UNITED STATES OF AMERICA
Before the
SECURITIES AND EXCHANGE COMMISSION

SECURITIES EXCHANGE ACT OF 1934
Release No. 89149 / June 25, 2020

ACCOUNTING AND AUDITING ENFORCEMENT
Release No. 4150 / June 25, 2020

ADMINISTRATIVE PROCEEDING
File No. 3-19835

In the Matter of **NOVARTIS AG** **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 Novartis AG ("Novartis" 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, Respondent admits the Commission's jurisdiction over it and the subject matter of these proceedings, and 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[1] that:

Summary

1. These proceedings arise out of improper activities by subsidiaries and affiliates of Novartis AG, a global pharmaceutical and healthcare company headquartered in Basel, Switzerland, to increase the use of products in several geographic markets between 2012 and 2016.

2. In Korea, Vietnam, and Greece, Novartis or Alcon local subsidiaries and affiliates engaged in schemes to make improper payments or to provide benefits to public and private healthcare providers ("HCPs") in exchange for prescribing or using Novartis or Alcon products. These schemes varied in method and amount but were known among certain managers of the local subsidiaries or affiliates. Within Novartis' former Alcon Asia business, internal accounting controls weaknesses associated with Equipment Financing Arrangements ("EFAs") in China from 2013 to 2015 resulted in forged contracts, missing surgical equipment, as well as a significant EFA accounts receivable balance associated with poor performing EFAs, for which Alcon China recorded large bad-debt provisions.

3. False books and records were maintained in connection with the various schemes, and Novartis also lacked sufficient internal accounting controls with respect to certain aspects of the operations of these subsidiaries and affiliates. As a result, Novartis violated the books and records and internal accounting controls provisions of the Foreign Corrupt Practices Act of 1977 (the "FCPA") [15 U.S.C. § 78m], and was unjustly enriched by approximately $92.3 million.

Respondent

4. **Novartis AG** ("Novartis") is a global provider of pharmaceutical and healthcare products. Novartis' products are available in approximately 155 countries and Novartis Group companies employ approximately 104,000 individuals. It is a corporation organized under the laws of Switzerland with headquarters in Basel, Switzerland. During the relevant period, Novartis was the sole owner of Alcon Inc., an eye care company, until it was spun off in 2019. Novartis issued and maintains a class of publicly traded securities registered pursuant to Section 12(b) of the Exchange Act, which are traded on the New York Stock Exchange under the ticker symbol "NVS."[2]

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[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.

[2] On March 23, 2016, Novartis settled a FCPA action with the Commission alleging violations arising from conduct in China. In the Matter of Novartis AG, Sec. Exch. Act Release No. 77431, *available at* http://www.sec.gov/litigation/admin/2016/34-77431-s.pdf

Other Relevant Entities

5. **Novartis (Hellas) S.A.C.I.** ("Novartis Greece"), a Greek corporation headquartered in Athens, Greece, is an indirect wholly-owned subsidiary of Novartis. Novartis Greece conducts sales and marketing activities throughout Greece for Novartis prescription drugs. Novartis Greece financial statements were consolidated with those of Novartis.

6. **Novartis Korea Ltd** ("Novartis Korea") is an indirect majority-owned subsidiary of Novartis. Novartis Korea conducts sales and marketing activities throughout the Republic of South Korea with annual sales of between $300 million and $400 million during the relevant period. Novartis Korea financial statements were consolidated with those of Novartis.

7. **Alcon, Inc.** ("Alcon") was a multinational eye care company with headquarters in Fort Worth, Texas, and was incorporated in Hünenberg, Switzerland. In or around April 2011, Alcon merged with Novartis, after which Alcon became an indirect wholly-owned subsidiary of Novartis. Alcon's financial statements were consolidated with those of Novartis during the relevant period. Alcon Inc. was spun off of Novartis in 2019 and currently maintains a class of publicly traded securities registered pursuant to Section 12(b) of the Exchange Act, which are traded on the New York Stock Exchange. Alcon Inc. is currently the largest eye care company in the world with 20,000 employees conducting business in more than 140 countries.

