



DIVISION OF
CORPORATION FINANCE

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

January 6, 2023

Larry Zhang
Principal Financial Officer
CASI Pharmaceuticals, Inc.
9620 Medical Center Drive
Suite 300
Rockville, MD 20850

Re: CASI Pharmaceuticals, Inc.
Form 10-K for the Fiscal Year Ended December 31, 2021
Form 10-Q for the Interim Period Ended September 30, 2022
File No. 000-20713

Dear Larry Zhang:

We have reviewed your December 16, 2022 response to our comment letter and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to these comments within ten business days by providing the requested information or advise us as soon as possible when you will respond. If you do not believe our comments apply to your facts and circumstances, please tell us why in your response.

After reviewing your response to these comments, we may have additional comments. Unless we note otherwise, our references to prior comments are to comments in our December 7, 2022 letter.

Form 10-K for the Fiscal Year Ended December 31, 2021

Part I

Item 1. Business, page 4

1. We note your proposed revisions in response to prior comment 1. In future filings, please revise the diagram of your corporate structure to indicate who owns the remaining 20% of CASI Pharmaceuticals (Wuxi) Co., Ltd.
2. We note your proposed revisions to the risk factors section in response to prior comment 2. In future filings, please also revise Item 1. Business to provide prominent disclosure about the legal and operational risks associated with being based in or having the majority of the company's operations in China. Your disclosure should make clear whether these

risks could result in a material change in your operations and/or the value of your securities or could significantly limit or completely hinder your ability to offer or continue to offer securities to investors and cause the value of such securities to significantly decline or be worthless. Your disclosure should address how recent statements and regulatory actions by China's government, such as those related to data security or anti-monopoly concerns, have or may impact the company's ability to conduct its business, accept foreign investments, or list on a U.S. or other foreign exchange.

3. We note your proposed revisions to the risk factors section in response to prior comment 3. In future filings, please also revise Item 1. Business to prominently disclose that your auditor is subject to the determinations announced by the PCAOB on December 16, 2021 and disclose whether and how the Holding Foreign Companies Accountable Act and related regulations will affect your company. In addition, disclose that trading in your securities may be prohibited under the Holding Foreign Companies Accountable Act if the PCAOB determines that it cannot inspect or investigate completely your auditor, and that as a result an exchange may determine to delist your securities.
4. We note your proposed revisions in response to prior comment 4. In future filings, please also revise Item 1. Business to provide a clear description of how cash is transferred through your organization. Disclose your intentions to distribute earnings. Quantify any cash flows and transfers of other assets by type that have occurred between the holding company and its subsidiaries, and direction of transfer. Quantify any dividends or distributions that a subsidiary has made to the holding company and which entity made such transfer, and their tax consequences. Similarly quantify dividends or distributions made to U.S. investors, the source, and their tax consequences. Your disclosure should make clear if no transfers, dividends, or distributions have been made to date. Describe any restrictions on foreign exchange and your ability to transfer cash between entities, across borders, and to U.S. investors. Describe any restrictions and limitations on your ability to distribute earnings from the company, including your subsidiaries, to the parent company and U.S. investors. We also note your disclosure that CASI Pharmaceuticals, Inc. paid service fees of \$19.5 million to CASI Pharmaceuticals (China) Co., Ltd. in the year ended December 31, 2021 and that no assets other than cash were transferred through the organization during that time. Please revise to make it clear whether the service fees were the only cash that was transferred during the fiscal year. If not, please specifically disclose the other transfers that were made.
5. We note your proposed revisions to the risk factors section in response to prior comment 5. In future filings, please also revise Item 1. Business to disclose each permission or approval that you or your subsidiaries are required to obtain from Chinese authorities to operate your business and to offer securities to foreign investors. State whether you or your subsidiaries are covered by permissions requirements from the China Securities Regulatory Commission (CSRC), Cyberspace Administration of China (CAC) or any other governmental agency that is required to approve your operations, and state affirmatively whether you have received all requisite permissions or approvals and

whether any permissions or approvals have been denied. Please also describe the consequences to you and your investors if you or your subsidiaries: (i) do not receive or maintain such permissions or approvals, (ii) inadvertently conclude that such permissions or approvals are not required, or (iii) applicable laws, regulations, or interpretations change and you are required to obtain such permissions or approvals in the future.

Item 1 A. Risk Factors, page 20

6. We note your proposed revision to add a risk factor in response to prior comment 6 and re-issue. In your summary of risk factors, disclose the risks that your corporate structure and being based in or having the majority of the company's operations in China poses to investors. In particular, describe the significant regulatory, liquidity, and enforcement risks. For example, specifically discuss risks arising from the legal system in China, including risks and uncertainties regarding the enforcement of laws and that rules and regulations in China can change quickly with little advance notice; and the risk that the Chinese government may intervene or influence your operations at any time, or may exert more control over offerings conducted overseas and/or foreign investment in China-based issuers, which could result in a material change in your operations and/or the value of your securities. Acknowledge any risks that any actions by the Chinese government to exert more oversight and control over offerings that are conducted overseas and/or foreign investment in China-based issuers could significantly limit or completely hinder your ability to offer or continue to offer securities to investors and cause the value of your securities to significantly decline or be worthless.

General

7. Please provide us with a copy of your proposed disclosure for comments one through six in your response letter.

You may contact Christine Torney at 202-551-3652 or Kevin Vaughn at 202-551-3494 if you have questions regarding comments on the financial statements and related matters. Please contact Ada Sarmento at 202-551-3798 or Joe McCann at 202-551-6262 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences