

CASI PHARMACEUTICALS ANNOUNCES THIRD QUARTER 2020 FINANCIAL RESULTS

*- EVOMELA Third Quarter 2020 Revenue Exceeds Expectations; Company Increasing
EVOMELA Full-Year Revenue Guidance for 2020 –*

*- Expands Pipeline with First-In-Class Anti-FcyRIIB Monoclonal Antibody with
Potential Application Across Multiple Tumor Types –*

*-Co-Commercial Clinical Asset, CNCT-19 (CD19 CAR-T), Phase 1 Enrollment Progressing Ahead
of Schedule; Registration Trials Now Expected to Be Initiated by the end of 2020 -*

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

ROCKVILLE, MD., and BEIJING (November 9, 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 third quarter of 2020.

Wei-Wu He, Ph.D., CASI's Chairman and Chief Executive Officer, commented, "We are pleased to report that EVOMELA revenues for Q3 were \$4.2 million. For the full year 2020 revenue, we expect to exceed \$14 million, performing better than we had previously forecasted. We are thrilled with the progress we are seeing across our hematology oncology product portfolio. With our recently announced partnership with BioInvent, we gained exclusive Greater China development and commercialization rights to BI-1206, a first-in-class anti-FcyRIIB monoclonal antibody. BI-1206 has broad potential clinical applications across multiple tumor types in many first line indications and in refractory settings, which we look forward to exploring."

Dr. He continued, "With respect to our commercial asset CNCT-19 (CD19 CAR-T), our partner Juventas is making good progress with their current Phase 1 trials in B-NHL and B-ALL, and is expecting to initiate registration trials by the end of 2020. We expect to initiate our Phase 1 study for CID-103 (anti-CD38 monoclonal antibody) in the EU during the first quarter of 2021. We will continue to execute on a number of key milestones across our broad portfolio in the quarters ahead. In parallel, our team will continue tactically evaluating additional strategic opportunities that complement our growing portfolio."

Third Quarter 2020 Financial Results

- Revenues consisted primarily of product sales of EVOMELA that launched in August of 2019. Revenues were \$4.2 million for the three months ended September 30, 2020 compared to \$2.7 million for the three months ended September 30, 2019.
- Costs of revenues were \$1.8 million for the three months ended September 30, 2020 compared to \$2.6 million for the three months ended September 30, 2019. The decrease in cost of revenues is a result of the transfer to a new manufacturer, resulting in a considerable decrease in the unit cost of inventories of EVOMELA.
- Research and development expenses for the three months ended September 30, 2020 were \$2.8 million, compared with \$1.8 million for the three months ended September 30, 2019. The increases

in R&D expenses are primarily due to increases in 2020 R&D expenses incurred related to the development of CID-103, and costs associated with the EVOMELA post marketing study.

- General and administrative expenses for the three months ended September 30, 2020 were \$5.3 million, compared with \$8.0 million for the three months ended September 30, 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 for the three months ended September 30, 2020 were \$2.1 million, compared with \$975,000 for the three months ended September 30, 2019. 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 September 30, 2020 was \$10.9 million, compared to \$0 million for the three months ended September 30, 2019. Expense of \$0.6 million relates to 2020 milestone fees paid to Pharmathen due to the first submission to the National Medical Products Administration in China for Octreotide which was achieved during 2020 and \$10.3 million relates to milestone fees paid to Juventas.
- Net loss for the third quarter of 2020 was \$16.8 million compared to \$9.7 million for the same period in 2019.
- As of September 30, 2020, the Company had cash and cash equivalents of \$74.6 million compared to \$44.9 million as of June 30, 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 September 30, 2020, can be found at www.casipharmaceuticals.com.

Conference Call

The Company will host a conference call reviewing the third 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), (580) 86567 (Hong Kong) to listen to the live conference call. The conference ID number for the live call is 8835514.

This call will be recorded and available for replay by dialing (855) 589-2056 (U.S.) or (404)-537-3406 (international) and enter 8835514 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., 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. 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.

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

<u>COMPANY CONTACT:</u> <i>CASI Pharmaceuticals, Inc.</i> 240.864.2643 ir@casipharmaceuticals.com	<u>INVESTOR CONTACT:</u> <i>Solebury Trout</i> Jennifer Porcelli 646.378.2962 jporcelli@troutgroup.com
--	--

###

(Financial Table Follows)

CASI Pharmaceuticals, Inc.

