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CASI PHARMACEUTICALS ANNOUNCES FULL YEAR 2019 FINANCIAL RESULTS

- Company to host Conference Call Today at 4:30 p.m. ET-

ROCKVILLE, MD., and BEIJING (March 16, 2020) CASI Pharmaceuticals, Inc. (Nasdaq: CASI), a U.S. biopharmaceutical company focused on developing and commercializing innovative therapeutics and pharmaceutical products, today reported financial results for the year ended December 31, 2019, and provided a business update.

Wei-Wu He, Ph.D., CASI's Chairman and Chief Executive Officer, commented, "We made significant progress in 2019 with the August launch of EVOMELA® and ended the year with $4.1 million in revenues. We also in-licensed our other key programs, including CNCT-19 (CD19 CAR-T) and CID-103 (anti-CD38 Mab) strengthening CASI's position in the hematology/oncology therapeutic area. In 2019, we completed the buildout of our China infrastructure including in the marketing and sales, medical affairs, regulatory and clinical development areas. Despite a slow-down in the first quarter of 2020 due to the coronavirus outbreak (COVID-19), we will continue to drive sales of EVOMELA so that we can fully serve the patients that can benefit from EVOMELA, the only commercially available melphalan in China."

Dr. He continued, "We are pleased that the CNCT19 (CD19 CAR-T) B-NHL Phase I study is progressing at anticipated pace. Based on previous data, we are excited about the advancement of this very promising therapy, and despite the initial slow-down, we look forward to advancing this study. We remain on track with our other clinical trials planned for 2020."

Selected Business Highlights

EVOMELA® (melphalan for injection)

In August 2019, the Company launched its first product, EVOMELA (melphalan for injection), in China, marking the transition of CASI to an integrated commercial operation. EVOMELA is unique in that the Captisol®-enabled formulation avoids the use of propylene glycol, which is used as a co-solvent in other forms of melphalan. EVOMELA has greater stability when reconstituted, allowing longer preparation and infusion times, and is currently the only form of melphalan commercially available in China. CASI has built a strong sales and marketing team that is detailing all major hospitals and physicians in the hematology/oncology therapeutic area. CASI intends to continue to drive market awareness and market penetration for EVOMELA in 2020. A post-marketing study for EVOMELA in China is planned for later this year.

CNCT19 (CD19 CAR-T)

In June 2019, CASI acquired exclusive global commercialization rights to CNCT19 (CD19 CAR-T) from Juventas Cell Therapy Ltd., a China-based domestic company specializing in innovative immune cell therapy. CNCT19 targets CD19, a B-cell surface protein widely expressed during all phases of B-cell development and a validated target for B-cell driven hematological malignancies. Other CD19-targeted CAR constructs from several different institutions have demonstrated antitumor efficacy in children and adults with relapsed B-cell acute lymphoblastic leukemia (B-ALL), chronic lymphocytic leukemia (CLL), and B-cell non-Hodgkin lymphoma (B-NHL). Currently, there are no CD-19 CAR-T therapy products marketed in China. CASI intends for CNCT (CD19 CAR-T) to be locally developed and manufactured so that it can be more affordable and widely accessible to patients. The China National Medical Product Administration (NMPA)

has approved the clinical trial applications for CNCT19 in B-ALL and B-NHL. CASI expects that the first patient for the B-NHL and B-ALL Phase 1 studies will be dosed in the first half of 2020.

CID-103 (Anti-CD38 Mab)

In April 2019, CASI acquired exclusive global rights to CID-103, a novel anti-CD38 monoclonal antibody program. Preclinical data demonstrate CID-103 to have enhanced activity against a broad array of malignancies which express CD38, and potentially better safety and best in class when compared to other CD38 monoclonal antibodies. CASI expects to file an IMPD/CTA for CID-103 in the first half of 2020, with Phase 1 trials expected to start in the United Kingdom during the second half of 2020.

ZEVALIN® (Ibritumomab Tiuxetan)

In February 2019 the NMPA approved the Company's clinical trial application for a confirmatory registration trial to evaluate the drug's efficacy and safety. ZEVALIN is a CD20-directed radiotherapeutic antibody indicated for the treatment of patients with NHL. The ZEVALIN therapeutic regimen consists of two components: rituximab, and Yttrium-90 (Y-90), a beta-emitting radioisotope. CASI intends to advance the development, import drug registration, and market approval of this product in China and is currently in the preparation stage with suppliers. The Company expects the registration study to be initiated by early 2021.

Octreotide Long Acting Injectable (LAI) Microsphere

In November 2019, CASI acquired exclusive China rights for the development and distribution of octreotide long-acting injectable (LAI) microsphere. Octreotide LAI formulations are considered a standard of care for the treatment of acromegaly and the control of symptoms associated with certain neuroendocrine tumors. Octreotide LAI has recently been approved in various European countries. CASI intends to advance the development, import drug registration, and market approval of this product in China, and expects the trial to be initiated later this year.

