



NASDAQ: CASI

June 2018

Forward-Looking Statements

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act with respect to the outlook for expectations for future financial or business performance, strategies, expectations and goals. Forward-looking statements are subject to numerous assumptions, risks and uncertainties, which change over time. Forward-looking statements speak only as of the date they are made, and no duty to update forward-looking statements is assumed. Actual results could differ materially from those currently anticipated due to a number of factors. Such factors, among others, could have a material adverse effect upon our business, results of operations and financial condition. Additional information about the factors and risks that could affect our business, financial condition and results of operations, are contained in our filings with the U.S. Securities and Exchange Commission, which are available at www.sec.gov.

CASI Pharmaceuticals

CASI (NASDAQ: CASI) is a U.S. biopharmaceutical company focused on the acquisition, development, and commercialization of high quality, innovative therapeutics addressing cancer and other unmet medical needs, with a focus on China and the U.S.

Corporate Headquarters in Maryland, U.S.A. with a wholly owned subsidiary and local R&D Center in Beijing, China



Beijing R&D Center

- Discovery Research
- Regulatory Affairs
- Clinical Development
- Business Development
- Finance
- Commercial

Corporate Headquarters

- Corporate Administration
- Clinical Development
- Regulatory Affairs
- Business Development
- Finance / Investor Relations
- Legal

Company Overview

- **Management:** Experienced team with accomplished track record in North America and China
- **Diversified product portfolio:**
 - ***In-licensed from Spectrum Pharmaceuticals*** EVOMELA® (CE-Melphalan), MARQIBO® (vinCRISTine sulfate LIPOSOME), ZEVALIN® (ibritumomab tiuxetan)
 - ***Acquired from Sandoz Inc.*** 25 US FDA-approved ANDAs, including Entecavir, Ondansetron, Methimazole, and Repaglinide
 - ***Internally developed*** ENMD-2076 - Phase 2 small molecule multi-kinase inhibitor targeting triple-negative breast cancer: enrollment complete; biomarker/genomic analysis ongoing
- **Compelling business model:** Capitalizing on critical U.S./China synergies & competitive advantages for efficient/cost-effective drug development and commercialization
 - Beijing-based operations dedicated to all aspects of IND/CTA submissions, clinical trials, patient safety and project management to navigate successful regulatory filings with CFDA
- **Well-capitalized:** Strong financial position, backed by successful investment funds; efficient financial management with low burn rate

Bi-Cultural Board, Management Team & Advisors

BOARD OF DIRECTORS

Dr. Wei-Wu He, Executive Chairman	IDG-ACCEL China Fund Venture Partner; Managing Director, ETP Global Fund, L.P.; Chairman & CEO, OriGene Technologies, Inc.
Dr. Quan Zhou	Founder, Managing Director and General Partner at IDG Capital Partners
James Huang	General Partner, Kleiner Perkins Caufield & Byers China
Dr. Rajesh C. Shrotriya	Ex-Chairman & CEO, Spectrum Pharmaceuticals, Inc.
Dr. Y. Alexander Wu	CEO, Crown Biosciences, Inc.
Franklin C. Salisbury, Jr.	President, National Foundation for Cancer Research

SENIOR MANAGEMENT

Wei-Wu He, Ph.D.	Executive Chairman
Ken K. Ren, M.D., Ph.D.	Director and Chief Executive Officer
Alexander A. Zukiwski, M.D.	Chief Medical Officer
Cynthia W. Hu, J.D.	Chief Operating Officer, General Counsel & Secretary
Jim Goldschmidt, Ph.D.	Senior Vice President, Business Development
Sara B. Capitelli	Vice President, Finance, Principal Accounting Officer

ADVISORS

Tak W. Mak, Ph.D.	Princess Margaret Hospital and University of Toronto
Ghassan K. Abou-Alfa, M.D.	Memorial Sloan-Kettering Cancer Center and Weill Cornell Medical College
S. Gail Eckhardt, M.D.	LIVESTRONG Cancer Institutes of the Dell Medical School
Robert J. Mayer, M.D.	Dana-Farber Cancer Institute and Harvard Medical School

Business Strategy

Bringing Innovative and High Quality Medicines to 1.5 Billion People in China while Addressing the U.S. and Global Markets Cost-Effectively

- Large patient population in China seeking innovative and high quality medicines
- Recent China FDA (CFDA) reforms allow for expedited approval of NDAs and ANDAs for innovative and high quality products
- CASI is in a unique position to capitalize on the CFDA reforms and has a successful record of licensing/acquisition of Innovative Products & ANDAs to be brought into the China market
- Leverage CASI's expertise and resources in China to accelerate the development, registration and commercialization of products for both the China and US/Global markets
 - Rapid patient recruitment to reach proof-of-concept data inflection points quickly and cost-effectively
- Lower cost of goods produced by high quality, GMP facilities in China can be leveraged on a worldwide basis

Historic Harmonization of China Regulatory Environment

Historic challenges:

- Issues with comparative quality (international standards vs local products & manufacturers)
- Longer timeframe for review & new drug approval
- Lack of capacity in regulatory bodies / application backlog

China State Council issued Reforms* in 2015 to bring marketed products in line with international standards (e.g. efficacy, safety, quality).

Objectives:

- Eliminate existing backlog of registration applications
- Establish environment for maximizing generic drug quality
- Create framework in China encouraging new drug R&D in line with global development
- Improve quality and transparency of review and approval process

* *Opinions on Reforming Review and Approval System for Drugs & Medical Devices*

Historic Harmonization of China Regulatory Environment

Recent Reforms & Implications:

- **Shortened IND / NDA review timelines:** Increased number of reviewers at CDE to resolve current backlog; goal is for review timelines to be ~six months by YE2018 with zero backlog
- **Priority reviews:** Target approval time from submission within six months
- **Increasing transparency and globalization:** CFDA encouraging foreign sponsors to undertake global studies in China and recommend local clinical sites join global studies
 - First-in-human (FIH) Phase I trials to POC and Pivotal trials: Foreign applicants now have full clinical development flexibility in China
- **China FDA's new guidelines:** accept data from overseas clinical trials to speed up approval of drugs in China
- **Simplified NDA/MAA Process:** China submissions & approvals can now be in parallel with (or earlier than) foreign NDA/MAA submissions and approvals
- **Stronger quality controls & Enhanced Quality of data:** Local CROs now challenged to enhance quality; Sponsors motivated to use reliable CROs with established standards

Sources:

Nature – Sept 2017, Volume 14: Zhou et al

Regulatory Rapporteur –July/August 2017, Vol 14, No 7/8: Bill Wang, Alistair Davidson

Diversified Product Portfolio

Through Acquisitions, In-licensing and Internally Developed Innovative, Targeted Oncology Therapeutics and High Quality ANDAs

Greater China Rights

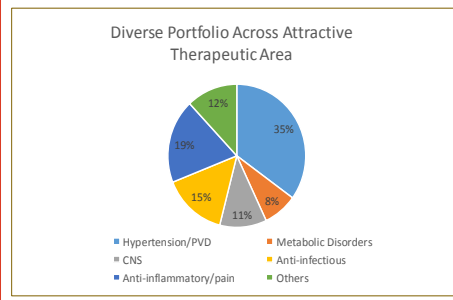
Acquired From SPPI



US FDA ANDAs

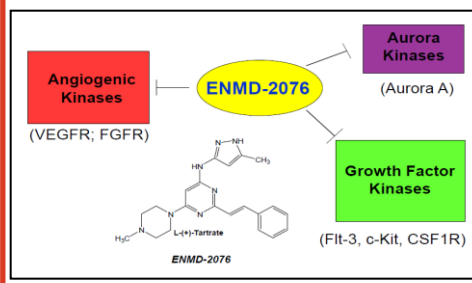
Acquired From Sandoz

- 25 FDA Approved ANDAs
- 4 FDA Pending ANDAs



ENMD-2076, Global Rights

Innovative Drug Candidate Targeted Therapy for Solid Tumors

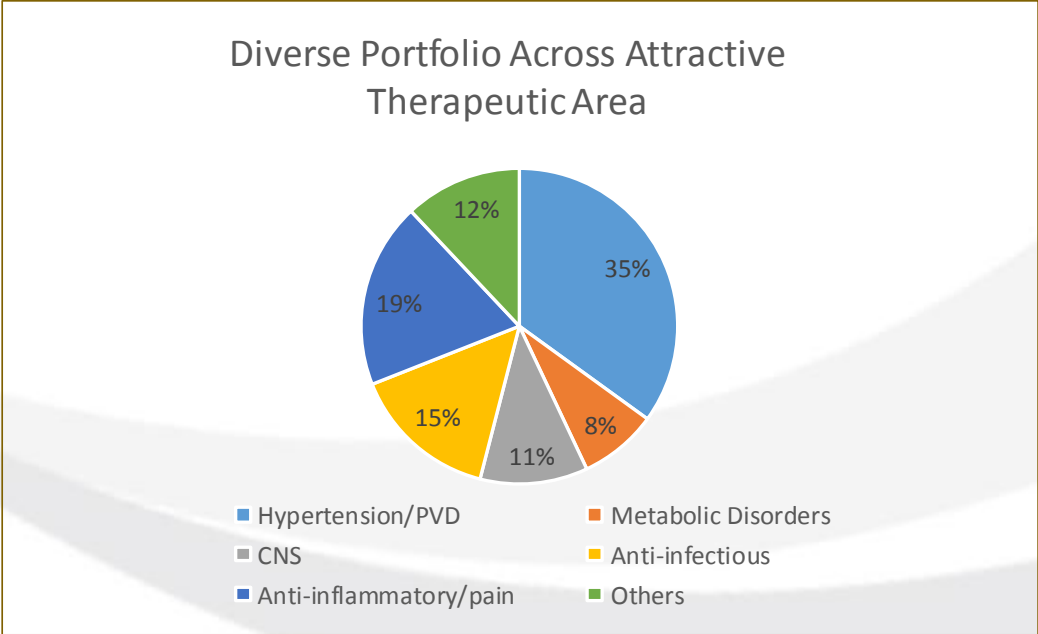


- CASI entered into licensing agreement with Spectrum Pharmaceuticals (Nasdaq: SPPI) for China development & commercialization of hematological oncology products
- **Exclusive rights to three commercial products (China Territories):**
 - **EVOMELA®** *Conditioning treatment prior to autologous stem cell transplant for patients with multiple myeloma; **CFDA PRIORITY REVIEW: Advisory committee meeting held Apr 26***
 - **MARQIBO®** *Treatment of acute lymphoblastic leukemia; **CFDA review in progress***
 - **ZEVALIN®** *Treatment of non-Hodgkin's Lymphoma; **CFDA review in progress***
- **CASI responsible for development and commercialization in China, including Taiwan, Hong Kong, and Macau**
 - Import drug registration applications
 - Confirmatory clinical studies
 - Premarketing and commercial launches

Acquired 29 ANDA Products & Pipeline



25 FDA Approved, 4 Pending FDA Approval ANDAs



Key Products	Indication
Entecavir	HBV Infection
Ondansetron	CINV
Methimazole	Hyperthyroidism
Repaglinide	Diabetes
Bisoprolol Fumarate	Hypertension
Cilostazol	Vascular Disease

Historical Opportunity for Rapid Entry of FDA-Approved ANDAs in China



CASI's Partnership Approach & Goals

- *Leverage CASI's development, regulatory, and commercial infrastructure in China*
- *Rapidly reach clinical milestone inflection points and registrations cost-effectively*
- *Accelerate product commercialization and life-cycle management*



