

UNITED STATES OF AMERICA
Before the
SECURITIES AND EXCHANGE COMMISSION

SECURITIES EXCHANGE ACT OF 1934
Release No. 89214 / July 2, 2020

ACCOUNTING AND AUDITING ENFORCEMENT
Release No. 4151 / July 2, 2020

ADMINISTRATIVE PROCEEDING
File No. 3-19852

In the Matter of

Alexion 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 that cease-and-desist proceedings be, and hereby are, instituted pursuant to Section 21C of the Securities Exchange Act of 1934 (“Exchange Act”), against Alexion Pharmaceuticals, Inc. (“Alexion” or “Respondent”).

II.

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 finds¹ that:

Summary

1. These proceedings arise out of Alexion's violations of the internal accounting controls and recordkeeping provisions of the Foreign Corrupt Practices Act of 1977.

2. From 2010 to 2015, Alexion's subsidiary in Turkey made payments to foreign officials in order to influence them to provide favorable regulatory treatment for Alexion's primary drug, Soliris, and to approve Soliris prescriptions for individual patients. In addition, from 2011 to 2015, Alexion's subsidiary in Russia made payments to foreign officials in order to influence the allocation of regional healthcare budgets for Soliris, increase the number of approved Soliris prescriptions, and favorably influence the regulatory treatment of Soliris. The payments were made in a variety of ways, including through the use of a third-party consultant, honoraria, and grants.

3. In connection with these improper payments, false books and records were maintained by Alexion's subsidiaries in Turkey and Russia. Alexion had insufficient internal accounting controls to detect and prevent these payments and to provide reasonable assurances that these transactions were recorded accurately in the books and records of these subsidiaries, which were consolidated into Alexion's books and records. The payments continued through 2015 due to Alexion's inadequate internal accounting controls and the lack of an effective anti-corruption compliance program. As a result, Alexion was unjustly enriched by over \$14 million.

4. In addition, Alexion's inadequate internal accounting controls resulted in the failure of Alexion's subsidiaries in Brazil and Colombia to maintain accurate books and records regarding third-party payments.

Respondent

5. Alexion is a global biopharmaceutical company that develops and sells drugs for patients with life-threatening rare and ultra-rare diseases. Alexion is incorporated in Delaware with its headquarters in Boston, Massachusetts. Alexion began commercial sales of its first drug, Soliris, in 2007. During the relevant time period, Soliris was approved to treat two ultra-rare diseases, paroxysmal nocturnal hemoglobinuria ("PNH") and atypical hemolytic uremic syndrome ("aHUS").

6. Alexion serves patients in approximately 50 countries and employs approximately 3,000 people worldwide.

¹ 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.

7. Alexion issued and maintains a class of publicly-traded securities registered pursuant to Section 12(b) of the Exchange Act, which have traded on the Nasdaq Stock Market LLC since 1996.

Other Relevant Entities

8. **Alexion İlaç Ticaret Limited Sirketi** (“Alexion Turkey”) is a wholly-owned Alexion subsidiary incorporated in 2010. Alexion Turkey’s books and records were consolidated into Alexion’s financial statements.

9. **Alexion Pharma OOO** (“Alexion Russia”) is a wholly-owned Alexion subsidiary incorporated in 2012. Alexion Russia’s books and records were consolidated into Alexion’s financial statements.

10. **Alexion Pharma Brazil** (“Alexion Brazil”) is a wholly-owned Alexion subsidiary incorporated in 2009. Alexion Brazil’s books and records were consolidated into Alexion’s financial statements.

11. **Alexion Pharma Colombia SAS** (“Alexion Colombia”) is a wholly-owned Alexion subsidiary incorporated in 2009. Alexion Colombia’s books and records were consolidated into Alexion’s financial statements.

Facts

Turkey

12. Alexion began selling Soliris through Turkey’s named patient sales (“NPS”) program in 2009. Under Turkish law, each patient’s application to begin Soliris therapy required review and approval by health care providers (“HCPs”) appointed to serve on commissions in Turkey’s Ministry of Health, separate approvals to pay for the prescription, and recurring approvals to continue the patient on Soliris therapy. Alexion Turkey paid HCPs employed at state-owned healthcare institutions for services, including research and educational events.

