# UNITED STATES OF AMERICA Before the SECURITIES AND EXCHANGE COMMISSION

## SECURITIES EXCHANGE ACT OF 1934 Release No. 77058 / February 4, 2016

## ACCOUNTING AND AUDITING ENFORCEMENT Release No. 3739 / February 4, 2016

## ADMINISTRATIVE PROCEEDING File No. 3-17101

In the Matter of

SciClone Pharmaceuticals, Inc.

**Respondent.** 

## ORDER INSTITUTING CEASE-AND-DESIST PROCEEDINGS PURSUANT TO SECTION 21C OF THE SECURITIES EXCHANGE ACT OF 1934, MAKING FINDINGS, AND IMPOSING A CEASE-AND-DESIST ORDER

I.

The Securities and Exchange Commission ("Commission") deems it appropriate and in the public interest that public administrative and cease-and-desist proceedings be, and hereby are, instituted pursuant to 21C of the Securities Exchange Act of 1934 ("Exchange Act") against SciClone Pharmaceuticals, Inc. ("SciClone" or "Respondent").

## П.

In anticipation of the institution of these proceedings, Respondent has submitted an Offer of Settlement (the "Offer") which the Commission has determined to accept. Solely for the purpose of these proceedings and any other proceedings brought by or on behalf of the Commission, or to which the Commission is a party, and without admitting or denying the findings herein, except as to the Commission's jurisdiction over it and the subject matter of these proceedings, which are admitted, Respondent consents to the entry of this Order Instituting Cease-and-Desist Proceedings Pursuant to Section 21C of the Securities Exchange Act of 1934, Making Findings, and Imposing a Cease-and-Desist Order ("Order"), as set forth below.

# III.

On the basis of this Order and Respondent's Offer, the Commission finds<sup>1</sup> that:

### <u>Summary</u>

1. These proceedings arise out of violations of the anti-bribery, books and records and internal accounting controls provisions of Foreign Corrupt Practices Act of 1977 (the "FCPA") [15 U.S.C. § 78dd] by SciClone concerning its pharmaceutical operations in China.

2. From at least 2007 to 2012, employees of SciClone subsidiaries, who acted as agents of SciClone in conducting business in China, gave money, gifts and other things of value to foreign officials, including healthcare professionals ("HCPs") who were employed by state-owned hospitals in China, in order to obtain sales of SciClone pharmaceutical products. Various means were employed, and these schemes were known to and condoned by various managers within SciClone's China-based corporate structure. The related transactions were falsely recorded in SciClone's books and records as legitimate business expenses, such as sponsorships, travel and entertainment, conferences, honoraria, and promotion expenses. During this period, SciClone also failed to devise and maintain a sufficient system of internal accounting controls and lacked an effective anti-corruption compliance program.

## Respondent

3. SciClone Pharmaceuticals, Inc. ("SciClone") is a pharmaceutical company organized under the laws of Delaware, with headquarters in Foster City, California. SciClone issued and maintains a class of publicly traded securities registered pursuant to Section 12(b) of the Securities Exchange Act of 1934, which are traded on the NASDAQ. SciClone's products are primarily marketed and sold in China.

### **Other Relevant Entities**

4. **SciClone Pharmaceuticals International Ltd.** ("SPIL") is a wholly-owned subsidiary of SciClone that is incorporated in the Cayman Islands with an affiliate in Hong Kong. SciClone operates internationally primarily through subsidiaries, including SPIL and SPIL's wholly-owned subsidiaries that sell and promote SciClone's products in China. SciClone directs the relevant operations of SPIL and its subsidiaries and oversees SPIL's operations through various means including through the appointment of directors and officers of SPIL, review and approval of its annual budget, business and financial goals, and oversight of its legal, audit, and compliance functions. SciClone also reviews and approves annual marketing and promotion budgets of SPIL and its subsidiaries. During relevant periods, some SciClone officers also served as officers and/or directors of SPIL, traveled frequently to China to participate in the management of SPIL, and were

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The findings herein are made pursuant to Respondent's Offer of Settlement and are not binding on any other person or entity in this or any other proceeding.

responsible for negotiating its contracts with its Chinese distributors. SPIL's books and records are consolidated by SciClone and reported in its financial statements.

