226,097**
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)**	**(3,176)**	**(3,938)**	**23,874**	**51,044**	**70,463**
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**	**(32,776)**	**(4,938)**	**22,874**	**21,044**	**69,463**

Source: Company filings, Zacks Investment Research estimates

KEY LEADERSHIP

Wei-Wu He, Ph.D. Dr. He was appointed Chief Executive Officer of CASI Pharmaceuticals in April 2019. He continues as Chairman of the Company, a role he has held since February 2012. Dr. He is currently the CEO and Chairman of OriGene Technologies, Inc. He also is the founder and General Partner of Emerging Technology Partners, LLC (ETP), a life sciences focused venture fund established since 2000. Dr. He has been involved in founding or funding over 20 biotech companies throughout his career, some of which went on to be acquired by significantly larger firms. In the earlier part of his career, Dr. He was one of the first few scientists at Human Genome Sciences, and prior to that, was a research fellow at Massachusetts General Hospital and Mayo Clinic. Dr. He is an author to more than 25 research publications and inventor of over 30 issued patents.

Ken K. Ren, Ph.D. Dr. Ren joined CASI Pharmaceuticals in April 2012, was appointed Chief Executive Officer in April 2013, and was elected to the Board of Directors in December 2014. He stepped down as CEO in April 2019, but will continue as a board member. Over the past 15 years, prior to CASI, Dr. Ren has been a founder and/or key executive in several start-up companies with business operations in both the U.S. and China. He was President of Accelovance (China), a clinical contract research organization, a co-founder and CEO of ImmunoVentis, a cell-based immunotherapy company, Novemed, a drug development company, and of China Innovation Center for Life Science (U.S.A.) Corp., a consulting company. Dr. Ren was also a Chief Investment Director of CCBI Healthcare Fund of China Construction Bank, responsible for private equity investment in China's healthcare industry. Dr. Ren was a research scientist at Pfizer from 1993–1995 and an Immunology Research Fellow at Rockefeller University from 1990–1993. He received his medical degree at the Shandong University School of Medicine in China in 1986 and a Ph.D. in immunology from the State University of New York at Buffalo in 1990 and a Certificate of Completion of Executive Business Management Program in Tsinghua University, Beijing China.

Larry Zhang Mr. Zhang joined CASI Pharmaceuticals in September 2018 as President of CASI (Beijing) Pharmaceuticals Co., Ltd., which is a subsidiary of CASI Pharmaceuticals, and has more than 20 years management experience in the healthcare and biopharmaceutical industries in the U.S., Asia Pacific, and China. Prior to joining CASI's Beijing office, Mr. Zhang was Vice President, Head of Public Affairs and Corporate Responsibly at Novartis Group (China) focusing on the public affairs/public relations strategy including initiating Novartis' China policy focusing on China FDA (CFDA) new drug approval reform, IP protection, generic quality consistency evaluation and new regulations on biosimilars. From 2011-2016, he was Chief Executive Officer of Sandoz Pharmaceutical (China), a Novartis Company. Dr. Zhang has also held executive leadership roles with Bayer Healthcare and Baxter International Corporation in the U.S. and Asia Pacific. He holds a bachelor and master degree in nuclear physics from University of Science & Technology of China, an MBA in marketing/finance from the University of California at Los Angeles (UCLA), and received Ph.D. training in political science from University of Utah.

George Chi, CPA, CFA joined CASI Pharmaceuticals in October 2018 as Chief Financial Officer. Prior to joining CASI, Mr. Chi was Vice President of Finance at Flavors Holdings where he led the global accounting function, including financial reporting, planning, treasury, investor relations, tax and auditing with global sales in 90 countries. Prior to Flavor Holdings, from 2014-2016, he was Chief Financial Officer at BPL Plasma delivering 60% sales growth and 300% EBITDA growth for a $180 million business. He consolidated business and finance operations to prepare for an IPO where the business was sold four times of the investment in three years. From 2008-2013, he was finance director at Unilever where he was responsible for leading the accounting function including financial reporting, annual budgeting and strategic planning for a $10 billion business across 12 categories. He also successfully managed a $12 billion debt portfolio and coordinate with investment banks for annual debt issuance and repayment. Mr. Chi holds a bachelor's degree in engineering from Tsinghua University, Beijing, China and a M.B.A. in finance and operations from the Yale School of Management. He also holds certifications as a CPA, CFA from Stanford University Risk Management.

Cynthia W. Hu, JD. Ms. Hu joined CASI Pharmaceuticals in June 2006 as Vice President, General Counsel & Secretary, and in December 2008 was appointed Chief Operating Officer. Prior to joining CASI Pharmaceuticals, from January 2000 to May 2006, Ms. Hu served as senior attorney for the corporate and finance practice group at Powell Goldstein LLP in Washington, DC, where she advised clients on all corporate and financing matters, including complex public and private financings, mergers and acquisitions, SEC and regulatory compliance, and corporate governance and compliance. Before that, Ms. Hu served as corporate and securities counsel for a NYSE-listed financial institution and prior to that was in private practice with increasing levels of responsibilities, including at Klehr, Harrison, Harvey & Branzburg, LLP and Littman & Krooks, LLP focusing on corporate transactions and compliance with corporate and securities laws.

Alexander A. Zukiwski, M.D. joined CASI Pharmaceuticals in April 2017 as Chief Medical Officer. Prior to joining CASI Pharmaceuticals Dr. Zukiwski was Chief Executive Officer and Chief Medical Officer of Arno Therapeutics and has been a Director of Arno Therapeutics since 2014. At Arno his responsibilities included leading the clinical development and regulatory affairs teams to support the company's pipeline. Prior to Arno in 2007, Dr. Zukiwski served as Chief Medical Officer and Executive Vice President of Clinical Research at MedImmune. Prior to MedImmune, Dr. Zukiwski held several roles of increasing responsibility at Johnson & Johnson's (J&J,) medical affairs and clinical development functions at Johnson & Johnson Pharmaceutical Research & Development LLC (J&JPRD); Centocor R&D and Ortho Biotech. Before joining J&J, he served in clinical oncology positions at pharmaceutical companies such as Hoffmann-LaRoche, Glaxo Wellcome and Rhone- Poulenc Rorer. Dr. Zukiwski has more than 21 years of experience in global drug development and supported the clinical evaluation and registration of many successful oncology therapeutic agents. He previously served as a Member of Medical Advisory Board at Gem Pharmaceuticals, LLC and served as a Director of Ambit Biosciences Corporation. Dr. Zukiwski holds a bachelor's degree in pharmacy from the University of Alberta and a Doctor of Medicine degree from the University of Calgary. He conducted his post-graduate training at St. Thomas Hospital Medical Center in Akron, Ohio and the University of Texas MD Anderson Cancer Center.

James E. Goldschmidt, Ph.D. joined CASI Pharmaceuticals in April 2016 as Senior Vice President of Business Development. Dr. Goldschmidt brings more than 25 years of commercial and business development experience in the biotechnology and pharmaceutical sectors. Before joining CASI, Dr. Goldschmidt held senior positions at several public and private biopharmaceutical companies, most recently as Chief Operating Officer at Macrophage Therapeutics. Prior, he was Vice President of Business Development at ImmuneXcite, an immuno-oncology biotech based in Lexington, MA. From 2007 to 2013, Dr. Goldschmidt was Vice President of Business and Commercial Development at TetraLogic Pharmaceuticals, where he led business development and supported the company's Initial Public Offering (IPO). Earlier in his career, Dr. Goldschmidt held several roles of increasing responsibility at Johnson & Johnson, Wyeth Pharmaceuticals, and SmithKline Beecham. Dr. Goldschmidt has had direct leadership responsibility for the development, pre-launch, launch and brand marketing of numerous oncology and specialty products over the course of his career. Dr. Goldschmidt is a graduate of Villanova University and went on to receive a master's degree from Drexel University and a Ph.D. from Temple University School of Medicine.

James Huang has been a Director of the Company since April 2013. Mr. Huang joined Kleiner Perkins Caufield & Byers China as a managing partner in 2011 and focuses on the firm's life sciences practice. His main investment interests are innovation around China's growing healthcare markets and helping entrepreneurs build companies. James has made more than 15 investments in China since 2007. Before coming to KPCB China, James was a managing partner at Vivo Ventures, a venture capital firm specializing in life sciences investments. While at Vivo, James led numerous investments in China. Before joining Vivo in 2007, James was president of Anesiva, a biopharmaceutical company focused on pain-management treatments. During his 20-year career in the pharmaceutical and biotech industry, he also held senior roles in business development, sales, marketing and R&D with Tularik Inc. (acquired by Amgen), GlaxoSmithKline LLC, Bristol-Meyers Squibb and ALZA Corp. (acquired by Johnson & Johnson). Meanwhile, James Huang is also founding partner of Panacea Venture, a global venture fund focusing on investments in innovative and transformative early and growth stage healthcare and life science companies. James is Chairman of Board at Kindstar Global, and Windtree Therapeutics (WINT),

JHL Biotech and XW Laboratory and Director at ChiralQuest, Zenesis and CASI. James received an M.B.A. from the Stanford Graduate School of Business and a B.S. degree in chemical engineering from the University of California, Berkeley.

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