www.casipharmaceuticals.com

CASI PHARMACEUTICALS ANNOUNCES SECOND QUARTER 2020 FINANCIAL RESULTS

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

ROCKVILLE, MD. and BEIJING (August 10, 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 and business highlights for the second quarter of 2020.

Wei-Wu He, Ph.D., CASI's Chairman and Chief Executive Officer, commented, "One of the positive developments with respect to EVOMELA this quarter was the successful transition to a new manufacturer for the commercial supply in China. This was a key accomplishment as we expect it to significantly reduce our cost of revenue. Despite the impact of COVID-19 and manufacturer change in the second quarter, we expect EVOMELA revenue to reach at least $10 million for the full year 2020. We also expect significant improvement in our margins for EVOMELA for the second half of 2020."

Dr. He continued, "The current Phase 1 trials for CNCT19, a CD19 CAR-T therapy, conducted by our development partner, Juventas, are well underway. Juventas expects to complete trials in B-NHL and B-ALL and initiate registration trials in the first quarter 2021, followed by NDA filing in China in early 2022. As Juventas' exclusive commercial partner, we expect that with a locally developed and manufactured CD19 CAR-T, we will be able to offer a much lower price point than imported therapies and thus be able to make this important cell-based therapy available to significantly more patients in China."

"With regard to CID-103, our anti-CD38 monoclonal antibody, we recently submitted our IMPD application with MHRA, the British health authority, to initiate our Phase 1 clinical study in the UK. Clinical centers in the EU continue to be impacted by COVID-19; however, we expect to initiate our study in the first quarter 2021 assuming the centers open back up for clinical trial activities."

"And finally, we were pleased to report our recent closing of an underwritten public offering for gross proceeds of $43.7 million. This successful financing attracted a number of 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."

Second Quarter 2020 Financial Results

- Revenues consisted primarily of product sales of EVOMELA that launched in August of 2019. Revenues were $2.7 million for the three months ended June 30, 2020. The decrease in the second quarter revenue figures, compared to those in the first quarter was primarily due to a manufacturer change and the effects caused by the global COVID-19 pandemic. We have since received shipment of EVOMELA from the new, lower-cost supplier and expect the product to be released into our distribution chain this month. We expect our revenue from EVOMELA will resume its original projected course in the second half of 2020.

- Costs of revenues were $2.5 million for the quarter ended June 30, 2020. Costs of revenues have been impacted by a previous supply arrangement which has since been replaced by a current lower-cost supplier. We expect that the unit cost of inventories of EVOMELA will be considerably lower in the second half of 2020.

- Research and development expenses for the second quarter ended June 30, 2020 were $1.9 million, compared with $3.0 million for the same period in 2019. The decrease in R&D expenses is primarily due to reduced regulatory costs associated with our ANDAs and lower costs associated with preclinical development activities, offset by an increase in R&D expenses incurred related to the development of CID-103.

- General and administrative expenses for the second quarter of 2020 were $4.1 million, compared with $7.0 million for the same period in 2019. The decrease in G&A 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 for the second quarter 2020 were $1.6 million. The increase is due to selling costs related to commercial sales of EVOMELA that began in August of 2019.

- Acquired in-process R&D expenses for the three months ended June 30, 2020 were $0 million, compared with $5.8 million for the same period in 2019, relating to the acquisition of the Black Belt license in April 2019.

- Net loss for the second quarter of 2020 was $8.5 million compared to $15.3 million for the same period in 2019.

- As of June 30, 2020, the Company had cash and cash equivalents of $44.9 million compared to $53.9 million as of March 31, 2020. As reported, the Company consummated an underwritten public offering in July 2020 generating gross proceeds of approximately $43.7 million.

Further information regarding the Company, including its Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, can be found at www.casipharmaceuticals.com.