8. **Alcon Pte Ltd** ("Alcon Singapore") was an affiliate of Alcon between 2011 and 2014. Among other functions, Alcon Singapore provided management oversight over two Alcon representative offices in Vietnam (collectively, "Alcon Vietnam"). Alcon Singapore's and Alcon Vietnam's financial statements were consolidated with those of Novartis during the relevant period.

FACTS

Conduct Relevant to Greece

9. From approximately 2012 through 2015, Novartis Greece engaged in a scheme to corruptly provide improper benefits and things of value to HCPs, including employees of state-owned and state-controlled hospitals and clinics, to obtain an improper advantage and to increase sales of Lucentis in Greece. In addition, from approximately 2009-2012, Novartis Greece conducted certain Phase IV and epidemiological studies that were primarily designed to promote sales of Novartis products in Greece, resulting in improper payments to HCPs.

10. The misuse of seemingly legitimate educational and scientific activities for improper purposes included the Novartis Greece Ophthalmology franchise ("Ophtha"), and was known and approved by Novartis Greece Ophtha managers of various levels, including brand managers and sales managers, who provided guidance to subordinate staff on the use of "investment" activities. Novartis Greece improperly recorded the payments related to these activities as legitimate advertising and promotion or marketing and sales expenses.

11. Certain Novartis Greece Ophtha employees ranked HCPs by their prescribing product preference and volume and, based upon their likelihood to prescribe, provided them with improper inducements as "investments" to increase their use of Novartis products. This was internally described as a return on investment ("ROI"), and sales and marketing staff were encouraged to plan their activities so as to maximize ROI. In strategy planning documents within the Ophtha business franchise, sales staff remarked that HCPs were reminded of their investment and obligation to prescribe. If an HCP was not meeting their return on investment, investment activities were reduced or eliminated.

12. Novartis Greece's Ophtha franchise misused international congress sponsorships to induce HCPs to write prescriptions for Lucentis, a drug sold by Novartis Greece that was used to treat neovascular (wet) age-related macular degeneration, among other indications. Novartis Greece targeted Greek HCPs that it designated Key Opinion Leaders ("KOLs") and paid their costs to attend the congresses, many of which exceeded $5,000 per HCP. Internal documents written by members of Novartis Greece Ophtha franchise and minutes of meetings within the ophthalmology business discussed use of international congresses, including to the United States, to "undermine [a competitor company's] aggressive congress policy," and described the need to increase pressure on HCPs to prescribe Lucentis, including stating that HCPs "must understand that their participation in [specific congresses in the United States and Europe] will be cancelled if sales performance is not improved significantly." An internal document went on to describe that Novartis Greece sales representatives "must make clear to their [HCP] customers that Lucentis is facing real difficulties in the market and for this reason there will be serious consequences." In his 2013 Action Plan, the Novartis Greece Ophtha KOL manager wrote that he would convey to one ophthalmology KOL, "to get you must write. No presents any more."

13. In certain instances, sales representatives also demanded that KOLs agree to "NON USE of [a competitor's product and] TOTAL COOPERATION," in exchange for Novartis Greece considering "DOUBLING THE GIFT IN 2014." Those Greek HCPs that were perceived to have a lower potential to prescribe Novartis drugs, and thus lower potential ROI, were excluded from obtaining sponsorships and other ostensibly educational and scientific activities.

14. Novartis Greece also engaged in improper conduct with respect to Phase IV and epidemiological studies. The Phase IV clinical studies were supposed to be used to assess the safety and efficacy of the studied prescription drug with a publication announcing the results of the study in order to inform medical decisions. In a phase IV clinical study, HCPs are selected by Novartis' Medical Affairs group. However, in certain instances, sales personnel made the selection of HCPs to participate in order to inappropriately promote particular products or induce HCPs to increase prescription sales.