Thiotepa

The Company recently acquired exclusive China rights for the development and distribution of a novel formulation of thiotepa, a chemotherapeutic agent, which has multiple indications including use as a conditioning treatment for use prior to hematopoietic stem cell transplantation. Thiotepa has a long history of established use in the hematology/oncology setting. CASI intends to advance the development, import drug registration, and market approval of this product in China, and expects the registration study to be initiated by early 2021.

Full Year 2019 Highlights

Product Sales:

Revenues consist of product sales of EVOMELA that launched during August 2019. Revenue was $4.1 million for the year ended 2019 compared to $0 for the year ended December 31, 2018.

Costs of Revenues:

Costs of revenues were $3.9 million for the year ended December 31, 2019 compared to $0 for the year ended December 31, 2018. The increase is due to the launch of EVOMELA that occurred during August 2019. Costs of revenues have been impacted by a transitional supply agreement that is in the process of being modified with an alternate manufacturer. We expect the unit cost of inventories of EVOMELA to be considerably reduced in the future.

Research and Development Expenses:

Research and development expenses for the year ended December 31, 2019 were $9.7 million, compared with $8.5 million for the year ended December 31, 2018. The increase in R&D expenses primarily reflects higher regulatory costs associated with our ANDAs in 2019, costs incurred with the development of CID-103 and higher consulting and manufacturing related services.

General and Administrative Expenses:

General and administrative expenses for the year ended December 31, 2019 were $27.3 million, compared with $18 million for the year ended December 31, 2018. The increase was related to a combination of factors primarily related to the Company's growth in China. These factors include an increase in salary, benefits and recruitment expense and facilities costs due to increases in head count in connection with the commercial launch of the Company's first commercial product (EVOMELA), professional services fees (including audit and legal services), and an increase in non-cash stock compensation expense largely attributed to stock options issued to CASI's CEO, President of CASI, and other employees.

Selling and Marketing Expenses:

Selling and marketing expenses for the year ended December 31, 2019 were $3.1 million, compared with $0 for the year ended December 31, 2018. The increase is due to selling costs related to the commercial sales of EVOMELA that began during August 2019.

Acquired In-Process Research and Development:

Acquired in-process R&D expenses for year ended December 31, 2019 were $7.0 million, primarily relating to the acquired Black Belt and Octreotide licenses, compared with $0.7 million for the year ended December 31, 2018, primarily relating to acquired ANDAs in January 2018.

Net Loss:

Net loss for the year ended December 31, 2019 was $45.4 million compared to $27.5 million for the year ended December 31, 2018. The increase is primarily due to the Company's growth in China to support the Company's 2019 commercial product launch of EVOMELA, as well as costs associated with the acquired Black Belt and Octreotide licenses.

Cash and Cash Equivalents:

As of December 31, 2019, CASI had cash and cash equivalents of $53.6 million compared to $84.2 million as of December 31, 2018. The decrease in cash is primarily due to the Black Belt and Juventas investments made during the second quarter 2019, along with normal operating expenses.

Further information regarding the Company, including its Annual Report on Form 10-K for the year ended December 31, 2019, can be found at www.casipharmaceuticals.com.

Conference Call

The Company will host a conference call reviewing the full year 2019 highlights at 4:30 p.m. ET on Monday, March 16, 2020. On the call, CASI's Chairman & CEO will provide an update on the Company's business and upcoming milestones. The conference call will be conducted in English, and can be accessed

by dialing (833) 647-4459 (U.S.), 8008700181 (China), 58086567 (Hong Kong) to listen to the live conference call. The conference ID number for the live call is 5894813.

About CASI Pharmaceuticals

CASI is a U.S. biopharmaceutical company focused on developing and commercializing innovative therapeutics and pharmaceutical products, with a product portfolio that includes approved and investigational assets. In August 2019, the Company launched its first commercial product, EVOMELA® (Melphalan for Injection), in China that is approved for use as a conditioning treatment prior to stem cell transplantation in the multiple myeloma setting. The Company's other core hematology/oncology assets in its pipeline include (i) an autologous CD19 CAR-T investigative product (CNCT19) being developed as a treatment for patients with B-ALL and B-NHL; (ii) CID-103, an anti-CD38 monoclonal antibody being developed for the treatment of patients with multiple myeloma; and (iii) greater China rights to ZEVALIN® (Ibritumomab Tiuxetan), a CD20-directed radiotherapeutic antibody that is approved in the U.S. to treat patients with NHL. The Company's oncology assets also include China rights to (i) octreotide long acting injectable (LAI) microsphere formulation indicated for the treatment of certain symptoms associated with particular neuroendocrine cancers and acromegaly, and (ii) a novel formulation of thiotepa, which has multiple indications and a long history of established use in the hematology/oncology setting, both of which are being developed for import registration and market approval in China. More information on CASI is available at www.casipharmaceuticals.com.

