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CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2616)

DISCLOSEABLE TRANSACTION IN RELATION TO THE ASSET PURCHASE AGREEMENT

ASSET PURCHASE AGREEMENT

On December 20, 2023 (Central European Time) (being December 21, 2023 Hong Kong time), CStone Suzhou, a wholly-owned subsidiary of the Company, and Les Laboratoires Servier entered into the Asset Purchase Agreement, which provides, among other things, that CStone will sell and Servier will purchase the CStone Ivosidenib Business and any goodwill thereof, including the Transferred Assets, for cash consideration of up to US\$50 million. Simultaneously with the Asset Purchase Agreement, CStone and Servier have entered into the Transition Plan Agreement, pursuant to which CStone has committed to provide certain deliverables to Servier in connection with the consummation of the Transaction in order to achieve an orderly transfer of the CStone Ivosidenib Business.

To the best of the Directors' knowledge, information and belief, having made all reasonable enquiry, as of the date of this announcement, Servier and its ultimate beneficial owners are third parties independent of the Company and its connected persons (as defined in the Listing Rules).

LISTING RULES IMPLICATIONS

As the highest applicable percentage ratio calculated in accordance with Chapter 14 of the Listing Rules for the Transaction exceeds 5% but is less than 25%, the Transaction constitutes a discloseable transaction of the Company under Chapter 14 of the Listing Rules and is subject to the reporting and announcement requirements under the Listing Rules but not subject to the circular and shareholders' approval requirements thereunder.

DISCLOSEABLE TRANSACTION

INTRODUCTION

The Board is pleased to announce that, on December 20, 2023 (Central European Time) (being December 21, 2023 Hong Kong time), CStone Suzhou, a wholly-owned subsidiary of the Company, and Les Laboratoires Servier entered into the Asset Purchase Agreement, which provides, among other things, that CStone will sell and Servier will purchase the CStone Ivosidenib Business and any goodwill thereof, including the Transferred Assets, for cash consideration of up to US\$50 million, as discussed below. Simultaneously with the Asset Purchase Agreement, CStone and Servier have entered into the Transition Plan Agreement, pursuant to which CStone has committed to provide certain deliverables to Servier in connection with the consummation of the Transaction in order to achieve an orderly transfer of the CStone Ivosidenib Business.

PRINCIPAL TERMS OF THE ASSET PURCHASE AGREEMENT

The terms of the Asset Purchase Agreement have been arrived at after arm's length negotiations between the parties on normal commercial terms, and the principal terms thereof are set out below.

Date: December 20, 2023 (Central European Time) (being December 21, 2023 Hong Kong time)

Parties: (i) CStone Suzhou; and
(ii) Les Laboratoires Servier.

To the best of the Directors' knowledge, information and belief, having made all reasonable enquiry, as of the date of this announcement, Les Laboratoires Servier and its ultimate beneficial owners are third parties independent of the Company and its connected persons (as defined in the Listing Rules).

Nature of the Transaction

The Company entered into the Ivosidenib License Agreement with Agios in June 2018. For a description of the principal terms of the Ivosidenib License Agreement, please refer to the discussion in the Prospectus under the heading "Business – Collaboration and Licensing Agreements – Collaboration with Agios." Thereafter, in April 2021, Agios completed the sale of its commercial, clinical and research-stage oncology portfolio to Servier, including Agios' rights and obligations under the Ivosidenib License Agreement. In 2023, the Company and Servier entered into negotiations concerning potential transfer of the CStone Ivosidenib Business.

Pursuant to the Asset Purchase Agreement, CStone will sell and Servier will purchase the CStone Ivosidenib Business and any goodwill thereof, including the Transferred Assets, and CStone has agreed to provide certain deliverables to Servier in accordance with the Transition Plan Agreement.

For details concerning the development of ivosidenib, please refer to the interim report published by the Company on September 25, 2023.

Consideration

In consideration for CStone's entry into and performance of the Asset Purchase Agreement, Servier has agreed (i) to pay an aggregated sum of US\$44 million to CStone within one (1) day of the Effective Date and if such date is not a Business Day, on the next Business Day; and (ii) subject to and within ten (10) Business Days following completion of the orderly transfer of the CStone Ivosidenib Business in accordance with the Transition Plan Agreement, to pay a maximum amount of US\$6 million to CStone.

