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CASI PHARMACEUTICALS
ANNOUNCES FULL YEAR 2020 FINANCIAL RESULTS

ROCKVILLE, MD., and BEIJING (March 30, 2021) 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, 2020 and provided an update on key highlights for 2021.

Wei-Wu He, Ph.D., CASI's Chairman and Chief Executive Officer, commented, "Despite the ongoing challenges presented by the pandemic, we are continuing to execute across each of our targeted initiatives, chiefly with respect to strategic growth through tactical business development, as evidenced by our recently announced in-licensing of a first-in-class VCP/p97 inhibitor for hematological malignancies and solid tumors from Cleave Therapeutics. Additionally, we remain laser focused on driving commercial preparations in advance of the CAR-T NDA filing, which is well positioned for success given the relatively lower cost of goods and potentially swifter regulatory pathway afforded by launching in the Greater China market."

Dr. He continued, "As we continue assembling a world class pipeline of assets and driving existing development forward, we are encouraged by the steady EVOMELA patient uptake we have observed, further underscored by the greater than 50% revenue growth we have forecasted in 2021. The EVOMELA launch has informed our business development strategy to a large extent, as we now possess a clear picture of the potential challenges and opportunities associated with launching a successful patient and physician marketing campaign, achieving regulatory support, and appropriately scaling manufacturing. We look forward to leveraging our existing commercial infrastructure as we continue evaluating new potentially complementary pipeline assets and move preparations along in advance of upcoming regulatory filings. Finally, we were pleased to report the closing of an underwritten public offering for gross proceeds of $32.5 million and adding a few new fundamentally-driven, long-term oriented, healthcare-dedicated investors to the CASI story, as well as continued investment by our management. We look forward to continuing to expand our U.S. investor base, and importantly, positioning CASI to accelerate long-term value creation for our shareholders."

Key Highlights for 2021

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 intravenous 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 2021 and beyond. A post-marketing study for EVOMELA in China is currently underway.

CNCT19 (CD19 CAR-T)

In June 2019, CASI acquired 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). CNCT19 received Breakthrough Therapy Designation based on initial data from the ongoing single-arm, open-label, non-randomized, dose-escalation, Phase 1 study designed to determine the safety and efficacy of CNCT19 in B-ALL. The Phase 2 registration study in patients with B-NHL is currently enrolling, and we expect Juventas to initiate the Phase II registration study in B-ALL in Q1 2021. The commercial team is making preparations for the launch of CNCT19, for which Juventas is expecting to file an NDA with the NMPA in 2021. 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.

CB-5339 (VCP/p97 inhibitor)

In March of 2021, CASI acquired CB-5339 (VCP/p97 inhibitor) from Cleave. CB-5339, an oral second-generation, small molecule VCP/p97 inhibitor, is being evaluated in a Phase 1 clinical trial in patients with acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS), while the National Cancer Institute (NCI) is sponsoring and evaluating CB-5339 in a Phase 1 clinical trial of patients with solid tumors and lymphomas.

BI-1206 (Anti-FcγRIIB antibody)

In October of 2020, CASI acquired BI-1206, Checkpoint Inhibitor Targeting FcγRIIB, from BioInvent. BI-1206 has a novel mode-of-action, blocking the single inhibitory antibody checkpoint receptor FcγRIIB to unlock anti-cancer immunity in both liquid and solid tumors. BI-1206 is BioInvent's lead drug candidate and is being investigated in a Phase I/II trial, in combination with anti-PD1 therapy Keytruda® (pembrolizumab), in solid tumors, and in a Phase I/IIa trial in combination with MabThera® (rituximab) for the treatment of non-Hodgkin lymphoma (NHL). Recently, BioInvent presented early clinical data from their Phase 1/2a trial on BI-1206. Objective responses (2CRs, 4 PRs) were demonstrated in 6 out of 9 patients evaluated, providing exciting evidence that BI-1206 has the potential to restore the activity of rituximab in non-Hodgkin's lymphoma patients who have relapsed after treatment with rituximab. CASI intends to file an IND for BI-1206 with the NMPA in 2021 to start the clinical trials in China.

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. The CID-103 Phase 1 study was initiated in March 2021.