Conference Call

The Company will host a conference call reviewing the second quarter highlights today at 4:30 p.m. ET. The conference call can be accessed by dialing (833) 647-4459 (U.S.), (800) 870-0181 (China), (400) 682-8629 (China, domestic), 800933597 (Hong Kong) to listen to the live conference call. The conference ID number for the live call is 5223239. Participants dialing in via International Toll-Free Service (ITFS) numbers will be required to provide the following passcode to join the conference call: 8336474459, 6025859887.

This call will be recorded and available for replay by dialing (800) 585-8367 (U.S.) or (404)-537-3406 (international) and enter 5223239 to access the replay.

About CASI Pharmaceuticals

CASI Pharmaceuticals, Inc. (“CASI” or the “Company”) 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. ("CASI China"), which is located in Beijing, China. The Company has built a commercial team of over 70 hematology and oncology sales and marketing specialists based in China. In August 2019, the Company launched its first commercial product, EVOMELA® (Melphalan for Injection). Evomela is indicated for use as a high-dose conditioning treatment prior to hematopoietic progenitor (stem) cell transplantation in patients with multiple myeloma and also indicated for the palliative treatment of patients with multiple myeloma for whom oral therapy is not appropriate. Other core hematology/oncology assets in the Company's pipeline include: (i) An autologous CD19 CAR-T investigative product (CNCT19) being developed by Juventas Cell Therapy Ltd ("Juventas") as a treatment for patients with B-cell acute lymphoblastic leukemia ("B-ALL") and B-cell non-Hodgkin lymphoma ("B-NHL") for which the Company has exclusive commercialization rights. The Company expects Juventas to complete its Phase 1 study of CNCT19 and initiate its registration trials in the first quarter of 2021; (ii) CID-103, an anti-CD38 monoclonal antibody being developed for the treatment of patients with multiple myeloma. The Company intends to initiate the Phase 1 study of CID-103 in the first quarter of 2021; and (iii) ZEVALIN® (Ibritumomab Tiuxetan), a CD20-directed radiotherapeutic antibody, that is approved in the U.S. to treat patients with non-Hodgkin lymphoma ("NHL"). The Company intends to begin the China registration study of ZEVALIN in 2021. Other assets in the Company's pipeline for which the Company have exclusive rights in China are (i) Octreotide Long Acting Injectable ("LAI"), and (ii) a novel formulation of Thiotepa. Octreotide LAI formulations, which are approved in various European countries, are considered a standard of care for the treatment of acromegaly and the control of symptoms associated with certain neuroendocrine tumors. The Company plans to begin the China registration study for Octreotide LAI in 2020. Thiotepa is a conditioning treatment for allogeneic haemopoietic stem cell transplants. The Company's partner for the novel formulation of Thiotepa plans to begin the China registration study in 2021. 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, revenue growth, 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 we assume no duty to update forward-looking statements. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Actual results could differ materially from those currently anticipated due to a number of factors, including: 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 ability to design and implement a development plan for our ANDAs held by CASI Wuxi; our inability to enter into strategic partnerships for the development, commercialization, manufacturing and distribution of our proposed product candidates or future candidates; risks relating to the need for additional capital and the uncertainty of securing additional funding on favorable terms, if at all; the risk that we may be unable to continue as a going concern if we are unable to raise sufficient capital for our operational needs; the volatility in the market price of our common stock; the possibility that we may be delisted from trading on The Nasdaq Capital Market; risks associated with our product candidates; risks associated with any early-stage products under development; the risk that results in preclinical models are not necessarily indicative of clinical results; uncertainties relating to preclinical and clinical trials, including delays to the commencement of such trials; the lack of success in the clinical development of any of our products; dependence on third parties; risks related to our dependence on Juventas to conduct the clinical development of 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® and ZEVALIN® are proprietary to Acrotech Biopharma LLC and its affiliates.

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(Financial Table Follows)

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

	June 30, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 44,888	$ 53,621
Investment in equity securities, at fair value	934	625
Accounts receivable, net of $0 allowance for doubtful accounts	2,604	1,293
Loan receivable from a related party	4,267	—
Inventories	430	4,542
Prepaid expenses and other	1,407	1,420
Assets held-for-sale	1,250	1,496
Total current assets	55,780	62,997
Property and equipment, net	809	985
Intangible assets, net	13,143	15,399
Long-term investments	13,563	14,038
Right of use assets	7,964	8,708
Other assets	310	504
Total assets	$ 91,569	$ 102,631
LIABILITIES, REDEEMABLE NONCONTROLLING INTEREST AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,825	$ 5,113
Accrued and other current liabilities	2,354	2,834
Total current liabilities	4,179	7,947
Deferred income	2,196	—
Other liabilities	781	1,019
Total liabilities	7,156	8,966
Commitments and contingencies (Note 19)		
Redeemable noncontrolling interest, at redemption value (Note 11)	21,074	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 June 30, 2020 and December 31, 2019; 101,008,374 shares and 97,851,243 shares issued at June 30, 2020 and December 31, 2019, respectively; 100,928,829 shares and 97,771,698 shares outstanding at June 30, 2020 and December 31, 2019, respectively	1,010	979
Additional paid-in capital	614,617	606,686
Treasury stock, at cost: 79,545 shares held at June 30, 2020 and December 31, 2019	(8,034)	(8,034)
Accumulated other comprehensive loss	(3,890)	(2,728)
Accumulated deficit	(540,364)	(523,908)
Total stockholders' equity	63,339	72,995
Total liabilities, redeemable noncontrolling interest and stockholders' equity	$ 91,569	$ 102,631

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

	Three Months Ended		Six Months Ended	
	June 30, 2020	June 30, 2019	June 30, 2020	June 30, 2019
Revenues:				
Product sales	$ 2,638	$ —	$ 6,010	$ —
Lease income	33	—	67	—
Total revenues	2,671	—	6,077	—
Costs and expenses:				
Costs of revenues	2,517	—	5,728	—
Research and development	1,862	2,979	4,879	5,545
General and administrative	4,085	6,982	8,143	12,693
Selling and marketing	1,557	—	2,817	—
(Gain) loss on disposal of intangible assets	—	—	(450)	48
Impairment of intangible assets	1,537	—	1,537	—
Acquired in-process research and development	—	5,849	1,081	5,849
Total costs and expenses	11,558	15,810	23,735	24,135
Loss from operations	(8,887)	(15,810)	(17,658)	(24,135)
Non-operating income/(expense):				
Interest income, net	153	320	343	369
Other income	27	—	27	—
Foreign exchange (losses) gains	(115)	480	248	551
Change in fair value of investment in equity securities	324	(241)	309	(196)
Net loss	(8,498)	(15,251)	(16,731)	(23,411)
Less: (loss)/ income attributable to redeemable noncontrolling interest	(166)	62	(275)	76
Accretion to redeemable noncontrolling interest redemption value	362	158	679	161
Net loss attributable to CASI Pharmaceuticals, Inc.	$ (8,694)	$ (15,471)	$ (17,135)	$ (23,648)
Net loss per share (basic and diluted)	$ (0.09)	$ (0.16)	$ (0.17)	$ (0.25)
Weighted average number of common shares outstanding (basic and diluted)	100,921	95,717	99,847	95,684
Comprehensive loss:				
Net loss	$ (8,498)	$ (15,251)	$ (16,731)	$ (23,411)
Foreign currency translation adjustment	(336)	(1,112)	(1,162)	(800)
Total comprehensive loss	$ (8,834)	$ (16,363)	$ (17,893)	$ (24,211)
Less: Comprehensive (loss)/income attributable to redeemable noncontrolling interest	(166)	62	(275)	76
Comprehensive loss attributable to common stockholders	$ (8,668)	$ (16,425)	$ (17,618)	$ (24,287)