Unaudited Condensed Consolidated Balance Sheets

(In thousands, except share and per share data)

	<u>September 30, 2020</u>	<u>December 31, 2019</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 74,592	\$ 53,621
Investment in equity securities, at fair value	1,796	625
Accounts receivable, net of \$0 allowance for doubtful accounts	4,078	1,293
Inventories	720	4,542
Prepaid expenses and other	1,794	1,420
Assets held-for-sale	298	3,221
Total current assets	<u>83,278</u>	<u>64,722</u>
Property and equipment, net	984	985
Intangible assets, net	13,015	13,674
Long-term investments	27,569	14,038
Right of use assets	9,015	8,708
Other assets	377	504
Total assets	<u>\$ 134,238</u>	<u>\$ 102,631</u>
LIABILITIES, REDEEMABLE NONCONTROLLING INTEREST AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,697	\$ 5,113
Accrued and other current liabilities	2,858	2,834
Total current liabilities	<u>5,555</u>	<u>7,947</u>
Deferred income	2,270	—
Other liabilities	13,615	1,019
Total liabilities	<u>21,440</u>	<u>8,966</u>
Commitments and contingencies		
Redeemable noncontrolling interest, at redemption value	21,271	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	656,639	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	(1,507)	(2,728)
Accumulated deficit	<u>(556,811)</u>	<u>(523,908)</u>

Total stockholders' equity	91,527	72,995
Total liabilities, redeemable noncontrolling interest and stockholders' equity	\$ 134,238	\$ 102,631

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

	Three Months Ended September 30		Nine Months Ended September 30	
	2020	2019	2020	2019
Revenues:				
Product sales	\$ 4,205	\$ 2,749	\$ 10,215	\$ 2,749
Lease income	37	38	104	38
Total revenues	<u>4,242</u>	<u>2,787</u>	<u>10,319</u>	<u>2,787</u>
Costs and expenses:				
Costs of revenues	1,828	2,648	7,556	2,648
Research and development	2,803	1,829	7,682	7,375
General and administrative	5,347	7,977	13,490	20,669
Selling and marketing	2,062	975	4,879	975
(Gain) loss on disposal of intangible assets	—	—	(450)	48
Impairment of intangible assets	—	—	1,537	—
Acquired in-process research and development	10,862	—	11,943	5,849
Total costs and expenses	<u>22,902</u>	<u>13,429</u>	<u>46,637</u>	<u>37,564</u>
Loss from operations	(18,660)	(10,642)	(36,318)	(34,777)
Non-operating income/(expense):				
Interest income, net	432	414	775	783
Other income	20	—	47	—
Foreign exchange (losses) gains	(526)	719	(278)	1,269
Change in fair value of investment in equity securities	1,978	(160)	2,287	(355)
Net loss	<u>(16,756)</u>	<u>(9,669)</u>	<u>(33,487)</u>	<u>(33,080)</u>
Less: (loss)/ income attributable to redeemable noncontrolling interest	(309)	(23)	(584)	53
Accretion to redeemable noncontrolling interest redemption value	506	245	1,185	406
Net loss attributable to CASI Pharmaceuticals, Inc.	<u>\$ (16,953)</u>	<u>\$ (9,891)</u>	<u>\$ (34,088)</u>	<u>\$ (33,539)</u>
Net loss per share (basic and diluted)	<u>\$ (0.14)</u>	<u>\$ (0.10)</u>	<u>\$ (0.32)</u>	<u>\$ (0.35)</u>
Weighted average number of common shares outstanding (basic and diluted)	<u>117,940</u>	<u>95,891</u>	<u>105,922</u>	<u>95,753</u>
Comprehensive loss:				
Net loss	\$ (16,756)	\$ (9,669)	\$ (33,487)	\$ (33,080)
Foreign currency translation adjustment	2,383	(1,836)	1,221	(2,636)
Total comprehensive loss	<u>\$ (14,373)</u>	<u>\$ (11,505)</u>	<u>\$ (32,266)</u>	<u>\$ (35,716)</u>
Less: Comprehensive (loss)/income attributable to redeemable noncontrolling interest	(309)	(23)	(584)	53
Comprehensive loss attributable to common stockholders	<u>\$ (14,064)</u>	<u>\$ (11,482)</u>	<u>\$ (31,682)</u>	<u>\$ (35,769)</u>