Basis of Consideration

The amounts of the payments due under the Asset Purchase Agreement were determined after arm's length negotiations between the Company and Servier on normal commercial terms. In arriving at its decision, the Board considered the following principal factors, among others: (i) the relative capabilities and status of the Company and Servier as the best partners to expand indications of and maximize patient access to ivosidenib in the Territory; (ii) the historical revenue and profit attributable to ivosidenib since its commercialization; (iii) the future commercial value of ivosidenib including revenue potential, costs and risks associated with the commercialization; (iv) the historical investment made by the Company related to ivosidenib; (v) the substantial after-tax proceeds to be received by the Company in the Transaction; and (vi) the types of deliverables to be provided by CStone under the Transition Plan Agreement and the costs involved.

To reflect the above factors in the total consideration, the Board specifically considered, among others, the following items:

- (i) the overall value of commercializing ivosidenib in the Territory, including revenue potential of ivosidenib in the Territory, net of drug supply costs for commercialization, royalty expenses, and the sales and marketing-related expenses;
- (ii) total upfront payments and milestone payments paid by the Group under the Ivosidenib License Agreement in an aggregate amount equivalent to US\$24 million;
- (iii) expenses incurred for the development and commercialization of ivosidenib after entry into the Ivosidenib License Agreement in 2018, including but not limited to the costs and expenses relating to (a) labour costs related to clinical development of ivosidenib; (b) the conducting of registrational clinical trials, regulatory filings and submission, and other expenses relating to drug registration, etc.; (c) the engagement of third party vendors, including but not limited to contract research organizations; and (d) commercialization infrastructure; and
- (iv) future expenses to further develop and commercialize ivosidenib, e.g., the costs and expenses to conduct additional trials in the Territory for indication expansions, as well as potential future development milestone payments.

To further illustrate the basis of consideration, the Board considered (a) the future revenue potential to be realized by ongoing commercialization of ivosidenib (the “**Future Revenue**”); (b) the expenses incurred for the development and commercialization of ivosidenib (the “**Incurred Expenses**”), which consist of items (ii) and (iii) above; and (c) the future expenses to be incurred or allocated to the development and commercialization of ivosidenib (the “**Future Expenses**”), which consists of item (iv) above. All these along with other factors mentioned above constitute the basis for determining the consideration. In addition, the Board also specifically took into account the clinical and regulatory achievements of ivosidenib, which have been reflected in the Incurred Expenses.

The Group expects to utilize the consideration to be received to extend additional operating runway and prioritize its resources on the development of other pipeline assets, as disclosed below under the heading “Use of Proceeds from the Transaction.” Additional reasons for and benefits of the Transaction are set out in the paragraph headed “Reasons for and Benefits of Entering into the Transaction” below.

Transfer of the CStone Ivosidenib Business

Subject to the exclusion of certain liabilities as set out in the Asset Purchase Agreement, on the Effective Date, CStone shall sell, assign, transfer and convey (or cause to be sold, assigned, transferred and conveyed) to Servier, free and clear of any liens, and Servier shall purchase and accept from the CStone (or its designees), all of CStone’s and its affiliates’ rights to the CStone Ivosidenib Business and any goodwill thereof, including the Transferred Assets set forth below:

- (i) all right, title, and interest in intellectual property owned by CStone or its affiliates, including any of their right, title or interest in any licensee technology and joint combination therapy technology (as defined in the Ivosidenib License Agreement), as solely related to ivosidenib. With respect to intellectual property related to ivosidenib or necessary or reasonably useful for the commercialization of ivosidenib (a) controlled but not owned by CStone or its affiliates; or (b) owned by them but not solely related to ivosidenib, CStone and its affiliates grant to Servier an exclusive (even as to CStone and its affiliates), worldwide, fully sublicensable (through multiple tiers), royalty-free, irrevocable, perpetual, unlimited, transferable license under such intellectual property to, directly or indirectly, research, develop, manufacture, or commercialize ivosidenib, in any indication, by any processes and media, and for any purposes, in any country of the world;
- (ii) all CStone’s right, title, and interest in and to all regulatory documents (including regulatory filings and regulatory approvals) related to ivosidenib;
- (iii) all portions of customer lists (including hospitals currently using ivosidenib in treatment and hospitals that have market potentials, key opinion leaders, including speakers and advisors and distributors at all tiers), promotional materials including but not limited to any samples, technical data, point of sale, sales, promotional and marketing materials or aids, advertising and display materials (including journal and broadcast advertisements), websites and accounts in other social media and internet platforms, product literature, stationary, training materials, in each case, in whatever medium relating to the ivosidenib;

- (iv) all transferable or assignable rights under all contracts, agreements included but not limited to companion diagnostic agreement, clinical trial agreements, confidentiality agreements, research and development, consulting, clinical research organization or similar agreements, distribution, packaging, sub-licensing, sales, marketing, services, sub-contracts and any other commercial agreements or similar agreements or contracts, licenses, commitments, sales, purchase orders and other instruments as set out in an exhibit to the Asset Purchase Agreement;
- (v) all inventory of ivosidenib owned by CStone, which is in transit or deposited in a warehouse, in hospitals, direct-to-patients, with distributors, other persons or otherwise in the possession or control of CStone or any of its representatives;
- (vi) trade receivables specifically listed in a schedule to the Asset Purchase Agreement, accrued prior to the Effective Date and payable after the Effective Date in accordance with the terms of the Transferred Contracts, other than cash and cash equivalents; and
- (vii) all right, title, and interest in any other assets owned by CStone or its affiliates which are primarily related to ivosidenib or the CStone Ivosidenib Business.

Reversion of Rights under the Ivosidenib License Agreement to Servier

Because the Ivosidenib License Agreement is no longer needed following transfer of the CStone Ivosidenib Business to Servier, the Ivosidenib License Agreement and other related existing agreements shall be terminated in their entirety on the Effective Date, and all licenses and rights to sublicense and subcontract granted by Servier to CStone or any of its affiliates under the Ivosidenib License Agreement shall revert to Servier. CStone will cease from any activity of research, development, manufacturing and commercialization of ivosidenib, and, more generally, from any use of the intellectual property licensed under the Ivosidenib License Agreement, and Servier will be free to further use, research, develop, manufacture and commercialize ivosidenib, anywhere in the world, in any indication.

Transition Plan

CStone and Servier have entered into the Transition Plan Agreement, pursuant to which CStone has committed to provide certain deliverables to Servier in connection with the consummation of the Transaction in order to achieve an orderly transfer of the CStone Ivosidenib Business.

Parent Guarantee

The Company, as the parent company of CStone Suzhou, has assumed responsibility and liability for compliance by its affiliates (including CStone Suzhou) with the applicable provisions of the Asset Purchase Agreement.

REASONS FOR AND BENEFITS OF ENTERING INTO THE TRANSACTION

The Directors are of the view that the Transaction will maximize the value and impact of ivosidenib and represent the best opportunity to optimize value for Shareholders and patients worldwide. The Transaction is expected to allow the Group to focus on growing other pipeline assets and to pursue additional opportunities to further expand its existing pipeline of drug products. In addition, the proceeds derived from the Transaction would be best deployed and aligned with the overall and long-term goals of the Group that will best serve the interests of the Company and its shareholders in the long run.

USE OF PROCEEDS FROM THE TRANSACTION

The expected total proceeds from the Transaction amount to US\$50 million (equivalent to approximately RMB354.8 million) on a pre-tax basis, assuming ordering and provision of certain optional deliverables pursuant to the Transition Plan Agreement. After deduction of applicable transaction fees, value-added tax and other relevant estimated expenses in relation to the Transaction, the expected net proceeds from the Transaction amount to up to approximately US\$46.4 million (equivalent to approximately RMB329.3 million).

Having considered the prospects that the Transaction may bring to the Group and the reasons for and benefits of the Transaction, in order to better allocate and utilize its financial resources, the Board has reviewed the net proceeds from the Transaction, and resolved to apply the net proceeds from the Transaction in the following areas: (i) 60% to drive clinical advancements across its evolving pipeline including but not limited to the development of receptor tyrosine kinase-like orphan receptor 1 antibody-drug conjugate candidate(s); (ii) 25% for the research and development of products at early pipeline stage (including the expansion of preclinical assets); and (iii) 15% for working capital and general administrative purposes.

In view of the above, the Directors consider that the Asset Purchase Agreement and the Transaction contemplated thereunder have been entered into on normal commercial terms, and that the terms thereof are fair and reasonable and in the interests of the Company and the Shareholders as a whole.

The Board is of the view that the Transaction will not have any material adverse impact on the business operations or financial position of the Group.

FINANCIAL EFFECT OF THE TRANSACTION

Ivosidenib was commercially launched and generated sales in the financial year ended December 31, 2022. The gross profits attributable to ivosidenib for the financial year ended December 31, 2022 amounted to approximately RMB53.6 million.

The unaudited book value of the Transferred Assets that are the subject of the Transaction as at June 30, 2023 was approximately RMB49.2 million.

The maximum gain to be derived from the Transaction (assuming the receipt of the entire consideration of up to approximately US\$50 million (equivalent to approximately RMB354.8 million) upon completion of an orderly transfer of the CStone Ivosidenib Business and provision of certain deliverables by CStone) is estimated to be approximately US\$39.5 million (equivalent to approximately RMB280.3 million) on an unaudited basis. This estimate is made based on the amount of net consideration to be received under the Asset Purchase Agreement less the book value of the Transferred Assets. The actual amount of gain to be recognised by the Company as a result of the Transaction will be subject to (i) the extent, if any, to which CStone provides certain additional deliverables to Servier upon request pursuant to the applicable provisions of the Transition Plan Agreement; as well as (ii) other contingent events and audit, and the amount of actual gain incurred in relation to the Transaction may be different from the aforementioned expected amount. Following completion of the transfer of the CStone Ivosidenib Business, the Company will cease to have any interests in the assets that are the subject of the Transaction.

LISTING RULES IMPLICATIONS

As the highest applicable percentage ratio calculated in accordance with Chapter 14 of the Listing Rules for the Transaction exceeds 5% but is less than 25%, the Transaction constitutes a discloseable transaction of the Company under Chapter 14 of the Listing Rules and is subject to the reporting and announcement requirements under the Listing Rules but not subject to the circular and shareholders' approval requirements thereunder.

INFORMATION ABOUT THE PARTIES

About CStone

CStone Suzhou is a wholly-owned subsidiary of CStone Pharmaceuticals. CStone Pharmaceuticals is a biopharmaceutical company focused on research, development, and commercialization of innovative immuno-oncology and precision medicines to address the unmet medical needs of cancer patients in China and worldwide. Established in 2015, CStone Pharmaceuticals has assembled a management team with extensive experience in innovative drug development, clinical research, and commercialization. CStone Pharmaceuticals has built an oncology-focused pipeline of 13 drug candidates with a strategic emphasis on immuno-oncology combination therapies. Currently, CStone Pharmaceuticals has received 12 new drug application approvals for its three drugs (excluding ivosidenib). Multiple late-stage drug candidates are now under pivotal clinical trials or registration. CStone Pharmaceuticals' vision is to bring innovative oncology therapies to cancer patients worldwide.

For more information about CStone, please visit: www.cstonepharma.com.

About Servier

Servier is a global group of pharmaceutical companies governed by a non-profit governance foundation without capital, namely the Fondation Internationale de Recherche Servier. It focuses on research, development, and commercialization of drugs for treating various diseases, including cardiovascular and metabolic diseases, oncology and immuno-inflammatory, and neurodegenerative diseases. Servier sells drugs in more than 150 countries. Servier focuses on a limited number of diseases in which accurate patient profiling makes it possible to offer a targeted therapeutic response through precision medicine. Currently, Servier has four medicines approved in acute lymphoblastic leukemia, acute myeloid leukemia and cholangiocarcinoma. To promote access to quality care for all at a lower cost, Servier also offers a range of quality generic drugs covering most pathologies across its global network.

No persons own any stake in Servier's capital. The share capital is held by Servier through a legal scheme allowing a company to hold its own capital.

For more information about Servier, please visit <https://servier.com>.

Forward Looking Statements

There is no assurance that any forward-looking statements regarding the business development of the Group in this announcement or any of the matters set out herein are attainable, will actually occur or will be realized or are complete or accurate. The financial and other data relating to the Group as disclosed in this announcement has also not been audited or reviewed by its auditors. Shareholders and/or potential investors of the Company are advised to exercise caution when dealing in the securities of the Company and not to place any excessive reliance on the information disclosed herein. Any shareholder or potential investor who is in doubt is advised to seek advice from professional advisors.

DEFINITIONS

In this announcement, the following expressions have the meanings set out below unless the context otherwise requires:

“Agios”	Agios Pharmaceuticals, Inc., a corporation incorporated under the laws of the State of Delaware, U.S., whose shares are listed on NASDAQ (ticker symbol: AGIO);
“Asset Purchase Agreement”	the Asset Purchase Agreement entered into between CStone Suzhou and Servier on December 20, 2023 (Central European Time) (being December 21, 2023 Hong Kong time) in respect of the Transaction;
“Board”	the board of Directors;
“Business Day”	a day, other than Saturday, Sunday or other day on which commercial banks in Beijing, China or Paris, France are authorized or required by applicable law to close;