15. As described in a 2012 Novartis Internal Audit review of the phase IV studies conducted by Novartis Greece, there was a lack of transparency outside of the Medical Affairs function in the planning, design, and execution of clinical studies in Greece, and it determined that weaknesses in process and control design in execution did not ensure that the studies were of a non-promotional nature. The review identified numerous control deficiencies surrounding Phase IV studies conducted in Greece, including (1) unsupported medical or scientific rationale to

perform the studies; and (2) indications the studies were promotional and designed to achieve commercial advantage. Internal audit also found controls weaknesses in the collection of data and publication of study results. In response to the internal audit review, Novartis Greece agreed to engage in a remediation plan, and to improve the Finance Department's oversight of clinical studies.

16. Internal audit reported its findings to Novartis corporate security, which conducted its own review in 2012. Among the studies that Novartis corporate security reviewed were EXACTLY related to the products Diovan, Exforge, and Rasilez; OBVIOUS related to product Aclasta; and REGINA related to product Xolair. Novartis corporate security had similar findings. In summary, corporate security found weak scientific rationales for several clinical studies, suggesting that some clinical studies were used primarily, and inappropriately, as a marketing tool to increase sales of Novartis products. Corporate security also found control weaknesses that made it difficult to ensure that HCPs were paid the correct amounts for their participation in the clinical studies. For example, in the EXACTLY study, approximately four times as many HCP names were submitted to the local health authority than actually received payments. Additionally, some payments were made to HCPs using a vendor named "dummy vendor."

17. Of the patient medical information submitted on 42,000 clinical research forms, 25,500 forms had mistakes. Further, an audio recording of a debrief following the EXACTLY study showed that some Novartis Greece employees were aware that some HCPs who participated in EXACTLY believed that they were obtaining payments in return for their prescriptions of Novartis products and not for their role in the study. For instance:

- "you all know this very well, I just repeat, that the doctor believes that he/she participates in a study and gets paid for what he prescribes in reality and not for what he/she write in the study…"
- "To be honest, the studies were conducted in a similar way in the past as well; they were conducted as marketing projects. That's within quotation markes. Between us."

18. From the perspective of Novartis Greece's Finance Department, clinical studies were a "black box," in that the Finance Department lacked visibility into clinical study budgets and due to a lack of internal accounting controls there was no proper reconciliation between budget and actual spend. Moreover, in some instances, because of deficiencies in Novartis Greece's internal accounting and supplier management controls, Novartis Greece used "dummy vendors" to try to track which HCPs were paid for which studies and to monitor payments relative to the approved budget. Some HCPs received approximately 60 euros (then approximately $83 USD) per patient clinical form and some received as much as 38,000 euros (then approximately $52,820 USD) for completing clinical forms. A follow-up Internal Audit review in 2013 concluded that Novartis Greece addressed many of the deficiencies identified in the 2012 review. Over the next several years, Novartis Greece reduced the number of local Phase IV studies it performed and eventually stopped conducting them altogether.

19. As described in a 2013 Novartis Internal Audit review, Novartis Greece also lacked sufficient controls around grants provided to HCPs, and they were sometimes provided without complete due diligence of the recipient, without clear details regarding the use of the funds, and in circumstances where there was an improper connection to sales strategies. In response to the internal audit review, Novartis Greece agreed to improve internal controls over the grant approval and governance processes.

20. During the relevant period, Novartis was unjustly enriched byover $70.1 million from sales in Greece of Lucentis and products related to the OBVIOUS and REGINA studies.

Conduct Relevant to Alcon Vietnam

21. Alcon conducted its business operations in Vietnam through two representative offices (collectively "Alcon Vietnam"). Alcon Vietnam's management and financial reporting were overseen by the regional management team of Alcon Singapore, which was an indirect wholly-owned subsidiary of Novartis. In light of local laws, Alcon Vietnam conducted all sales and marketing activities of Alcon surgical equipment (e.g., phacoemulsification and refractive surgery lasers) and consumables (e.g., intraocular lenses ("IOLs")) through a Vietnamese distributor ("Distributor Company"). Under a 2006 distributorship agreement, the Distributor Company was guaranteed a margin of 24.7% for "importation, technical service, product registration, and distribution services."

22. Beginning in approximately 2007 and continuing into 2014, Alcon Vietnam and Distributor Company engaged in a scheme to make improper payments to HCPs, both private and publicly employed at Vietnam state-owned and state-controlled hospitals and clinics, to increase the sale of Alcon's IOLs. In connection with the scheme, from 2008 to late 2011, the Distributor Company implemented a "consultancy program" through which it paid bribes to HCPs in exchange for their agreement to recommend the benefits of Alcon products to patients and thereby increase sales of Alcon products. Distributor Company made the improper payments directly to the HCPs with the approval of Alcon Vietnam managers and employees, who reimbursed Distributor Company for up to 50 percent of the costs associated with the payments through the use of credit notes.

23. Alcon Vietnam personnel and Distributor Company coordinated the amounts of the improper payments to HCPs through the consultancy program and also coordinated which types of doctors to target for the payments. For example, in July 2008 the Distributor Company proposed payments to, "Doctor in consult[ation] room," "Doctor in the exam room," "Nurse in consult[ation] room," "and the "Chief of [Operating Room] in certain eye hospitals in Vietnam. Other communications made clear that the purpose of the payments was to "encourage[] doctors to introduce and use Alcon's IOLs and … speed up IOLs sales."

24. Following the 2011 merger of Novartis and Alcon, Novartis failed to take sufficient steps to ensure the improper payments to HCPs halted. After 2011, the program was instead revised and referred to by different names (e.g., "patient education"), and Distributor Company's payments to HCPs continued. For example, a profit-and-loss statement provided by the Distributor

Company to Alcon Vietnam Representative Office personnel in June 2014 showed a line item for "[c]onsultant cost" through mid-2014. Despite awareness by some personnel at the representative offices of ongoing payments to HCPs by Distributor Company, Alcon Vietnam approved Distributor Company's inflated requests to Alcon Vietnam for reimbursement for marketing, human resources, and margin reconciliation funds.

25. Up until June 2014, Alcon Vietnam allowed for the Distributor Company to be paid annually as partial reimbursement for payments that it made to HCPs (for instance, reimbursing up to approximately $180,000 in 2010, and up to $100,000 in 2013 and 2014), pursuant to the consultancy program and the post-2011 variations of the program.

26. During a phone call in or around late summer 2014, a Distributor Company executive told an Alcon Singapore executive that it had used up all of its funds to pay for Alcon surgical equipment and could no longer pay the "usual considerations" to HCPs to ensure they purchased Alcon products. A former Alcon Singapore executive who was aware of the improper payments signed and transmitted two false Sarbanes-Oxley sub-certification letters to Alcon's Chief Executive Officer and Chief Financial Officer in which the executive did not identify the improper reimbursements to the Distributor Company. The payments were falsely recorded as legitimate consultant payments in the consolidated books and records of Novartis.

27. During the relevant period, Novartis was unjustly enriched by approximately $8.4 million as a result of improper conduct in Vietnam.

Conduct Relevant to Korea

28. Between 2011 and August, 2016, Novartis Korea employees made corrupt payments to HCPs to increase prescriptions and sales of Novartis products over that of its competitors. These payments were made through one of several means, and each of which was improperly recorded in Novartis' consolidated books and records. One scheme to make improper payments to HCPs was disguised as payments made for ostensible medical journal activities organized by a third party vendor. Under local law, pharmaceutical companies are prohibited from making any type of payment directly to HCPs for the purpose of promoting sales. One intent of the local restriction was to discourage pharmaceutical companies from concentrating more on marketing and promotional activities towards HCPs rather than on competition based on product quality through research and development.

29. In an effort to circumvent local law, certain employees of Novartis Korea made the improper payments to HCPs via certain third-party medical journals that forwarded the payments to the HCPs for participating in roundtable meetings organized by the medical journal. Novartis Korea sales personnel selected HCPs to participate in editorial and roundtable meetings, at some of which Novartis Korea sales representatives marketed Novartis products, and some meetings were followed by recreational activities with the HCPs.

30. HCPs who participated in the round-table meetings received honoraria in amounts ranging from $268 to $447 USD per event, and the amount of fees paid to HCPs averaged $2550

USD per journal. The honoraria came from advertising fees Novartis Korea paid to the medical journals and were improperly recorded in the books and records as such. Novartis Korea paid the medical journals over $16.3 million between 2011 and 2015, some of which was improperly passed on to HCPs as honoraria. As these events were conducted through a vendor, they were not subjected to compliance review as otherwise required by Novartis' policies.

31. For the conduct described above, the Korean Ministry of Health and Welfare and the Korean Ministry of Food and Drug Safety imposed in 2017 civil administrative fines totaling approximately $50.3 million USD on Novartis Korea and suspended sales and reimbursements of certain Novartis products for 3-6 months. In 2020, criminal proceedings by the South Korean authorities against Novartis Korea and several former Novartis Korea employees found Novartis Korea and one of its former sales staff guilty for the same conduct, and Novartis Korea was fined approximately $35,000 USD.

32. In another scheme, Novartis Korea sales managers and employees organized the sponsorship of HCPs to international medical conferences as an inducement for HCPs to increase their prescriptions of Novartis products. Between 2011 and August 2016, Novartis Korea provided funding for 2,032 HCPs to attend 381 international conferences at a combined cost of approximately $7 million. Of those conferences, 645 HCPs attended 112 conferences in the United States at a cost of approximately $2.5 million. The types of conferences varied across therapeutic area, including oncology, cardiometabolic, neuroscience, and ophthalmology. As a result of internal accounting controls weaknesses, certain of these ostensibly legitimate congress sponsorship fees were used to improperly influence HCPs. In connection with some congresses, Novartis Korea employees took into account the prescription sales activities of certain HCPs when targeting them for sponsorships in an effort to encourage the HCPs to increase their prescriptions.

33. Novartis Korea incorrectly recorded the improper payments on its books and records as legitimate advertising and promotional fees. Novartis Korea failed to have in place a control system reasonably designed to ensure that its sales staff were not using sponsorships as improper inducements. Novartis Korea also failed to have adequate internal accounting controls over its payments for these trips. In June 2017, Novartis Korea was charged and fined approximately $446,000 by the Korea Fair Trade Commission with unfair trade practices for the conduct described above.

34. In yet a third scheme, Novartis Korea employees in the neuroscience business unit devised a local non-interventional clinical study with 17 pre-selected HCPs to improve relationships with those HCPs. The study was organized in May 2013 through a local medical journal with Novartis Korea providing the list of HCPs to participate and the $100,000 funding necessary to complete the study. Novartis Korea recorded the funding to complete the study as advertising expenses and failed to have the study reviewed and approved by medical affairs as required by internal procedures.

35. Over the relevant time period, Novartis was unjustly enriched by over $13.8 million from the improper conduct in Korea.

Conduct Relevant to Alcon Asia

36. In 2011, Novartis merged with Alcon, which until that time had publicly traded securities in the United States. After the merger, Novartis operated Alcon as a separate reporting segment through which it sold vision care equipment and other products, such as IOLs and other consumables.

37. From 2013 to 2015, within Novartis' Alcon Asia business, including its operations in China, employees placed Alcon surgical equipment at hospitals or clinics for no or little money down in exchange for contractual assurances that those hospitals or clinics would either pay for the equipment directly or finance it over several years through payments associated with the purchase of Alcon's IOLs and consumables during the contract's term.

38. This business model was in place both before and after Novartis merged with Alcon, and it facilitated long-term relationships between Alcon and its customers. Beginning in 2013, Alcon called these agreements "equipment financing arrangements" (i.e., EFAs). Certain Alcon Asia managers used aggressive sales techniques and employees in China at times falsified documents in order to enter into these EFAs. Novartis lacked adequate internal accounting controls to ensure the appropriate accounting treatment for the arrangements and to appropriately record the transactions in its books and records.

39. Before 2013, Novartis generally accounted for Alcon's equipment placement agreements as operating leases, and recognized associated revenue as payment was received, whether on the equipment or on associated sales of Alcon IOLs and/or consumables. In 2013, Novartis generally started accounting for Alcon's EFAs as finance leases or sales, recognizing revenue up front at the time of placement (after installation and training).

40. Novartis lacked sufficient internal accounting controls needed in light of the degree of accounting, contractual, and financial complexity presented by EFAs. For example, in connection with Alcon EFA's in China, Novartis lacked appropriate internal accounting controls to ensure that a written instrument reflected the terms negotiated with a hospital, that agreements were signed or "chopped" by the counterparty hospital, and that agreements contained the price of consumables to be purchased or the premium to be paid. Other controls issues existed with respect to Alcon China's credit assessments of counterparty hospitals, allowances for bad debt established at inception, compliance billing, equipment repossession, proof of delivery or installation and completion of required training associated with EFAs.

41. Particularly in markets such as China, where the customer base of Alcon's local subsidiary ("Alcon China") was dominated by public hospitals and state HCPs, EFAs presented issues of validity, profitability, and misaligned incentives. A significant portion of Alcon's surgical sales in China were derived from EFAs with state HCPs.

42. After the switch to finance lease accounting, sales personnel – who until mid-2015 were compensated, in part, based upon the amount of equipment placed under EFAs rather than

upon how EFAs ultimately performed – entered into certain EFAs that did not satisfy relevant revenue recognition criteria or that inaccurately projected future IOL and/or consumable purchases. Despite knowing that customers' "compliance rates" with respect to EFA contractual purchase obligations were sometimes very low, Alcon China continued entering into certain EFAs that lacked adequate profitability safeguards.

43. In late 2015, a new management team of Alcon China initiated a comprehensive review of most equipment placed in hospitals and clinics and the associated contractual paperwork. The on-site check was completed in the summer of 2016 and revealed that of the 1348 pieces of equipment in scope (with about 700 customers) that 844 pieces of equipment had been placed pursuant to 466 contracts, with which Alcon China had identified potential issues. Nearly half of the 844 pieces of equipment in question had been placed pursuant to contracts that lacked a formal hospital "chop" but had been validated by the hospital; the remaining pieces of equipment either could not be located, had been moved to other hospitals, or were obtained pursuant to forged or unverified contracts. Group, Division, region, and local management became aware of the controls deficiencies through various internal audit reports, remediation exercises, and local financial certifications, including the 2016 internal audit of Alcon China, which resulted in a "Needs Major Improvement" rating for the second consecutive audit.

44. Over time, efforts to ensure that EFAs in China were properly executed and recorded were unsuccessful, and Novartis management became aware of EFA-related controls deficiencies. As described by a senior Alcon executive in a letter to several senior Novartis executives in response to a 2016 internal audit,

> A historically high pressure sales culture that prioritized meeting sales targets over compliance and a high tolerance of unacceptable risks still persists residually in the organization. A very poorly executed legal EFA remediation exercise characterized by high pressure and coercion to obtain remediated contracts resulted in a large number of fraudulent, falsified, invalid and unenforceable contracts. This resulted in a number of non-performing EFAs that are difficult to remediate commercially as the underlying agreement itself is in question.

The letter observed that "[d]eveloping a strong compliance culture requires a comprehensive program and holistic approach with clear commitment from senior management" and then laid out the specific actions that Alcon's new management team intended to take in late 2016 to implement enhanced compliance processes to address the historical issues.

45. During the relevant period, Novartis and Alcon attempted to strengthen controls to address these issues through various remediation exercises. Novartis and Alcon ultimately abandoned the EFA business model for surgical sales in China and moved to a cash-sale business model beginning in late 2016. The lack of appropriate internal accounting controls throughout the relevant period contributed to Novartis and Alcon ultimately provisioning over $50M in bad debt due to the poor performance of its EFAs in China.

Legal Standards and Violations

46. Under Section 21C 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, 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.

47. As a result of the conduct described above, Novartis violated Section 13(b)(2)(A) of the Exchange Act, which requires issuers that have a class of securities registered pursuant to Section 12 of the Exchange Act and issuers with reporting obligations pursuant to Section 15(d) of the Exchange Act to make and keep books, records, and accounts which, in reasonable detail, accurately and fairly reflect their transactions and disposition of their assets. [15 U.S.C. § 78m(b)(2)(A)].

48. As a result of the conduct described above Novartis violated Section 13(b)(2)(B) of the Exchange Act, which requires issuers that have a class of securities registered pursuant to Section 12 of the Exchange Act and issuers with reporting obligations pursuant to Section 15(d) of the Exchange Act 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. [15 U.S.C. § 78m(b)(2)(B)].

Cooperation and Remediation

49. In determining to accept the Offer, the Commission considered remedial acts promptly undertaken by Respondent and cooperation afforded the Commission staff. Novartis' cooperation included providing translations of certain relevant documents, making current or former employees available to the Commission staff, and timely providing facts developed during the course of its own internal investigation. Novartis' remediation included the termination of select personnel and third-party entities involved in the misconduct and certain additions to and strengthening of its internal accounting controls. Novartis also retained a dedicated chief compliance officer, improved its due diligence and business justification process for third parties, and enhanced training provided to employees.

Undertakings

50. Respondent shall report to the Commission staff periodically during a three-year term, the status of its remediation and implementation of compliance measures, particularly as to the areas of due diligence on prospective and existing third-party consultants and vendors, FCPA

training and the testing of relevant controls including the collection and analysis of compliance data. During this period, should Respondent discover credible evidence, not already reported to 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 two follow-up reviews and reports, as described below:

a. Respondent shall submit to the Commission staff a written report within 360 calendar days of the entry of this Order setting forth a complete description of its 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 review (the "Initial Report"). The Initial Report shall be transmitted to Tracy L. Price, Deputy Chief, FCPA Unit, Division of Enforcement, Securities and Exchange Commission, 100 F St., NE, Washington, DC 20549-5631. Respondent may extend the time period for issuance of the Initial Report with prior written approval of the Commission staff.

b. Respondent shall undertake two 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 Follow-up Report shall be completed by no later than 720 days after the Initial Report. The second Follow-up Report shall be completed by no later than 1050 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.

e. During this three-year period of review, Respondent shall provide its external auditors with its annual internal audit plan and reports of the results of internal audit

procedures and its assessment of its FCPA compliance policies and procedures.

f. During the three-year period of review, Respondent shall provide Commission staff with any written reports or recommendations provided by Respondent's external auditors in response to Respondent's annual internal audit plan, reports of the results of internal audit procedures, and its assessment of its FCPA compliance policies and procedures.

51. 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 Tracy L. Price, Deputy Chief, FCPA Unit, Division of Enforcement, Securities and Exchange Commission, 100 F St., NE, Washington, DC 20549-5631 no later than sixty (60) days from the date of the completion of the undertakings.

Deferred-Prosecution Agreements

52. Novartis Hellas S.A.C.I., a Novartis subsidiary, has entered into a three-year deferred prosecution agreement with the U.S. Department of Justice, in which it acknowledged responsibility for criminal conduct relating to certain findings in the Order. *See* United States v. Novartis Hellas S.A.C.I, Crim No. 20-CR-538 (DNJ Jun 25, 2020) (SDW). Alcon Pte Ltd, a current subsidiary of Alcon Inc. and a former subsidiary of Novartis, independently entered into a three-year deferred prosecution agreement with the U.S. Department of Justice, in which Alcon Pte Ltd acknowledged responsibility for criminal conduct relating to certain findings in the Order. *See* United States v. Alcon Pte Ltd, Crim No. 20-CR-539 (DNJ Jun 25, 2020) (SDW).

Non-Imposition of a Civil Penalty

53. Novartis acknowledges that the Commission is not imposing a civil penalty based upon the imposition of a $233,925,000 criminal fine as part of the above referenced resolutions with the U.S. Department of Justice.

IV.

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

Accordingly, it is hereby ORDERED that**:**

A. Pursuant to Section 21C of the Exchange Act, Respondent 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 comply with the undertakings enumerated in paragraphs 50-51 above.

C. Respondent shall, within fourteen days of the entry of this Order, pay disgorgement of $92,300,000 and prejudgment interest of $20,500,000 for a total of $112,800,000 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 SEC Rule of Practice 600.

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 Novartis 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 Tracy L. Price, FCPA Deputy Unit Chief, Division of Enforcement, Securities and Exchange Commission, 100 F St., NE, Washington, DC 20549-5631.

By the Commission.

Vanessa A. Countryman
Secretary