

**CASI PHARMACEUTICALS ANNOUNCES
THIRD QUARTER 2021 FINANCIAL RESULTS**

- *EVOMELA Third Quarter 2021 Revenue Continues Strong Upward Trend –*
- *Additional Positive Clinical Data on BI-1206 -*
- *Partner Juventas completed Series C financing round RMB410 million (approximately \$63 million USD) -*
- *Company to host Conference Call Today at 8:00 AM. ET -*

ROCKVILLE, MD. and BEIJING, China (November 12, 2021) CASI Pharmaceuticals, Inc. (Nasdaq: CASI), is a U.S. biopharmaceutical company focused on developing and commercializing innovative therapeutics and pharmaceutical products, today reported financial results for the third quarter of 2021.

Wei-Wu He, Ph.D., CASI’s Chairman and Chief Executive Officer, commented, “We are pleased to report \$8.1 million in EVOMELA® revenues for the quarter. We remain confident in our guidance for our full-year 2021 revenue growth to exceed 2020 revenues by over 80%. This continued growth further demonstrates our 100+ person sales and marketing team’s ability to cover all major hospitals and key multiple myeloma transplant physicians. We look forward to leveraging this success in the anticipated launch of our next product, Juventas’ CNCT-19, which our partner announced has officially entered phase II of a registered clinical trial, and other products.”

Dr. He continued, “Our partner BioInvent announced additional positive, interim top-line data from the Phase 1/2a clinical trial of its novel anti-FcγRIIB antibody BI-1206 in combination with rituximab (anti-CD20 monoclonal antibody) for the treatment of patients with indolent relapsed or refractory B-cell non-Hodgkin's lymphoma (NHL). BI-1206, in combination with rituximab, demonstrated an objective response rate (ORR) of 50%, with three complete responses and three partial responses seen in twelve patients evaluated for therapeutic benefit. The treatment stabilized the disease in one additional patient, giving a disease control rate of 58% (7 out of 12 patients). We believe BI-1206 has potential application across multiple tumor types in both first-line treatments and relapsed/refractory settings. Additionally, our CNCT-19 CAR-T partner, Juventas, completed a Series C financing round through which it raised more than RMB410 million (approximately \$63 million USD). CASI has a 12.01% ownership stake in Juventas and shares global co-commercial and profit-sharing rights for CNCT-19 with Juventas. We believe this financing will allow Juventas to continue the rapid development and registration of CNCT-19 in China. Overall, we are pleased with our momentum and will continue to execute on key milestones across our broad portfolio in the quarters ahead.”

Third Quarter 2021 Financial Results

- Revenues consist of product sales of EVOMELA that launched during August 2019. Revenue was \$8.1 million for the three months ended September 30, 2021 compared to \$4.2 million for the three months ended September 30, 2020. Revenues increased by 93% in the third quarter of 2021 as compared to same quarter in 2020 due to the continued strong growth in EVOMELA sales.
- Costs of revenues were \$3.4 million for the three months ended September 30, 2021, compared to \$1.8 million for the three months ended September 30, 2020, which includes royalty payment of \$1.6 million and \$0.8 million for the same period. Costs of revenues excluding royalty were \$1.8 million and \$1.0 million for the three months ended September 30, 2021, and 2020. Costs of revenues, excluding royalty as a percentage of revenues, decreased significantly in the three months ended September 30, 2021, compared within the three months ended September 30, 2020, due to the alternate manufacturer in place, resulting in a considerable decrease in the unit cost of inventories of EVOMELA.
- General and administrative expenses for the three months ended September 30, 2021 were \$5.3 million, compared with \$5.3 million for the three months ended September 30, 2020.
- Selling and marketing expenses for the three months ended September 30, 2021 were \$3.4 million, compared with \$2.1 million for the three months ended September 30, 2020. The increase in selling and marketing expenses was due to expansion of sales team in China in 2021.

- R&D expenses for the three months ended September 30, 2021 were \$2.9 million, compared to \$2.8 million for the three months ended September 30, 2020.
- Net loss for the three months ended September 30, 2021 was \$10 million compared to \$16.7 million for the three months ended September 30, 2020 due to the increase in revenues. As of September 30, 2021, CASI had cash and cash equivalents of \$53.1 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 conference call can be accessed by dialing 1-877-870-4263 (U.S.) or 1-412-317-0790 (international) and ask to be joined into the CASI Pharmaceuticals call to listen to the live conference call.

