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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

_____, Individually and on behalf of all others similarly situated, Plaintiff, v. NOVARTIS AG, VASANT NARASIMHAN, and HARRY KIRSCH, Defendants.	Case No: **CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **JURY TRIAL DEMANDED**

Plaintiff _____ ("Plaintiff"), individually and on behalf of all other persons similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants (defined below), alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through his attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by

Defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Novartis AG ("Novartis" or the "Company"), and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a class action on behalf of persons or entities who purchased or otherwise acquired publicly traded Novartis securities between December 3, 2018 and August 5, 2019, inclusive (the "Class Period"). Plaintiff seeks to recover compensable damages caused by Defendants' violations of the federal securities laws under the Securities Exchange Act of 1934 (the "Exchange Act").

JURISDICTION AND VENUE

2. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

3. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, and Section 27 of the Exchange Act (15 U.S.C. §78aa).

4. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)) as Defendants

conduct business in this district and the alleged misstatements entered and the subsequent damages took place in this judicial district.

5. In connection with the acts, conduct and other wrongs alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mails, interstate telephone communications and the facilities of the national securities exchange.

PARTIES

6. Plaintiff, as set forth in the accompanying certification, incorporated by reference herein, purchased Novartis securities during the Class Period and was economically damaged thereby.

7. Defendant Novartis, through its subsidiaries, researches, develops, manufactures, and markets healthcare products worldwide. Novartis is incorporated in and has its principal executive offices in Switzerland. Novartis' sponsored ADRs trade on the New York Stock Exchange ("NYSE") under the ticker symbol "NVS".

8. Defendant Vasant Narasimhan ("Narasimhan") has served as the Company's Chief Executive Officer ("CEO") since February 1, 2018.

9. Defendant Harry Kirsch ("Kirsch") has served as the Company's Chief Financial Officer ("CFO") since 2013.

10. Defendants Narasimhan and Kirsch are collectively referred to herein as the "Individual Defendants."

11. Each of the Individual Defendants:

(a) directly participated in the management of the Company;

(b) was directly involved in the day-to-day operations of the Company at the highest levels;

(c) was privy to confidential proprietary information concerning the Company and its business and operations;

(d) was directly or indirectly involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein;

(e) was directly or indirectly involved in the oversight or implementation of the Company's internal controls;

(f) was aware of or recklessly disregarded the fact that the false and misleading statements were being issued concerning the Company; and/or

(g) approved or ratified these statements in violation of the federal securities laws.

12. Novartis is liable for the acts of the Individual Defendants and its employees under the doctrine of *respondeat superior* and common law principles

of agency because all of the wrongful acts complained of herein were carried out within the scope of their employment.

13. The scienter of the Individual Defendants and other employees and agents of the Company is similarly imputed to Novartis under *respondeat superior* and agency principles.

14. Defendants Novartis and the Individual Defendants are collectively referred to herein as "Defendants."

SUBSTANTIVE ALLEGATIONS

Materially False and Misleading Statements Issued During the Class Period

15. On December 3, 2018, Novartis issued a press release announcing that the U.S. Food & Drug Administration ("FDA") accepted the Biologics License Application ("BLA") for Zolgensma, stating, in pertinent part:

> **Basel, December 3, 2018 -** Novartis today announced that the U.S. Food and Drug Administration (FDA) has accepted the company's Biologics License Application (BLA) for AVXS-101, now known as ZOLGENSMA® *(onasemnogene abeparvovec-xxxx)[1]*, an investigational gene replacement therapy for the treatment of spinal muscular atrophy (SMA) Type 1. ZOLGENSMA is designed to address the genetic root cause of SMA Type 1, a deadly neuromuscular disease with limited treatment options. ZOLGENSMA previously received Breakthrough Therapy designation and has been granted Priority Review by the FDA, with regulatory action anticipated in May 2019.

16. On January 30, 2019, Novartis filed a Form 20-F with the SEC, which provided its financial results and position for the fiscal year ended December 31, 2018 (the "2018 20-F"). The 2018 20-F was signed by Defendants Narasimhan and Kirsch. The 2018 20-F contained signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by Defendants Narasimhan and Kirsch attesting to the accuracy of financial reporting, the disclosure of any material changes to the Company's internal control over financial reporting and the disclosure of all fraud.