Forward-Looking Statements

This news release 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, including: the difficulty of executing our business strategy in China; our ability to design and implement a development plan for our ANDAs; the development of major public health concerns, including the coronavirus or other pandemics arising in China or elsewhere; our lack of experience in manufacturing products and uncertainty about our resources and capabilities to do so on a clinical or commercial scale; risks relating to the commercialization, if any, of our products and proposed products (such as marketing, safety, regulatory, patent, product liability, supply, competition and other risks); our inability to predict when or if our product candidates will be approved for marketing by the FDA, NMPA, or other regulatory authorities; our inability to enter into strategic partnerships for the development, commercialization, manufacturing and distribution of our proposed product candidates or future candidates; the volatility in the market price of our common stock; risks relating to the need for additional capital and the uncertainty of securing additional funding on favorable terms; risks associated with CID-103, CNCT19, and our other early-stage products under development; risks that result in preclinical and early clinical models are not necessarily indicative of later clinical results; uncertainties relating to preclinical and clinical trials, including delays to the commencement of such trials; our ability to protect our intellectual property rights; the lack of success in the clinical development of any of our products; and our dependence on third parties. Such factors, among others, could have a material adverse effect upon our business, results of operations and financial condition. We caution readers not to place undue reliance on any forward-looking statements, which only speak as of the date made. 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.

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(Financial Table Follows)

CASI Pharmaceuticals, Inc.
Consolidated Balance Sheets
(In thousands, except share and per share data)

	December 31,	
	2019	**2018**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 53,621	$ 84,205
Investment in equity securities, at fair value	625	912
Accounts receivable, net of $0 allowance for doubtful accounts	1,293	-
Inventories	4,542	283
Prepaid expenses and other	1,420	7,165
Total current assets	61,501	92,565
Property and equipment, net	985	1,751
Intangible assets, net	16,895	18,785
Long-term investments	14,038	-
Right of use assets	8,708	-
Other assets	504	310
Total assets	$ 102,631	$ 113,411
LIABILITIES, REDEEMABLE NONCONTROLLING INTEREST AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,113	$ 968
Accrued liabilities	2,834	1,406
Note payable, net of discount	-	1,499
Total current liabilities	7,947	3,873
Other liabilities	1,019	74
Total liabilities	8,966	3,947
Commitments and contingencies (Note 20)		
Redeemable noncontrolling interest, at redemption value (Note 11)	20,670	-
Stockholders' equity:		
Preferred stock, $1.00 par value: 5,000,000 shares authorized and 0 shares issued and outstanding	-	-
Common stock, $.01 par value: 250,000,000 shares and 170,000,000 shares authorized at December 31, 2019 and 2018, respectively; 97,851,243 shares and 95,366,813 shares issued at December 31, 2019 and 2018, respectively; 97,771,698 shares and 95,287,268 shares outstanding at December 31, 2019 and 2018, respectively	979	954
Additional paid-in capital	606,686	596,712
Treasury stock, at cost: 79,545 shares held at December 31, 2019 and 2018	(8,034)	(8,034)
Accumulated other comprehensive loss	(2,728)	(1,227)
Accumulated deficit	(523,908)	(478,941)
Total stockholders' equity	72,995	109,464
Total liabilities, redeemable noncontrolling interest and stockholders' equity	$ 102,631	$ 113,411

CASI Pharmaceuticals, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except per share data)

	Year Ended December 31,	
	2019	**2018**
Revenues:		
Product sales	$ 4,063	$ -
Lease income	68	-
Total revenues	4,131	-
Costs and expenses:		
Costs of revenues	3,935	-
Research and development	9,748	8,507
General and administrative	27,336	17,997
Selling and marketing	3,103	-
Acquired in-process research and development	6,967	687
Total costs and expenses	51,089	27,191
Loss from operations	(46,958)	(27,191)
Non-operating income/(expense):		
Interest income, net	1,062	40
Foreign exchange gains	817	-
Change in fair value of investment in equity securities	(288)	(320)
Other income	5	-
Net loss	(45,362)	(27,471)
Less: loss attributable to redeemable noncontrolling interest	(395)	-
Accretion to redeemable noncontrolling interest redemption value	1,065	-
Net loss attributable to CASI Pharmaceuticals, Inc.	$ (46,032)	$ (27,471)
Net loss per share (basic and diluted)	$ (0.48)	$ (0.32)
Weighted average number of common shares outstanding (basic and diluted)	95,948	84,752
Comprehensive loss:		
Net loss	$ (45,362)	$ (27,471)
Foreign currency translation adjustment	(1,501)	(1,227)
Total comprehensive loss	$ (46,863)	$ (28,698)
Less: Comprehensive loss attributable to redeemable noncontrolling interest	(395)	-
Comprehensive loss attributable to common stockholders	$ (46,468)	$ (28,698)