



## **CASI PHARMACEUTICALS ANNOUNCES FIRST QUARTER 2022 FINANCIAL RESULTS**

**ROCKVILLE, MD. and BEIJING, China (May 12, 2022)** 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 first quarter of 2022.

Wei-Wu He, Ph.D., CASI's Chairman and Chief Executive Officer, commented, "We are pleased to report \$9.0 million in EVOMELA<sup>®</sup> sales revenue for the first quarter of 2022. This is an increase of 58% compared to the same period last year. Our first commercial product, EVOMELA has been instrumental in treating patients with multiple myeloma prior to stem cell transplantation in China. We have achieved our goal for full-year 2021 EVOMELA revenue to reach 100% growth. Our achievements in 2021 provide a great foundation that we plan to build upon throughout 2022 and beyond."

Dr. He continued, "Our strategic focus in 2022 will continue to advance the development and commercialization of the portfolio. Through our partner Juventas, the CNCT-19 NDA submission to the National Medical Products Administration (NMPA) is on track, and we are in preparation for the anticipated launch in China; We expect the start of the BI-1206 phase I trial in China; We expect CB-5339 to receive Clinical Trial Application approval from the NMPA during 2022; Meanwhile, our CID-103's Phase I study continues. We are excited by our momentum and will continue to execute on several key milestones across our broad portfolio in the quarters ahead."

### **First Quarter 2022 Financial Highlights**

- Revenues consist primarily of product sales of EVOMELA. Revenue was \$9.0 million for the three months ended March 31, 2022, compared to \$5.7 million for the three months ended March 31, 2021.
- Costs of revenues were \$3.8 million for the three months ended March 31, 2022, compared to \$2.4 million for the three months ended March 31, 2021, which included royalty payment of \$1.8 million and \$1.1 million, respectively.
- Research and development expenses for the three months ended March 31, 2022, were \$4.0 million, compared with \$5.3 million for the three months ended March 31, 2021.
- General and administrative expenses for the three months ended March 31, 2022, were \$5.3 million, compared with \$5.5 million for the three months ended March 31, 2021.
- Selling and marketing expenses for the three months ended March 31, 2022, were \$3.3 million, compared with \$2.7 million for the three months ended March 31, 2021.
- As of March 31, 2022, CASI had cash and cash equivalent of \$29.3 million.

Further information regarding the Company, including its Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, can be found at [www.casipharmaceuticals.com](http://www.casipharmaceuticals.com).

### **Conference Call**

The conference call can be accessed by dialing 1-866-218-2402 (U.S.) or 1-412-902-6605 (international) and ask to be joined into the CASI Pharmaceuticals call to listen to the live conference call. Confirmation #: 10165613

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 2360248 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 majority of the Company's operations are now located in China. 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 is executing its plan to become a biopharmaceutical leader by launching medicines in the greater China market, leveraging its China-based regulatory, clinical 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., located in Beijing, China. The Company has built a commercial team of more than 100 hematology and oncology sales and marketing specialists based in China. More information on CASI is available at [www.casipharmaceuticals.com](http://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, including with respect to BI-1206, CB-5339 and CID-103; 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, including with respect to our partnerships with Juventas and BioInvent; 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](http://www.sec.gov).

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

COMPANY CONTACT:

Rui Zhang  
*CASI Pharmaceuticals, Inc.*  
240.864.2643  
ir@casipharmaceuticals.com

INVESTOR CONTACT:

Xuan Yang  
*Solebury Trout*  
646.378.2975  
xyang@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)

