UNITED STATES OF AMERICA
Before the
SECURITIES AND EXCHANGE COMMISSION

SECURITIES ACT OF 1933
Release No. 11400 / January 16, 2026

ADMINISTRATIVE PROCEEDING
File No. 3-22577

In the Matter of **ANKIT MAHADEVIA and SATYAVRAT SHUKLA** **Respondents.**	**ORDER INSTITUTING CEASE-AND-DESIST PROCEEDINGS, PURSUANT TO SECTION 8A OF THE SECURITIES ACT OF 1933, 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 8A of the Securities Act of 1933 ("Securities Act") against Ankit Mahadevia ("Mahadevia") and Satyavrat Shukla ("Shukla" and, together with Mahadevia, "Respondents").

II.

In anticipation of the institution of these proceedings, Mahadevia and Shukla each has submitted an Offer of Settlement (the "Offers"), 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 them and the subject matter of these proceedings, which are admitted, and except as provided herein in Section V, Respondents consent to the entry of this Order Instituting Cease-and-Desist Proceedings, Pursuant to Section 8A of the Securities Act of 1933, Making Findings, and Imposing a Cease-and-Desist Order ("Order"), as set forth below.

III.

On the basis of this Order and Respondents' Offers, the Commission finds[1] that:

[1] The findings herein are made pursuant to Respondents' Offers of Settlement and are not binding on any other person or entity in this or any other proceeding.

Summary

1. This matter involves violations of the federal securities laws by Dr. Ankit Mahadevia, the former Chief Executive Officer of Spero Therapeutics Inc. ("Spero"), and Satyavrat Shukla, the former Chief Financial Officer of Spero. Spero is a Cambridge, Massachusetts-based biopharmaceutical company. In October 2021, Spero submitted a new drug application ("NDA") to the U.S. Food and Drug Administration ("FDA") to obtain approval of its lead drug candidate, tebipenem pivoxil hydrobromide ("tebipenem"), a drug intended to treat complex urinary tract infections. In February 2022, at a mid-cycle meeting in the FDA's review of Spero's NDA, the FDA review team identified as a "significant issue" Spero's inclusion of certain patients in its analysis of the clinical trial that was the basis for the NDA. The FDA review team told Spero that they had conducted their own analysis of the study results that excluded those patients, and they expressed concern that this analysis did not demonstrate the efficacy of tebipenem. Despite this, Mahadevia and Shukla continued to state that the clinical trial had met its primary efficacy endpoint, and thus, "achieved its primary objective as specified in the protocol." These statements were misleading, because they did not disclose the FDA review team's specific concern about efficacy. On May 3, 2022, Spero disclosed that the FDA had conducted its own analysis that excluded certain patients, as a result of which the FDA considered Spero's trial not to have met its primary efficacy endpoint, and that Spero would cease commercialization of tebipenem and lay off approximately 75% of its personnel. Spero's stock price closed down 64% that day, with analysts calling the news "particularly unexpected" and "shocking."

Respondents

2. **Ankit Mahadevia**, 45, is a resident of Brookline, Massachusetts. From 2016 to 2023, Mahadevia served as President and Chief Executive Officer of Spero, and, from 2023 to January 2025, he served as Chairman of Spero's board of directors. Mahadevia has continued to serve as a member of the board since January 2025.

3. **Satyavrat Shukla**, 53, is a resident of Milton, Massachusetts. From 2021 to 2023, Shukla served as Spero's Chief Financial Officer and, from 2023 to January 2025, he served as Spero's President and Chief Executive Officer and a member of the board of directors. Shukla served as a member of the board until May 2025.

Other Relevant Entity

4. **Spero Therapeutics Inc.** is a Delaware corporation with a principal place of business in Cambridge, Massachusetts. It is a biopharmaceutical company focused on the development of treatments for rare diseases and diseases caused by multi-drug-resistant bacterial infections with high unmet need. Spero's common stock is registered with the Commission under Section 12(b) of the Securities Exchange Act of 1934 ("Exchange Act") and traded on the NASDAQ under the ticker symbol SPRO. Spero is required to file periodic reports, including annual reports on Form 10-K, with the Commission under Section 13(a) of the Exchange Act and

related rules thereunder. During the relevant period, Spero granted stock options and restricted stock units through an employee stock incentive plan.

Background

The Tebipenem Phase 3 Trial and New Drug Application

5. Tebipenem was developed as a potential oral antibiotic treatment alternative to intravenous antibiotic therapy for complicated urinary tract infections. If approved by the FDA, tebipenem is poised to be the only oral antibiotic treatment option for this indication, allowing patients to be treated at home in lieu of hospitalization.