# **Facts**

5. Although SciClone has local distributor relationships in China, its sales and marketing activities there are conducted through SPIL. Sales representatives in China regularly reported to senior management of SPIL on their efforts to increase sales. In these reports, sales representatives openly referred to instances in which they provided weekend trips, vacations, gifts, expensive meals, foreign language classes, and entertainment to HCPs in order to obtain an increase in prescriptions from those HCPs. As described by one sales manager, this was "luring them with the promise of profit."

6. Some sales representatives referred to those HCPs with the greatest impact on their sales volume as VIP clients, and provided details on their volume of prescriptions when reporting to SPIL. This practice was known and encouraged by certain former SPIL managers at the time SPIL and SciClone had overlapping officers and/or directors. These reports included such things as:

- In August 2005, numerous surgical VIP clients including several hospital presidents attended the annual Qingdao Beer Festival consisting of golf in the morning and beer-drinking in the evening. In later years, SPIL continued to sponsor VIPs to the annual festival.
- In February 2007, VIP clients were provided with vacations to Anji, China.
- In November 2007, a sales representative recounted the experience of recruiting a VIP client by paying for family vacations and regular family dinners through an employee expense account. The sales representative attributed a nearly four-fold sales increase to that VIP as a result.

7. In 2007, SciClone submitted a license application to the State Food and Drug Administration for a new medical device product and had a renewal pending for its largest product. SciClone hired a well-connected regulatory affairs specialist ("Specialist") to facilitate that licensing.

8. The Specialist arranged trips for two foreign officials to attend an academic conference in Greece at SciClone's expense. The conference was solely related to the new medical device. One of the foreign officials had oversight over new product approvals, and the other foreign official had oversight over renewals for existing licensed products. At the time the trip was arranged, both SciClone's renewal application and its application for a new license were pending.

9. As the foreign officials were unable to obtain travel visas in time to attend the conference in Greece, the Specialist instead provided them at least \$8,600 in lavish gifts. The

Specialist submitted two expense reimbursements for the gifts, the first of which was approved by the senior vice president of SPIL.

10. After learning of the gifts, SciClone terminated the Specialist and conducted an internal investigation related to the Specialist's conduct and practices in China. The review did not look more broadly at sales and marketing practices in China. No further action or remedial measures were taken by SciClone or SPIL after the conclusion of the internal investigation in 2008.

11. Local Chinese travel companies were routinely hired to provide services (such as arranging transportation, accommodations, and meals for HCPs) in connection with what were ostensibly legitimate conferences, seminars, and other events. In addition to a lack of due diligence for these third party vendors, prior to 2012, there was a lack of controls over the events to ensure they had an appropriate business purpose and that the events actually occurred. Many events did not include a legitimate educational purpose or the educational activities were minimal in comparison to the sightseeing or recreational activities. For example:

- Between at least 2008 and 2010, SciClone sponsored dozens of Chinese HCPs to attend liver and oncology conferences in the United States. While a portion of the travel was devoted to educational purposes, it also consisted of significant sightseeing that involved, for example, travel to Las Vegas and Los Angeles with tours of the Grand Canyon or Disneyland.
- In April 2010, SPIL sponsored Chinese HCPs to attend a seminar in Japan regarding Zadaxin, its principle product. While a portion of the meeting appeared to involve half a day of educational activities, the remaining six days involved sightseeing and tourist locations such as Mt. Fuji.
- In March 2010, SPIL held its annual sales meeting in China on the island of Hainan, a resort destination. The sales meeting was attended by the sales representatives and senior management from SPIL. The weekend before the sales meeting, SPIL hosted VIP clients to a weekend stay on Hainan. There was no educational component to the VIP clients' stay.

12. As part of its remedial efforts, SciClone conducted a detailed, comprehensive internal review of promotion expenses of employees from 2011 to early 2013. This review found high exception rates indicating violations of corporate policy that ranged from fake fapiao, inconsistent amounts or dates with fapiao, excessive gift or meal amounts, unverified events, doctored honoraria agreements, and duplicative meetings. A portion of the funds generated through the reimbursements were used as part of the sales practices described above that continued through at least 2012.