This call will be recorded and available for replay by dialing 1-877-344-7529 (U.S.) or 1-412-317-0088 (international) and enter 10160251 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 100 hematology 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)

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

	<u>September 30, 2021</u>	<u>December 31, 2020</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 53,126	\$ 57,064
Investment in equity securities, at fair value	9,503	9,309
Accounts receivable, net of \$0 allowance for doubtful accounts	5,418	4,645
Inventories	1,727	1,356
Prepaid expenses and other	2,190	1,651
Total current assets	<u>71,964</u>	<u>74,025</u>
Property, plant and equipment, net	6,778	2,062
Intangible assets, net	12,358	13,210
Long-term investments	34,177	29,442
Right of use assets	9,499	8,696
Other assets	1,498	299
Total assets	<u>\$ 136,274</u>	<u>\$ 127,734</u>
LIABILITIES, REDEEMABLE NONCONTROLLING INTEREST AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 6,324	\$ 3,669
Accrued and other current liabilities	2,550	3,015
Bank borrowings	1,084	826
Notes payable	—	466
Total current liabilities	<u>9,958</u>	<u>7,976</u>
Deferred income	2,342	2,351
Other liabilities	14,460	13,834
Total liabilities	<u>26,760</u>	<u>24,161</u>
Commitments and contingencies (Note 18)		
Redeemable noncontrolling interest, at redemption value (Note 11)	22,907	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 September 30, 2021 and December 31, 2020 139,877,032 shares and 124,023,374 shares issued at September 30, 2021 and December 31, 2020, respectively; 139,797,487 shares and 123,943,829 shares outstanding at September 30, 2021 and December 31, 2020, respectively	1,399	1,240
Additional paid-in capital	692,041	658,246
Treasury stock, at cost: 79,545 shares held at September 30, 2021 and December 31, 2020	(8,034)	(8,034)
Accumulated other comprehensive income	1,169	589
Accumulated deficit	(599,968)	(570,501)
Total stockholders' equity	<u>86,607</u>	<u>81,540</u>
Total liabilities, redeemable noncontrolling interest and stockholders' equity	<u>\$ 136,274</u>	<u>\$ 127,734</u>

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

	Three Months Ended September 30		Nine Months Ended September 30	
	2021	2020	2021	2020
Revenues:				
Product sales	\$ 8,075	\$ 4,205	\$ 20,900	\$ 10,215
Lease income	37	37	110	104
Total revenues	8,112	4,242	21,010	10,319
Costs of revenues:				
Cost of goods sold	1,831	1,012	4,625	5,549
Royalty fee	1,586	816	4,132	2,006
Total costs of revenues	3,417	1,828	8,757	7,556
Operating expenses:				
Research and development	2,895	2,803	10,408	7,682
General and administrative	5,259	5,347	16,184	13,490
Selling and marketing	3,433	2,062	9,508	4,879
Loss on disposal of property, plant, equipment	—	—	65	—
Gain on disposal of intangible assets	—	—	—	(450)
Impairment of intangible assets	—	—	—	1,537
Acquired in-process research and development	—	10,862	6,555	11,943
Total operating expenses	11,587	21,074	42,720	39,081
Loss from operations	(6,892)	(18,660)	(30,467)	(36,318)
Non-operating income/(expense):				
Interest income, net	79	432	261	775
Other income	487	20	540	47
Foreign exchange gains (losses)	(6)	(526)	289	(278)
Change in fair value of investments	(3,687)	1,978	(205)	2,287
Impairment loss of long-term investments	—	—	(865)	—
Net loss	(10,019)	(16,756)	(30,447)	(33,487)
Less: loss attributable to redeemable noncontrolling interest	(314)	(309)	(980)	(584)
Accretion to redeemable noncontrolling interest redemption value	519	506	1,586	1,185
Net loss attributable to CASI Pharmaceuticals, Inc.	\$ (10,224)	\$ (16,953)	\$ (31,053)	\$ (34,088)
Net loss per share (basic and diluted)	\$ (0.07)	\$ (0.14)	\$ (0.23)	\$ (0.32)
Weighted average number of common shares outstanding (basic and diluted)	139,797,487	117,940,405	134,861,366	105,922,281
Comprehensive loss:				
Net loss	\$ (10,019)	\$ (16,756)	\$ (30,447)	\$ (33,487)
Foreign currency translation adjustment	15	2,383	848	1,221
Total comprehensive loss	\$ (10,004)	\$ (14,373)	\$ (29,599)	\$ (32,266)
Less: Comprehensive loss attributable to redeemable noncontrolling interest	(309)	(309)	(712)	(584)
Comprehensive loss attributable to common stockholders	\$ (9,695)	\$ (14,064)	\$ (28,887)	\$ (31,682)