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CASI PHARMACEUTICALS ANNOUNCES SECOND QUARTER 2021 FINANCIAL RESULTS

-EVOMELA Second Quarter 2021 Revenue Continues Upward Trend;
Revenue Growth Guidance in 2021 Revised to Exceed 80% Over 2020-
- CID-103 Reaches Milestone with Dosing of First Patient –
-Notice of Patent Allowance Issued in China for BI-1206 -
- Company to host Conference Call Today at 8:00 AM. ET -

ROCKVILLE, MD. and BEIJING, China (August 12, 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 second quarter of 2021.

Wei-Wu He, Ph.D., CASI's Chairman and Chief Executive Officer, commented, "We are pleased to report $7.1 million EVOMELA® revenues for the quarter. Based on the current trend, we are revising our guidance for full-year 2021 revenue growth to exceed 80% over 2020. We are proud of our commercial franchise execution for EVOMELA and have expanded to over 100 FTEs on the commercial and marketing teams. In addition to the continued EVOMELA revenue growth, we achieved dosing of first patient of CID-103 in our Phase 1 clinical trial for relapse or refectory multiple myeloma. CID-103 has previously shown encouraging preclinical efficacy, a favorable preclinical safety profile, and greater antibody-dependence cellular cytotoxicity activity over other anti-CD38 mAbs, and we are hopeful this will translate into patient benefit."

Dr. He continued, "We are thrilled with the progress we continue to see throughout our hematology oncology pipeline. Our partner, Juventas, has completed CNCT19's (CD19 CAR-T) Phase 1 studies of B-ALL and B-NHL in China. The Phase 2 B-NHL and B-ALL registration studies of CNCT19 are currently enrolling in China. Additionally, BioInvent recently announced that the China National Intellectual Property Administration (CNIPA) has issued a notice of allowance, informing the company that a patent application relating to the anti-FcγRIIB antibody BI-1206 is expected to be granted. Together with BioInvent we plan to continue to develop BI-1206 in both hematological malignancies and solid tumors, with CASI responsible for development and commercialization in Greater China."

Second Quarter 2021 Financial Results

- Revenues consist of product sales of EVOMELA that launched during August 2019. Revenue was $7.1 million for the three months ended June 30, 2021 compared to $2.6 million for the three months ended June 30, 2020. Revenues increased by 173% in the second quarter of 2021 as compared to same quarter in 2020 due to the continued growth in EVOMELA sales.

- Costs of revenues were $2.9 million for the three months ended June 30, 2021, compared to $2.5 million for the three months ended June 30, 2020, which includes royalty payment of $1.4 million and $0.5 million for the same period. Costs of revenues excluding royalty were $1.5 million and $2.0 million for the three months ended June 30, 2021, and 2020. Costs of revenues, excluding royalty as a percentage of revenues, decreased significantly in the three months ended June 30, 2021, compared within the three months ended June 30, 2020, due to the new alternate manufacturer now in place, resulting in a considerable decrease in the unit cost of inventories of EVOMELA.

- General and administrative expenses for the three months ended June 30, 2021 were $5.4 million, compared with $4.1 million for the three months ended June 30, 2020.

- Selling and marketing expenses for the three months ended June 30, 2021 were $3.4 million, compared with $1.6 million for the three months ended June 30, 2020. The increase in selling and marketing expenses was due to expansion of sales team in China in 2021.

- Acquired in-process R&D expenses for the three months ended June 30, 2021 was $1.06 million, compared to $0 million for the three months ended June 30, 2020. In June 2021, the Company achieved the First-Patient-In (FPI) in the Phase 1 dose escalation and expansion study of CID-103, and made $750,000 milestone payment and accrued €250,000 ($305,000) payment under the terms of the agreement.

- Net loss for the three months ended June 30, 2021 was $6.7 million compared to $8.5 million for the three months ended June 30, 2020 due to significant revenue increase. As of June 30, 2021, CASI had cash and cash equivalents of $60.4 million compared to $57.1 million as of December 31, 2020.

Further information regarding the Company, including its Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, can be found at www.casipharmaceuticals.com.

Conference Call

The Company will host a conference call reviewing the second quarter highlights today at 8:00 a.m. ET. The conference call can be accessed by dialing (833) 420-0382 (U.S.), (800) 870-0181 (China), (400) 682-8629 (China, domestic), 58086567 (Hong Kong) to listen to the live conference call. The conference ID number for the live call is 5639775. 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) 859-2056 (U.S.) or (404) 537-3406 (international) and enter 5639775 to access the replay.