#### Legal Standards and Violations

13. Under Section 21C(a) of the Exchange Act, the Commission may impose a ceaseand-desist order upon any person who is violating, has violated, or is about to violate any provision of the Exchange Act or any rule or regulation thereunder, and upon any other person that is, was, or would be a cause of the violation, due to an act or omission the person knew or should have known would contribute to such violation.

#### FCPA Violations

14. Under Section 30A(g) of the Exchange Act it shall also be unlawful for any issuer organized under the laws of the United States, or a State, territory, possession, or commonwealth of the United States or a political subdivision thereof and which has a class of securities registered pursuant to section 781 of this title or which is required to file reports under section 780(d)) of this title, or for any United States person that is an officer, director, employee, or agent of such issuer or a stockholder thereof acting on behalf of such issuer, to corruptly do any act outside the United States in furtherance of an offer, payment, promise to pay, or authorization of the payment of any money, or offer, gift, promise to give, or authorization of the giving of anything of value to any of the persons or entities set forth in paragraphs (1), (2), and (3) of this subsection (a) of this section for the purposes set forth therein, irrespective of whether such issuer or such officer, director, employee, agent, or stockholder makes use of the mails or any means or instrumentality of interstate commerce in furtherance of such offer, gift, payment, promise, or authorization. [15 U.S.C. § 78dd-1].

15. Under Section 13(b)(2)(A) of the Exchange Act issuers are required to make and keep books, records, and accounts, which, in reasonable detail, accurately and fairly reflect the transactions and disposition of the assets of the issuer. [15 U.S.C. § 78m(b)(2)(A)].

16. Under Section 13(b)(2)(B) of the Exchange Act issuers are required to devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances that (i) transactions are executed in accordance with management's general or specific authorization; (ii) transactions are recorded as necessary (I) to permit preparation of financial statements in conformity with generally accepted accounting principles or any other criteria applicable to such statements, and (II) to maintain accountability for assets; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets at reasonable intervals and appropriate action is taken with respect to any differences. [15 U.S.C. § 78m(b)(2)(B)].

17. As described above, SciClone through SPIL violated Section 30A(g) by providing things of value to foreign officials, including healthcare professionals ("HCPs") who were employed by state-owned hospitals in China, in order to obtain sales of SciClone pharmaceutical products. SciClone violated 13(b)(2)(A) of the Exchange Act by improperly recording the payments to health care providers as sales, marketing, and promotion expenses. The false entries were initially recorded by SPIL which were then consolidated and reported by SciClone in its consolidated financial statements. SciClone violated Section 13(b)(2)(B) by failing to devise and

maintain a sufficient system of internal accounting controls to detect and prevent the making of improper payments to foreign officials.

### **SciClone's Remedial Efforts**

18. SciClone has taken steps to improve its internal accounting controls and to create a dedicated compliance function. These include the following: (1) hiring a compliance officer for its China operations; (2) undertaking an extensive review of the policies and procedures surrounding employee travel and entertainment reimbursements; (3) substantially reducing the number of suppliers providing third-party travel and event planning services; (4) improving its policies and procedures around third-party due diligence and payments; (5) incorporating anti-corruption provisions in its third-party contracts; (6) providing anti-corruption training to its third-party travel and event planning employees (and their managers) who violate SciClone's policies; and (8) creating an internal audit department and compliance department.

#### **Undertakings**

- 19. Respondent has undertaken to:
  - Report to the Commission staff periodically, at no less than nine-month intervals during a three-year term, the status of its remediation and implementation of compliance measures. During this three-year period, should Respondent discover credible evidence, not already reported to the Commission staff, that questionable or corrupt payments or questionable or corrupt transfers of value may have been offered, promised, paid, or authorized by Respondent, or any entity or person acting on behalf of Respondent, or that related false books and records have been maintained, Respondent shall promptly report such conduct to the Commission staff. During this three-year period, Respondent shall: (1) conduct an initial review and submit an initial report, and (2) conduct and prepare at least three follow-up reviews and reports, as described below:
    - a. Respondent shall submit to the Commission staff a written report within 180 calendar days of the entry of this Order setting forth a complete description of its Foreign Corrupt Practices Act ("FCPA") and anti-corruption related remediation efforts to date, its proposals reasonably designed to improve the policies and procedures of Respondent for ensuring compliance with the FCPA and other applicable anticorruption laws, and the parameters of the subsequent reviews (the "Initial Report"). The Initial Report shall be transmitted to Charles Cain, Deputy Unit Chief, FCPA Unit, Division of Enforcement, United States Securities and Exchange Commission, 100 F St NE, Washington, DC 20549. Respondent

may extend the time period for issuance of the Initial Report with prior written approval of the Commission staff.