6. Spero initiated a Phase 3 "non-inferiority" study for tebipenem in or around September 2020. The trial compared tebipenem to an already-approved intravenous drug called ertapenem. To demonstrate non-inferiority—the primary trial endpoint—the trial needed to show that tebipenem was "not materially worse" than ertapenem, defined as no more than 12.5% less effective than ertapenem at treating complicated urinary tract infections caused by different types of bacterial infections.

7. Spero's Form 10-K for the fiscal year 2020, which Spero released on March 11, 2021, disclosed that the results of the Phase 3 trial had been positive, and that it had "achieved its primary objective, demonstrating that oral tebipenem HBr was statistically non-inferior to intravenous ertapenem . . . ."

8. In October 2021, Spero submitted an NDA to the FDA. In a press release announcing the submission, Spero repeated the claim that the Phase 3 trial had been successful. It was widely anticipated inside and outside of Spero, including by Respondents, that the FDA would approve tebipenem, because most NDAs based on successful Phase 3 trials are approved.

9. Respondents understood that the status of the tebipenem NDA was important to Spero's investors. Spero characterized tebipenem as its "lead drug candidate" and said that the company was "heavily dependent on its success."

The FDA's Negative Feedback Concerning Spero's Phase 3 Tebipenem Trial

10. On February 8, 2022, at a mid-cycle meeting in the FDA's review of Spero's NDA, the FDA review team told Spero for the first time that its Phase 3 trial had improperly included patients infected with enterococcus bacteria. The review team also told Spero that the agency was conducting a separate analysis excluding those patients, and "highlighted their concern" that the Phase 3 trial "does not meet the [non-inferiority] margin" without the enterococcus patients. Respondents had not anticipated that FDA review team would take issue with the inclusion of enterococcus patients in Spero's analysis of the study, and they were surprised by the feedback.

11. Following the February 8, 2022 meeting, Spero advanced multiple arguments in an effort to persuade the FDA to either include enterococcus patients or loosen its efficacy parameters when analyzing the revised patient population in the FDA's subsequent analysis.

12. On February 18, 2022, the FDA review team told Spero that they did not agree with Spero's arguments that enterococcus patients should be included in the FDA's analysis of the study results, and that the noninferiority margin "was not met" in the patient population that excluded enterococcus patients, which raised "serious concerns about the efficacy" of tebipenem.

13. On February 28, 2022, the FDA cancelled a previously scheduled advisory committee meeting at which it had planned to receive independent, external advice regarding Spero's NDA. The FDA subsequently told Spero that the cancellation was "due to the nature of the concerns previously conveyed" about the NDA—*i.e.*, the inclusion of enterococcus patients.

14. In a March 10, 2022 telephone conference, the FDA review team reiterated its concern that Spero's Phase 3 trial for tebipenem had included enterococcus patients. The FDA also told Spero that the agency continued to deliberate the NDA and would discuss Spero's arguments internally.

15. On March 25, 2022, the FDA notified Spero it was cancelling a previously scheduled discussion of drug labeling and post-marketing requirements for tebipenem, citing "deficiencies" in the NDA. The most senior FDA reviewer told Spero that the "major concern" precluding labeling and post-marketing discussions was the enterococcus issue, and that he had not been persuaded by Spero's arguments in favor of including enterococcus patients. He also told Spero that the FDA remained in a deliberative posture, and that that the matter would be reviewed by the Medical Policy and Program Review Council within the agency's Center for Drug Evaluation and Research.

Respondents' Misleading Disclosures

16. On March 31, 2022, Spero filed its 2021 Form 10-K, which Mahadevia and Shukla reviewed, approved, signed, and certified. In it, Spero disclosed that the FDA had canceled the advisory committee meeting, as well as drug labeling discussions, due to unspecified "deficiencies" with the NDA. Spero also stated that the Phase 3 tebipenem trial had "achieved its primary objective as specified in the protocol, demonstrating that oral tebipenem HBr was statistically non-inferior to intravenous ertapenem . . . ."

17. Respondents added the phrase "as specified in the protocol," which was not included in Spero's prior disclosures, to make a distinction between their analysis of the Phase 3 trial results and the FDA's subsequent analysis, which had excluded enterococcus patients. However, the Form 10-K omitted the FDA's specific concern with Spero's analysis, that the FDA had conducted its own analysis that excluded enterococcus patients, and that the endpoint was not met when those patients were excluded.