	<u>March 31, 2022</u>	<u>December 31, 2021</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 29,259	\$ 38,704
Investment in equity securities, at fair value	8,225	9,868
Accounts receivable, net of \$0 allowance for doubtful accounts	10,086	9,803
Inventories	3,721	1,907
Prepaid expenses and other	1,404	1,688
Total current assets	<u>52,695</u>	<u>61,970</u>
Property, plant and equipment, net	14,580	12,712
Intangible assets, net	11,900	12,203
Long-term investments	40,320	40,128
Right of use assets	8,809	9,107
Other assets	1,260	2,178
Total assets	<u>\$ 129,564</u>	<u>\$ 138,298</u>
<b>LIABILITIES, REDEEMABLE NONCONTROLLING INTEREST AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 7,171	\$ 4,789
Accrued and other current liabilities	6,701	8,397
Total current liabilities	<u>13,872</u>	<u>13,186</u>
Deferred income	2,821	2,828
Other liabilities	14,156	14,325
Total liabilities	<u>30,849</u>	<u>30,339</u>
Commitments and contingencies		
Redeemable noncontrolling interest, at redemption value	23,726	23,457
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 March 31, 2022 and December 31, 2021		
137,335,787 shares and 139,877,032 shares issued at March 31, 2022 and December 31, 2021, respectively;		
136,062,495 shares and 139,797,487 shares outstanding at March 31, 2022 and December 31, 2021, respectively	1,374	1,399
Additional paid-in capital	694,180	694,826
Treasury stock, at cost: 1,273,292 shares and 79,545 shares held at March 31, 2022 and December 31, 2021	(9,068)	(8,034)
Accumulated other comprehensive income	2,129	1,954
Accumulated deficit	(613,626)	(605,643)
Total stockholders' equity	<u>74,989</u>	<u>84,502</u>
Total liabilities, redeemable noncontrolling interest and stockholders' equity	<u>\$ 129,564</u>	<u>\$ 138,298</u>

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

	<b>Three Months Ended March 31</b>	
	<b>2022</b>	<b>2021</b>
<b>Revenues:</b>		
Product sales	\$ 9,025	\$ 5,700
Lease income from a related party	37	36
<b>Total revenues</b>	<b>9,062</b>	<b>5,736</b>
<b>Costs of revenues:</b>		
Cost of goods sold	1,977	1,237
Royalty fee	1,781	1,121
<b>Total costs of revenues</b>	<b>3,758</b>	<b>2,358</b>
<b>Gross Profit</b>	<b>5,304</b>	<b>3,378</b>
<b>Operating expenses:</b>		
Research and development	3,992	5,258
General and administrative	5,325	5,502
Selling and marketing	3,277	2,715
Acquired in-process research and development	—	5,500
<b>Total operating expenses</b>	<b>12,594</b>	<b>18,975</b>
<b>Loss from operations</b>	<b>(7,290)</b>	<b>(15,597)</b>
<b>Non-operating income (expense):</b>		
Interest income, net	74	106
Other income	38	20
Foreign exchange gain	333	219
Change in fair value of investments	(1,555)	1,568
<b>Loss before income tax expense</b>	<b>(8,400)</b>	<b>(13,684)</b>
Income tax expense	—	—
<b>Net loss</b>	<b>(8,400)</b>	<b>(13,684)</b>
Less: loss attributable to redeemable noncontrolling interest	(417)	(349)
Accretion to redeemable noncontrolling interest redemption value	613	548
<b>Net loss attributable to CASI Pharmaceuticals, Inc.</b>	<b>\$ (8,596)</b>	<b>\$ (13,883)</b>
<b>Net loss per share (basic and diluted)</b>	<b>\$ (0.06)</b>	<b>\$ (0.11)</b>
<b>Weighted average number of common stock outstanding (basic and diluted)</b>	<b>137,955,910</b>	<b>124,824,588</b>
<b>Comprehensive loss:</b>		
Net loss	\$ (8,400)	\$ (13,684)
Foreign currency translation adjustment	248	(172)
<b>Total comprehensive loss</b>	<b>\$ (8,152)</b>	<b>\$ (13,856)</b>
Less: Comprehensive loss attributable to redeemable noncontrolling interest	(344)	(417)
<b>Comprehensive loss attributable to common stockholders</b>	<b>\$ (7,808)</b>	<b>\$ (13,439)</b>