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.*.

COMPANY CONTACT:	INVESTOR CONTACT:
CASI Pharmaceuticals, Inc. 240.864.2643 ir@casipharmaceuticals.com	Bob Ai Solebury Trout 646-389-6658 bai@soleburytrout.com

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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, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 60,357	$ 57,064
Investment in equity securities, at fair value	12,588	9,309
Accounts receivable, net of $0 allowance for doubtful accounts	5,767	4,645
Inventories	3,475	1,356
Prepaid expenses and other	1,318	1,651
Total current assets	83,505	74,025
Property, plant and equipment, net	3,348	2,062
Intangible assets, net	12,691	13,210
Long-term investments	34,679	29,442
Right of use assets	9,797	8,696
Other assets	506	299
Total assets	$ 144,526	$ 127,734
LIABILITIES, REDEEMABLE NONCONTROLLING INTEREST AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,519	$ 3,669
Accrued and other current liabilities	2,488	3,015
Bank borrowings	1,548	826
Notes payable	466	466
Total current liabilities	10,021	7,976
Deferred income	2,354	2,351
Other liabilities	14,654	13,834
Total liabilities	27,029	24,161
Commitments and contingencies (Note 18)		
Redeemable noncontrolling interest, at redemption value (Note 11)	22,697	22,033
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, 2021 and December 31, 2020 139,877,032 shares and 124,023,374 shares issued at June 30, 2021 and December 31, 2020, respectively; 139,797,487 shares and 123,943,829 shares outstanding at June 30, 2021 and December 31, 2020, respectively	1,399	1,240
Additional paid-in capital	690,539	658,246
Treasury stock, at cost: 79,545 shares held at June 30, 2021 and December 31, 2020	(8,034)	(8,034)
Accumulated other comprehensive income	1,159	589
Accumulated deficit	(590,263)	(570,501)
Total stockholders' equity	94,800	81,540
Total liabilities, redeemable noncontrolling interest and stockholders' equity	$ 144,526	$ 127,734

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

	Three Months Ended June 30		Six Months Ended June 30	
	2021	2020	2021	2020
Revenues:				
Product sales	$ 7,125	$ 2,638	$ 12,825	$ 6,010
Lease income	37	33	73	67
Total revenues	7,162	2,671	12,898	6,077
Costs and expenses:				
Costs of revenues	2,982	2,517	5,340	5,728
Research and development	2,255	1,862	7,513	4,879
General and administrative	5,423	4,085	10,925	8,143
Selling and marketing	3,360	1,557	6,075	2,817
Loss on disposal of property, plant, equipment	65	—	65	—
Gain on disposal of intangible assets	—	—	—	(450)
Impairment of intangible assets	—	1,537	—	1,537
Acquired in-process research and development	1,055	—	6,555	1,081
Total costs and expenses	15,140	11,558	36,473	23,735
Loss from operations	(7,978)	(8,887)	(23,575)	(17,658)
Non-operating income/(expense):				
Interest income, net	76	153	182	343
Other income	33	27	53	27
Foreign exchange gains (losses)	76	(115)	295	248
Change in fair value of investments	1,914	324	3,482	309
Impairment loss of long-term investments	(865)	—	(865)	—
Net loss	(6,744)	(8,498)	(20,428)	(16,731)
Less: loss attributable to redeemable noncontrolling interest	(317)	(166)	(666)	(275)
Accretion to redeemable noncontrolling interest redemption value	519	362	1,067	679
Net loss attributable to CASI Pharmaceuticals, Inc.	$ (6,946)	$ (8,694)	$ (20,829)	$ (17,135)
Net loss per share (basic and diluted)	$ (0.05)	$ (0.09)	$ (0.16)	$ (0.17)
Weighted average number of common shares outstanding (basic and diluted)	139,797,487	100,921,137	132,352,399	99,847,186
Comprehensive loss:				
Net loss	$ (6,744)	$ (8,498)	$ (20,428)	$ (16,731)
Foreign currency translation adjustment	1,005	(336)	833	(1,162)
Total comprehensive loss	$ (5,739)	$ (8,834)	$ (19,595)	$ (17,893)
Less: Comprehensive loss attributable to redeemable noncontrolling interest	14	(166)	(403)	(275)
Comprehensive loss attributable to common stockholders	$ (5,753)	$ (8,668)	$ (19,192)	$ (17,618)