- b. Respondent shall undertake at least three follow-up reviews, incorporating any comments provided by the Commission staff on the previous report, to further monitor and assess whether the policies and procedures of Respondent are reasonably designed to detect and prevent violations of the FCPA and other applicable anti-corruption laws (the "Follow-up Reports").
- c. The first Follow-up Report shall be completed by no later than 270 days after the Initial Report. The second Follow-up Report shall be completed by no later than 540 days after the completion of the Initial Report. The third Follow-up Report shall be completed by no later than 810 days after the completion of the Initial Report. Respondent may extend the time period for issuance of the Follow-up Reports with prior written approval of the Commission staff.
- d. The periodic reviews and reports submitted by Respondent will likely include proprietary, financial, confidential, and competitive business information. Public disclosure of the reports could discourage cooperation, impede pending or potential government investigations and thus undermine the objectives of the reporting requirement. For these reasons, among others, the reports and the contents thereof are intended to remain and shall remain nonpublic, except (a) pursuant to court order, (b) as agreed by the parties in writing, (c) to the extent that the Commission staff determines in its sole discretion that disclosure would be in furtherance of the Commission's discharge of its duties and responsibilities, or (d) is otherwise required by law.
- 2. Certify, in writing, compliance with the undertaking(s) set forth above. The certification shall identify the undertaking(s), provide written evidence of compliance in the form of a narrative, and be supported by exhibits sufficient to demonstrate compliance. The Commission staff may make reasonable requests for further evidence of compliance, and Respondent agrees to provide such evidence. The certification and supporting material shall be submitted to Charles Cain, with a copy to the Office of Chief Counsel of the Enforcement Division, no later than sixty (60) days from the date of the completion of the undertakings.

## IV.

In view of the foregoing, the Commission deems it appropriate to impose the sanctions agreed to in Respondent SciClone's Offer.

Accordingly, pursuant to 21C of the Exchange Act, it is hereby ORDERED that:

A. Respondent SciClone cease and desist from committing or causing any violations and any future violations of Sections 30A, 13(b)(2)(A), and 13(b)(2)(B) of the Exchange Act;

B. Respondent shall, within 14 days of the entry of this Order, pay disgorgement, of \$9,426,000 and prejudgment interest of \$900,000 to the Securities and Exchange Commission. If timely payment of disgorgement or prejudgment interest is not made, additional interest shall accrue pursuant to SEC Rule of Practice 600. Respondent shall, within 14 days of the entry of this Order, pay a civil money penalty in the amount of \$2,500,000 to the Securities and Exchange Commission to transfer to the general fund of the United States Treasury, subject to Exchange Act Section 21F(g)(3). If timely payment of civil money penalty is not made, additional interest shall accrue pursuant to 31 U.S.C. 3717. Payment must be made in one of the following ways:

- (1) Respondent may transmit payment electronically to the Commission, which will provide detailed ACH transfer/Fedwire instructions upon request;
- (2) Respondent may make direct payment from a bank account via Pay.gov through the SEC website at <u>http://www.sec.gov/about/offices/ofm.htm;</u> or
- (3) Respondent may pay by certified check, bank cashier's check, or United States postal money order, made payable to the Securities and Exchange Commission and hand-delivered or mailed to:

Enterprise Services Center Accounts Receivable Branch HQ Bldg., Room 181, AMZ-341 6500 South MacArthur Boulevard Oklahoma City, OK 73169

Payments by check or money order must be accompanied by a cover letter identifying SciClone as a Respondent in these proceedings, and the file number of these proceedings; a copy of the cover letter and check or money order must be sent to Charles Cain, Deputy Unit Chief, FCPA Unit, Division of Enforcement, Securities and Exchange Commission, 100 F St., NE, Washington, DC 20549.

C. Respondent shall comply with the undertakings enumerated in Section III above.

By the Commission.

Brent J. Fields Secretary