13. Alexion initially struggled to get these approvals for Soliris. In January 2010, a senior Ministry of Health official suggested to an Alexion Turkey regional account manager that, to obtain more patient approvals, Alexion Turkey may need to make payments to government officials. Thereafter, Alexion Turkey hired a consultant (“Consultant”) to assist Alexion Turkey with the patient approval process. The Consultant was hired in significant part due to the Consultant’s connections to top Ministry of Health officials.

14. From 2010 to 2015, Alexion Turkey paid the Consultant over \$1.3 million, consisting of consulting fees and purported expense reimbursements. The Consultant passed a portion of these funds on to Turkish government officials, in the form of cash, meals, or gifts, to secure favorable treatment for Soliris. As a result of these payments, Alexion Turkey not only secured approvals for patient prescriptions, but also received confidential information and

advance feedback from government officials on regulatory submissions. Alexion Turkey recorded these improper payments inaccurately, claiming them as legitimate expenses.

15. Two Alexion Turkey managers made some of the payments to the Consultant by asking a third-party vendor to pay the Consultant and provide falsified invoices for reimbursement to Alexion Turkey. Certain Alexion Turkey employees recorded these payments inaccurately in Alexion Turkey's books and records. Further, an Alexion Turkey manager directed that the description of the Consultant's claimed expenses should be written in pencil. The use of pencil would allow the description of the expenses to be easily changed or concealed.

16. Alexion Turkey failed to require that the Consultant provide sufficient documentation of expenses or services provided in return for the payments. From 2010 to 2015, the Consultant provided little or no explanation for many expenses, and failed to provide independent documentation for most of the purported expenses. Expense documentation that was submitted often sought reimbursement for large, vague expenses (e.g., categorized only as "other expense"). Even so, expense documentation associated with some of the payments indicates that the funds were for the benefit of government officials (e.g., noting first names of known government officials on submitted expense reports or notes attached thereto).

17. In addition to paying government officials through the Consultant, from 2012 to 2015, Alexion Turkey managers paid over \$100,000 to or at the request of HCPs serving on Ministry of Health commissions. These HCPs were responsible for approving or denying patient prescriptions for Soliris and had influence over key regulatory matters, such as treatment guidelines and reimbursement criteria. Alexion Turkey paid these HCPs to influence them to approve patient prescriptions and support regulatory actions favorable to Soliris. These payments were recorded inaccurately in Alexion Turkey's books and records as honoraria and grants.

18. For example, from 2012 to 2014, Alexion Turkey paid over \$15,000 to or at the request of an HCP who Alexion Turkey senior management recognized was "the decision maker for the reimbursement criteria[]" for aHUS and the decision-maker for the approval of patient prescriptions for Soliris. Alexion Turkey began paying the HCP once the HCP assumed responsibility for approving or denying patient prescriptions. Alexion Turkey made these payments to improperly influence the HCP to make decisions that would favor Alexion, including approving patient prescriptions for Soliris.

19. At the time these payments were made, Alexion Turkey employees had received limited training regarding anti-bribery compliance. Further, despite Alexion's knowledge of the risk of doing business in Turkey, Alexion failed to devise and maintain internal accounting controls that were sufficient to provide reasonable assurances that payments to third parties, including consultants and HCPs, were supported by adequate documentation and were for legitimate purposes.

20. As a result of the conduct described above in Turkey, Alexion was unjustly enriched by over \$6.6 million.

Russia

21. Alexion began selling Soliris in Russia in 2012. At that time, Soliris was sold through an NPS process and reimbursed through regional healthcare spending, which required the various regions in Russia to allocate funds to Soliris from regional healthcare budgets.

22. Alexion Russia paid HCPs employed at state-owned healthcare institutions for services, including research, consulting on specific topics, and hosting educational events and activities. Certain state-employed HCPs also served in official roles at the regional and federal levels of the Russian government healthcare system. These HCPs provided expert opinions relied upon by decision-makers regarding the allocation of regional healthcare budgets and the regulatory treatment of Soliris. Alexion Russia senior managers believed that these HCPs had decision-making authority regarding regional healthcare budgets and regulatory decisions. From 2011 to 2015, Alexion Russia made over \$1 million in payments to these HCPs, which included funds paid to influence the HCPs to take positions favorable to Alexion Russia in connection with regional budget allocations, to increase the number of approved Soliris prescriptions, and to favorably influence the regulatory treatment of Soliris. These payments were recorded inaccurately in Alexion Russia's books and records as honoraria, educational expenses, business meeting expenses, and scientific research.

23. Some specific examples of Alexion Russia's improper payments to HCPs in Russia are as follows:

a. In 2011 and 2012, certain Alexion Russia managers prioritized strengthening Alexion Russia's relationship with Physician A because Physician A was the chair of a committee that made recommendations concerning the allocation of rare disease funds in one region of Russia and because Physician A was tasked by the Russian government with proposing medical standards used to diagnose and treat PNH. Alexion Russia made honoraria and research payments to Physician A in significant part to influence the regional budget and standards in favor of Soliris. Physician A provided Alexion Russia with a copy of draft diagnostic standards and the ability to comment and revise the standards before they were submitted to the Ministry of Health. Patients requiring Soliris treatment were allocated 52% of the regional Ministry of Health budget in Physician A's region in 2013. Physician A received approximately \$100,000 from Alexion Russia from 2012 to 2015.

b. From 2011 to 2015, Alexion Russia paid over \$85,000 to Physicians B and C in the form of honoraria, research, and educational expenses, and in the form of a grant to the institution that employed Physician C. Physicians B and C were each geneticists and chief non-staff specialist advisors to the Ministry of Health. Physician B was tasked by the Ministry of Health with developing and submitting a list of rare diseases to the Ministry of Health, while Physician C was tasked with reviewing and advising the Ministry of Health on Alexion Russia's application to include Soliris on a list of drugs used to treat certain diseases. Internal Alexion Russia documents reflect that payments to Physicians B and C were made in significant part to improperly influence these Physicians in favor of Soliris. For example, Alexion Russia began paying Physician C and Physician C's organization after learning that Physician C was tasked

with advising the Ministry of Health regarding Soliris. After making payments to Physician C and Physician C's organization, an Alexion Russia employee recommended providing another payment to Physician C's organization and stated that Alexion Russia hoped to "receive support to include [ultra-rare diseases treated by Alexion drugs] in all possible lists," which would facilitate the prescription and reimbursement of Alexion's products. After making payments to Physician C and his organization, an Alexion Russia employee stated that Physician C "cooperated" with Alexion Russia on the "programs within [Physician C's] influence on regions in terms of standards and funding, through [Physician C's] specialized committee."

24. Despite Alexion's knowledge of the risk of doing business in Russia, Alexion failed to devise and maintain internal accounting controls that were sufficient to provide reasonable assurances that payments to HCPs in Russia were supported by adequate documentation and were for legitimate business purposes.

25. As a result of the conduct described above in Russia, Alexion was unjustly enriched by over \$7.5 million.

Brazil and Colombia

26. From 2013 to 2015, certain employees at Alexion Brazil and Alexion Colombia created or directed third parties to create inaccurate financial records concerning payments to third parties, including patient advocacy organizations ("PAOs").

27. For example, in 2013 and 2014, an Alexion Brazil manager caused a PAO to pay for the manager's personal expenses for alcohol and personal travel, and to submit a fictitious invoice, which was then reimbursed by Alexion Brazil. In 2014 and 2015, the same manager and an employee in Alexion Brazil submitted grant requests to Alexion's global grant review committee that misstated how the requested funds would be allocated to the different activities covered in the grant request.

28. As a further example, on one occasion in 2014, in order to provide funds to a PAO, an Alexion Colombia senior manager directed a PAO to submit an invoice that falsely described that the funds would be used for "legal support" services. This inaccurate invoice allowed Alexion Colombia to approve the payment locally instead of obtaining approval for the payment through the global grant process, as required by Alexion's policies.

29. Further, Alexion Brazil and Alexion Colombia failed to maintain adequate books and records of certain of its financial transactions involving payments to third parties. Notably, both subsidiaries failed to regularly maintain certain documents underlying a substantial number of financial transactions. Additionally, Alexion failed to prevent the destruction of relevant documents by certain employees of Alexion Brazil.

Legal Standards and Violations

30. Under Section 21C(a) of the Exchange Act, the Commission may impose a cease-and-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.

31. As a result of the conduct described above, Alexion violated Section 13(b)(2)(A) of the Exchange Act, which requires issuers to make and keep books, records, and accounts which, in reasonable detail, accurately and fairly reflect their transactions and dispositions of the assets of the issuer. As a result of the conduct described above, Alexion violated Section 13(b)(2)(B) of the Exchange Act, which requires issuers 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 is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

32. As a result of the conduct described above, Alexion violated Section 13(b)(2)(A) of the Exchange Act because its books and records did not accurately reflect certain expenses and payments, including improper payments to foreign officials and third parties. Alexion violated Section 13(b)(2)(B) of the Exchange Act by failing to devise and maintain sufficient internal accounting controls over the payments to foreign officials and third parties.

Alexion's Remedial Efforts and Cooperation

33. In determining to accept the Offer, the Commission considered remedial acts undertaken by Alexion and cooperation afforded to the Commission staff.

34. Alexion's cooperation included providing regular briefings to Commission staff regarding the facts developed in its internal investigation in multiple countries and the forensic accounting review that Alexion undertook, and identifying and providing translations of key documents.

35. Alexion's remediation included strengthening and expanding its global compliance organization; enhancing its policies and procedures regarding payments to third parties, **including the implementation of a centralized system to track and monitor third-party payments; revamping its HCP engagement process and oversight**; enhancing its internal audit function; conducting proactive compliance market reviews; and improving training provided to employees regarding anti-corruption.

IV.

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

Accordingly, it is hereby ORDERED that:

A. Pursuant to Section 21C of the Exchange Act, Respondent Alexion cease and desist from committing or causing any violations and any future violations of Sections 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 \$14,210,194 and prejudgment interest of \$3,766,337 to the Securities and Exchange Commission for transfer to the general fund of the United States Treasury, subject to Exchange Act Section 21F(g)(3). If timely payment 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 \$3,500,000 to the Securities and Exchange Commission for transfer to the general fund of the United States Treasury, subject to Exchange Act Section 21F(g)(3). If timely payment 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 <http://www.sec.gov/about/offices/ofm.htm>; 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 Alexion's name 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 Melissa Hodgman, Division of Enforcement, Securities and Exchange Commission, 100 F St., NE, Washington, DC 20549-5553.

C. Amounts ordered to be paid as civil money penalties pursuant to this Order shall be treated as penalties paid to the government for all purposes, including all tax purposes. To

preserve the deterrent effect of the civil penalty, Respondent agrees that in any Related Investor Action, it shall not argue that it is entitled to, nor shall it benefit by, offset or reduction of any award of compensatory damages by the amount of any part of Respondent's payment of a civil penalty in this action ("Penalty Offset"). If the court in any Related Investor Action grants such a Penalty Offset, Respondent agrees that it shall, within 30 days after entry of a final order granting the Penalty Offset, notify the Commission's counsel in this action and pay the amount of the Penalty Offset to the Securities and Exchange Commission. Such a payment shall not be deemed an additional civil penalty and shall not be deemed to change the amount of the civil penalty imposed in this proceeding. For purposes of this paragraph, a "Related Investor Action" means a private damages action brought against Respondent by or on behalf of one or more investors based on substantially the same facts as alleged in the Order instituted by the Commission in this proceeding.

By the Commission.

Vanessa A. Countryman
Secretary