17. The Company's 2018 20-F stated the following with respect to the status of Zolgensma's application:

> AVXS-101 (onasemnogene abeparvovec-xxxx, *Zolgensma*) is a gene replacement therapy candidate designed to address the genetic root cause of spinal muscular atrophy (SMA), a progressive neuromuscular disease and the leading cause of genetic mortality in infants globally. In December 2018, we announced that the FDA accepted the Biologics License Application for *Zolgensma* for the treatment of SMA type 1, the most severe form of the disease. Delivered as a single, one-time infusion, *Zolgensma* works by replacing the missing or defective SMN1 gene with a functional copy that makes the SMN protein, thereby improving motor neuron function and survival. The Biologics License Application filing is supported by data from the Phase I START trial, which demonstrated an increase in survival and improved achievement of developmental milestones compared to the natural history of SMA type 1. *Zolgensma* is currently being studied in a Phase III trial in patients with SMA type 1 in the US (STR1VE) and in Europe (STR1VE-EU), with a planned Phase III study in the Asia-Pacific region (STR1VE-AP). *Zolgensma* is also being studied in a Phase I trial in the US in patients with SMA type 2 (STRONG), and in a Phase III multinational trial in presymptomatic patients with SMA with two or three copies of the SMN2 gene (SPR1NT). A trial in

pediatric patients with SMA types 1, 2 and 3 (REACH) is planned for 2019. Patients from the START trial had the option to voluntarily enroll in a long-term, 15-year observational follow-up study. The brand name *Zolgensma* has been provisionally approved by the FDA for AVXS-101, but the product itself has not received marketing authorization or Biologics License Application approval from any regulatory authorities.

18. On May 24, 2019, the Company issued a press release announcing that it had received FDA approval for Zolgensma, stating, in pertinent part:

> **Basel, May 24, 2019 -** AveXis, a Novartis company, today announced the US Food and Drug Administration (FDA) has approved Zolgensma® (onasemnogene abeparvovac-xioi) for the treatment of pediatric patients less than 2 years of age with spinal muscular atrophy (SMA) with bi-allelic mutations in the survival motor neuron 1 (*SMN1*) gene. Zolgensma is designed to address the genetic root cause of SMA by providing a functional copy of the human SMN gene to halt disease progression through sustained SMN protein expression with a single, one-time intravenous (IV) infusion. Zolgensma is the first and only gene therapy approved by the FDA for the treatment of SMA, including those who are pre-symptomatic at diagnosis.
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> "A diagnosis of SMA is devastating, leaving untreated babies who have the most severe form with painfully short, highly medicalized lives, during which they are unable to lift their heads, sit or roll, have difficulty swallowing and breathing and need 24-hour care," said Jerry Mendell, M.D., principal investigator at the Center for Gene Therapy at The Abigail Wexner Research Institute of Nationwide Children's Hospital in Columbus, OH. "In the START clinical trial we conducted with Zolgensma, all children were alive at the conclusion of the study and many were able to sit, roll, crawl, play and some could walk. This level of efficacy, delivered as a single, one-time therapy, is truly remarkable and provides a level of unprecedented hope for families battling SMA Type 1. We now have data four years out from the trial, and we see the durability of this gene therapy."

19. The statements contained in ¶¶15-19 were materially false and/or misleading because they misrepresented and failed to disclose the following adverse facts pertaining to the Company's business, operations and prospects, which were known to Defendants or recklessly disregarded by them. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (1) the Company's BLA submitted to the FDA for Zolgensma contained improperly manipulated data; (2) despite having knowledge of such data manipulation, the Company did not inform the FDA until after Zolgensma was approved; (3) as a result of the aforementioned misconduct, Novartis would face regulatory scrutiny; and (4) due to the foregoing, Defendants' statements about its business, operations, and prospects, were materially false and misleading and/or lacked a reasonable basis at all relevant times.

THE TRUTH EMERGES

20. On August 6, 2019, the FDA issued a statement announcing that the data that Novartis submitted in its Biologics License Application for Zolgensma contained manipulated data, and that Novartis' subsidiary, AveXis, became aware of the data manipulation before the FDA approved the product, stating, in pertinent part:

> On May 24, the FDA approved Zolgensma, a gene therapy product intended to treat children less than two years of age with spinal muscular atrophy (SMA) with bi-allelic mutations in the survival

> motor neuron 1 gene — the most severe form of SMA. SMA is a leading genetic cause of infant mortality. ***Subsequently, on June 28, following the FDA's approval of the product, the agency was informed by AveXis Inc., the product's manufacturer, about a data manipulation issue that impacts the accuracy of certain data from product testing performed in animals submitted in the biologics license application (BLA) and reviewed by the FDA.***
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> * * *
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> ***We are also aware that AveXis became aware of the issue of the data manipulation that created inaccuracies in their BLA before the FDA approved the product, yet did not inform the FDA until after the product was approved. The agency will use its full authorities to take action, if appropriate, which may include civil or criminal penalties.***
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> (Emphasis added.)

21. On this news, Novartis ADRs fell $2.50 or approximately 3% to close at $88.82 per ADR on August 6, 2019, damaging investors.

22. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

23. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class consisting of all persons other than defendants who acquired Novartis securities publicly traded on the NYSE during the Class Period, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of Novartis,

members of the Individual Defendants' immediate families and their legal representatives, heirs, successors or assigns and any entity in which Officer or Director Defendants have or had a controlling interest.

24. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Novartis securities were actively traded on the NYSE. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds, if not thousands of members in the proposed Class.

25. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by defendants' wrongful conduct in violation of federal law that is complained of herein.

26. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

27. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the Exchange Act were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the financial condition and business Novartis;
- whether Defendants' public statements to the investing public during the Class Period omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;
- whether the Defendants caused Novartis to issue false and misleading public filings during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false public filings;
- whether the prices of Novartis' securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

28. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is

impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

29. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Novartis shares met the requirements for listing, and were listed and actively traded on NYSE, a highly efficient and automated market;
- As a public issuer, Novartis filed periodic public reports;
- Novartis regularly communicated with public investors via established market communication mechanisms, including through the regular dissemination of press releases via major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and
- Novartis was followed by a number of securities analysts employed by major brokerage firms who wrote reports that were widely distributed and publicly available.

30. Based on the foregoing, the market for Novartis securities promptly digested current information regarding Novartis from all publicly available sources and reflected such information in the prices of the shares, and Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

31. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information as detailed above.

COUNT I
For Violations of Section 10(b) And Rule 10b-5 Promulgated Thereunder Against All Defendants

32. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

33. This Count is asserted against Defendants is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

34. During the Class Period, Defendants, individually and in concert, directly or indirectly, disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they

contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

35. Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they:

- employed devices, schemes and artifices to defraud;
- made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or
- engaged in acts, practices and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of Novartis securities during the Class Period.

36. Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of Novartis were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated, or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the securities laws. These defendants by virtue

of their receipt of information reflecting the true facts of Novartis, their control over, and/or receipt and/or modification of Novartis' allegedly materially misleading statements, and/or their associations with the Company which made them privy to confidential proprietary information concerning Novartis, participated in the fraudulent scheme alleged herein.

37. Individual Defendants, who are the senior officers and/or directors of the Company, had actual knowledge of the material omissions and/or the falsity of the material statements set forth above, and intended to deceive Plaintiff and the other members of the Class, or, in the alternative, acted with reckless disregard for the truth when they failed to ascertain and disclose the true facts in the statements made by them or other Novartis personnel to members of the investing public, including Plaintiff and the Class.

38. As a result of the foregoing, the market price of Novartis securities was artificially inflated during the Class Period. In ignorance of the falsity of Defendants' statements, Plaintiff and the other members of the Class relied on the statements described above and/or the integrity of the market price of Novartis securities during the Class Period in purchasing Novartis securities at prices that were artificially inflated as a result of Defendants' false and misleading statements.

39. Had Plaintiff and the other members of the Class been aware that the market price of Novartis securities had been artificially and falsely inflated by Defendants' misleading statements and by the material adverse information which Defendants did not disclose, they would not have purchased Novartis securities at the artificially inflated prices that they did, or at all.

40. As a result of the wrongful conduct alleged herein, Plaintiff and other members of the Class have suffered damages in an amount to be established at trial.

41. By reason of the foregoing, Defendants have violated Section 10(b) of the 1934 Act and Rule 10b-5 promulgated thereunder and are liable to the plaintiff and the other members of the Class for substantial damages which they suffered in connection with their purchase of Novartis securities during the Class Period.

COUNT II
Violations of Section 20(a) of the Exchange Act
Against the Individual Defendants

42. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

43. During the Class Period, the Individual Defendants participated in the operation and management of Novartis, and conducted and participated, directly and indirectly, in the conduct of Novartis' business affairs. Because of their senior

positions, they knew the adverse non-public information about Novartis' misstatement of revenue and profit and false financial statements.

44. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Novartis' financial condition and results of operations, and to correct promptly any public statements issued by Novartis which had become materially false or misleading.

45. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Novartis disseminated in the marketplace during the Class Period concerning Novartis' results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Novartis to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of Novartis within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Novartis securities.

46. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Novartis.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment and relief as follows:

(a) declaring this action to be a proper class action, designating plaintiff as Lead Plaintiff and certifying plaintiff as a class representative under Rule 23 of the Federal Rules of Civil Procedure and designating plaintiff's counsel as Lead Counsel;

(b) awarding damages in favor of plaintiff and the other Class members against all defendants, jointly and severally, together with interest thereon;

(c) awarding plaintiff and the Class reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) awarding plaintiff and other members of the Class such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

Dated: August __, 2019

Respectfully submitted,

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