“China” and “PRC”	the People’s Republic of China, but for the purpose of this announcement and for geographical reference only and except where the context requires otherwise, references in this announcement to “China” and the “PRC” do not apply to Hong Kong, Macau Special Administrative Region and Taiwan;
“Company”	CStone Pharmaceuticals, an exempted company incorporated in the Cayman Islands with limited liability, the Shares of which are listed on the Main Board of the Stock Exchange;
“connected person(s)”	has the meaning ascribed to it under the Listing Rules;
“CStone Ivosidenib Business”	all of CStone’s business, operations, activities, programs, intellectual property, contracts and lists of clients, with respect to ivosidenib, including any development, or commercialization activities and any activities with respect to <i>vitro</i> diagnostic or medical devices related to such activities, including any companion diagnostics;
“CStone Suzhou” or “CStone”	CStone Pharmaceuticals (Suzhou) Co., Ltd. (基石藥業(蘇州)有限公司), a company established under the laws of the PRC and an indirectly wholly-owned subsidiary of the Company, for itself and its affiliates including Shenshi Pharmaceuticals;
“Director(s)”	the director(s) of the Company;
“Effective Date”	December 20, 2023;
“Global Offering”	the global offering of the Company in connection with the listing of the Shares on the Stock Exchange consummated on February 26, 2019;
“Group”	the Company and its subsidiaries from time to time;
“Hong Kong”	the Hong Kong Special Administrative Region of the PRC;
“Ivosidenib”	a small molecule inhibitor of isocitrate dehydrogenase1 (IDH1), which is sold under the trade name TIBSOVO® and 拓舒沃®;
“Ivosidenib License Agreement”	the exclusive license agreement dated June 25, 2018 entered into between the Company and Agios, pursuant to which Agios granted an exclusive license to the Company to develop and commercialize ivosidenib in the Territory, as amended and supplemented from time to time;
“Listing Rules”	the Rules Governing the Listing of Securities on the Stock Exchange, as amended from time to time;
“NDA”	new drug application;
“Prospectus”	the Prospectus dated February 14, 2019 relating to the Company’s listing on the Stock Exchange;

“RMB”	Renminbi Yuan, the lawful currency of China;
“Servier” or “Les Laboratoires Servier”	Les Laboratoires Servier, a corporation incorporated under the laws of France;
“Share(s)”	ordinary share(s) of par value of US\$0.0001 each in the capital of the Company;
“Shareholder(s)”	the holder(s) of the Share(s);
“Shenshi Pharmaceuticals”	Shenshi Pharmaceuticals (Shanghai) Co., Ltd. (申石生物醫藥(上海)有限公司), a company established under the laws of the PRC and an indirectly wholly-owned subsidiary of the Company;
“Stock Exchange”	The Stock Exchange of Hong Kong Limited;
“subsidiary” or “subsidiaries”	shall have the meaning ascribed to it under the Listing Rules;
“Territory”	China, Hong Kong, Macau Special Administrative Region, Taiwan and the Republic of Singapore;
“Transaction”	the transactions contemplated under the Asset Purchase Agreement, including but not limited to (i) the sale and purchase of the CStone Ivosidenib Business and any goodwill thereof, including the Transferred Assets; (ii) the termination of the Ivosidenib License Agreement and other related existing agreements; and (iii) provision of certain deliverables;
“Transferred Assets”	the assets to be transferred from CStone to Servier pursuant to the Asset Purchase Agreement, including but not limited to all inventory of ivosidenib, intellectual property rights, regulatory documents, customer lists, promotional materials, the Transferred Contracts (in each case as specified in the Asset Purchase Agreement), and all other assets owned by CStone or its affiliates which are related to ivosidenib or the CStone Ivosidenib Business;
“Transferred Contracts”	all transferable or assignable rights under all contracts, agreements included but not limited to companion diagnostic agreement, clinical trial agreements, confidentiality agreements, research and development, consulting, clinical research organization or similar agreements, distribution, packaging, sub-licensing, sales, marketing, services, sub-contracts and any other commercial agreements or similar agreements or contracts, licenses, commitments, sales, purchase orders and other instruments as set out in an exhibit to the Asset Purchase Agreement;

“Transition Plan Agreement”	the transition plan agreement to achieve orderly transfer of the Transferred Assets from CStone to Servier as set out in an exhibit to the Asset Purchase Agreement;
“US\$”	United States dollars, the lawful currency of the U.S.;
“%”	per cent.

By Order of the Board
CStone Pharmaceuticals
Dr. Wei Li
Chairman

Suzhou, the People’s Republic of China, December 21, 2023

As at the date of this announcement, the Board comprises Dr. Wei Li as Chairman and non-executive director, Dr. Jianxin Yang as executive director, Mr. Kenneth Walton Hitchner III, Mr. Xianghong Lin and Mr. Edward Hu as non-executive directors, and Dr. Paul Herbert Chew, Mr. Ting Yuk Anthony Wu and Mr. Hongbin Sun as independent non-executive directors.

For the purpose of this announcement, unless otherwise indicated, the exchange rate of US\$1.00 = RMB7.0966 has been used, where applicable, for the purpose of illustration only and does not constitute a representation that any amount has been, could have been or may be exchanged at such rate or any other rate or at all on the date or dates in question or any other date.