Full Year 2020 Highlights

Product Sales:

Revenues consist of product sales of EVOMELA that launched during August 2019. Revenue was $15.0 million for the year ended 2020 compared to $4.1 million for the year ended December 31, 2019.

Costs of Revenues:

Costs of revenues were $9.5 million for the year ended December 31, 2020 compared to $3.9 million for the year ended December 31, 2019. The increase is due to the launch of EVOMELA that occurred during

August 2019. The increase in cost of revenues is partially offset by a decrease in unit cost of inventories of EVOMELA as a result of the new alternate manufacturer now in place.

Research and Development Expenses:

Research and development expenses for the year ended December 31, 2020 were $11.5 million, compared with $9.3 million for the year ended December 31, 2019. The increase in R&D expenses primarily due to an increase in R&D expenses incurred related to the development of CID-103 and costs associated with the EVOMELA post marketing study. These costs were partially offset by reduced regulatory costs associated with our ANDAs and reduced costs associated with preclinical development activities related to an immune-oncology program terminated in 2019.

General and Administrative Expenses:

General and administrative expenses for the year ended December 31, 2020 were $19.7 million, compared with $27.3 million for the year ended December 31, 2019. The decrease in general and administrative expenses was primarily because the 2019 period included costs related to sales and marketing efforts to prepare for the August 2019 launch of EVOMELA, as well as lower professional fees and travel costs incurred during the 2020 period.

Selling and Marketing Expenses:

Selling and marketing expenses for the year ended December 31, 2020 were $7.8 million, compared with $3.1 million for the year ended December 31, 2019. The increase is due to selling costs related to the launch of EVOMELA that began during August 2019.

Acquired In-Process Research and Development:

Acquired in-process R&D expenses for the year ended December 31, 2020 were $17.8 million, compared with $7.0 million for the year ended December 31, 2019. Acquired in-process R&D expenses for the year ended December 31, 2020 comprised of the two 2020 milestone fees paid related to Pharmathen of $1.7 million, the 2020 milestone fees paid to Juventas of $10.3 million and fees paid to BioInvent of $5.9 million. Acquired in-process R&D expenses for the year ended December 31, 2019 included the $5.8 million acquisition of the Black Belt's license in April 2019 and $1.1 million milestone fee paid to Pharmathen.

Net Loss:

Net loss for the year ended December 31, 2020 was $47.5 million compared to $45.4 million for the year ended December 31, 2019. The increase is primarily due to the Company's increasing acquisitions of additional targeted drugs and activities in Research and Development.

About CASI Pharmaceuticals

CASI Pharmaceuticals, Inc. is a U.S. biopharmaceutical company focused on developing and commercializing innovative therapeutics and pharmaceutical products in China, the United States, and throughout the world. The Company is focused on acquiring, developing and commercializing products that augment its hematology oncology therapeutic focus as well as other areas of unmet medical need. The Company intends to execute its plan to become a leader by launching medicines in the greater China market leveraging the Company's China-based regulatory and commercial competencies and its global drug development expertise. The Company's operations in China are conducted through its wholly-owned subsidiary, CASI Pharmaceuticals (China) Co., Ltd., which is located in Beijing, China. The Company has built a commercial team of more than 80 hematology and oncology sales and marketing specialists based 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 risk that we may be unable to continue as a going concern as a result of our inability to raise sufficient capital for our operational needs; the possibility that we may be delisted from trading on The Nasdaq Capital Market; the volatility in the market price of our common stock; the outbreak of the COVID-19 pandemic and its effects on global markets and supply chains; the risk of substantial dilution of existing stockholders in future stock issuances; the difficulty of executing our business strategy in China; our inability to enter into strategic partnerships for the development, commercialization, manufacturing and distribution of our proposed product candidates or future candidates; 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 U.S. Food and Drug Administration (FDA), National Medical Products Administration (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 risks relating to the need for additional capital and the uncertainty of securing additional funding on favorable terms; the risks associated with our product candidates, and the risks associated with our other early-stage products under development; the risk that result in preclinical and clinical models are not necessarily indicative of 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; our ability to design and implement a development plan for our ANDAs held by CASI Wuxi; the lack of success in the clinical development of any of our products; and our dependence on third parties; the risks related to our dependence on Juventas to conduct the clinical development of CNCT19 and to partner with us to co-market CNCT19; risks related to our dependence on Juventas to ensure the patent protection and prosecution for CNCT19; risks relating to the commercialization, if any, of our proposed products (such as marketing, safety, regulatory, patent, product liability, supply, competition and other risks); risks relating to interests of our largest stockholders and our Chairman and CEO that differ from our other stockholders; and risks related to the development of a new manufacturing facility by CASI Wuxi. 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.

EVOMELA® is *proprietary to Acrotech Biopharma LLC and its affiliates.*

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(Financial Table Follows)

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

	December 31, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 57,064	$ 53,621
Investment in equity securities, at fair value	9,309	625
Accounts receivable, net of $0 allowance for doubtful accounts	4,645	1,293
Inventories	1356	4,542
Prepaid expenses and other	1,651	1,420
Assets held-for-sale	-	3,221
Total current assets	74,025	64,722
Property, Plant and equipment, net	2062	985
Intangible assets, net	13,210	13,674
Long-term investments	29,442	14,038
Right of use assets	8,696	8,708
Other assets	299	504
Total assets	$ 127,734	$ 102,631
LIABILITIES, REDEEMABLE NONCONTROLLING INTEREST AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,669	$ 5,113
Accrued and other current liabilities	3,015	2,834
Line of Credit	826	-
Notes Payable	466	-
Total current liabilities	7,976	7,947
Deferred income	2,351	—
Other liabilities	13,834	1,019
Total liabilities	24,161	8,966
Commitments and contingencies		
Redeemable noncontrolling interest, at redemption value	22,033	20,670
Stockholders' equity:		
Preferred stock, $1.00 par value: 5,000,000 shares authorized and 0 shares issued and outstanding	—	—
Common stock, $0.01 par value: 250,000,000 shares authorized at September 30, 2020 and December 31, 2019; 124,023,374 shares and 97,851,243 shares issued at September 30, 2020 and December 31, 2019, respectively; 123,943,829 shares and 97,771,698 shares outstanding at September 30, 2020 and December 31, 2019, respectively	1,240	979
Additional paid-in capital	658,246	606,686
Treasury stock, at cost: 79,545 shares held at September 30, 2020 and December 31, 2019	(8,034)	(8,034)
Accumulated other comprehensive loss	589	(2,728)
Accumulated deficit	(570,501)	(523,908)
Total stockholders' equity	81,540	72,995
Total liabilities, redeemable noncontrolling interest and stockholders' equity	$ 127,734	$ 102,631

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

	Year Ended December 31, 2020	2019
Revenues:		
Product sales	$ 15,001	$ 4,063
Lease income	140	68
Total revenues	15,141	4,131
Costs and expenses:		
Costs of revenues	9,508	3,935
Research and development	11,470	9,340
General and administrative	19,661	27,336
Selling and marketing	7,815	3,103
(Gain) loss on disposal of intangible assets	(1,152)	408
Impairment of intangible assets	1,537	0
Acquired in-process research and development	17,828	6,967
Total costs and expenses	66,667	51,089
Loss from operations	(51,526)	(46,958)
Non-operating income/(expense):		
Interest income, net	866	1,062
Other income	82	5
Foreign exchange (losses) gains	(1,255)	817
Change in fair value of investment in equity securities	4,322	(288)
Net loss	(47,511)	(45,362)
Less: (loss)/ income attributable to redeemable noncontrolling interest	(918)	(395)
Accretion to redeemable noncontrolling interest redemption value	1,694	1,065
Net loss attributable to CASI Pharmaceuticals, Inc.	$ (48,287)	$ (46,032)
Net loss per share (basic and diluted)	$ (0.44)	$ (0.48)
Weighted average number of common shares outstanding (basic and diluted)	110,452	95,948
Comprehensive loss:		
Net loss	$ (47,511)	$ (45,362)
Foreign currency translation adjustment	3,904	(1,501)
Total comprehensive loss	$ (43,607)	$ (46,863)
Less: Comprehensive (loss)/income attributable to redeemable noncontrolling interest	(331)	(395)
Comprehensive loss attributable to common stockholders	$ (43,276)	$ (46,468)