18. Spero's Form 10-K also disclosed the cancellation of the advisory committee due to deficiencies with the NDA, but not the nature of the deficiencies. And the 10-K identified as

hypothetical the risks that the FDA would disagree with the "design or implementation of our clinical trials," or of the trial "results not meeting the level of statistical significance required by the FDA," but failed to disclose the FDA's actual concerns with the Phase 3 trial.

19. During Spero's earnings call on March 31, 2022, Mahadevia stated, "we continue to believe that we have a very strong application, the foundation of which is our previously announced data from the Phase 3 . . . trial. These data showed the trial meeting its primary endpoint as specified in the protocol by demonstrating that oral tebipenem HBr was statistically non-inferior to intravenous ertapenem . . . ." Mahadevia declined to provide more information about the FDA's feedback to Spero in response to analyst questions. He also asserted that Spero was "continuing to invest to prepare for the precommercial activities that we're undertaking and thinking about launch, should tebipenem be approved," but did not mention that Spero was also planning for a potential FDA rejection.

20. On April 6, 2022, the New England Journal of Medicine published the results of Spero's Phase 3 trial in an article, and on April 25, 2022, Spero presented a scientific poster concerning the Phase 3 trial at a medical conference. The article and the poster were submitted by Spero before it learned of the FDA's efficacy concerns. On April 6 and April 21, 2022, Spero directed the article and the poster to investors through press releases reviewed and approved by Respondents, one of which (the press release announcing the article) was disclosed in a Form 8-K. The article and the poster both described the Phase 3 trial as having successfully met its primary endpoint, but neither they nor the press releases contained any information regarding the FDA's specific concerns.

21. When taken together, Spero's disclosures created the misleading impression that any issues the FDA had with the tebipenem NDA did not implicate the sufficiency of the Phase 3 trial underlying the application.

Spero's Eventual Disclosure of the FDA's Negative Feedback

22. On April 29, 2022, the FDA review team told Spero that the Medical Policy and Program Review Council had reviewed the NDA and agreed with the review team's "approach to defining the analysis population for the primary efficacy endpoint." In a follow-up conversation on May 2, 2022, the most senior FDA reviewer told Spero that it would need to conduct a second, successful Phase 3 trial to obtain approval.

23. On May 3, 2022, Spero disclosed that "the FDA conducted a separate analysis" that excluded enterococcus patients, "[a]s a result" of which "the FDA considers that the pre-specified non-inferiority (NI) margin of -12.5% was not met," and that Spero was suspending commercialization efforts, reducing its workforce by about 75%, and refocusing its business on other drugs.

24. After the disclosure, Spero's stock price fell 64%, or $3.24 per share (from a closing price of $5.09 per share on May 2 to a closing price of $1.85 per share on May 3). Equity research analysts covering the company characterized the news as "shocking" and "particularly

unexpected" given the market's prior belief in the "strength of the data supporting the tebipenem application."

Violation

25. As a result of the conduct described above, Respondents violated Securities Act Section 17(a)(2), which makes it unlawful for any person, in the offer or sale of a security, to "obtain money or property by means of any untrue statement of material fact" or a material omission necessary to make statements made not misleading. A violation of this provision does not require scienter and may rest on a finding of negligence. *See Aaron v. SEC*, 446 U.S. 680, 701-02 (1980).

IV.

In view of the foregoing, the Commission deems it appropriate and in the public interest to impose the sanctions agreed to in Respondents' Offers.

Accordingly, it is hereby ORDERED that:

A. Pursuant to Section 8A of the Securities Act, Respondents cease and desist from committing or causing any violations and any future violations of Section 17(a)(2) of the Securities Act.

B. Mahadevia shall, within 30 days of the entry of this Order, pay a civil money penalty in the amount of $112,500, 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. Shukla shall, within 30 days of the entry of this Order, pay a civil money penalty in the amount of $75,000, 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.

Payments must be made in one of the following ways:

(1) Respondents may transmit payment electronically to the Commission, which will provide detailed ACH transfer/Fedwire instructions upon request;

(2) Respondents 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) Respondents 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 Mahadevia and Shukla, respectively, 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:

John T. Dugan, Associate Director
Division of Enforcement
Securities and Exchange Commission
33 Arch Street, 24th Floor
Boston, MA 02110

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, Respondents agree that in any Related Investor Action, they shall not argue that they are entitled to, nor shall they 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, Respondents agree that they 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 Respondents 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.

V.

It is further Ordered that, solely for purposes of exceptions to discharge set forth in Section 523 of the Bankruptcy Code, 11 U.S.C. §523, the findings in this Order are true and admitted by Respondents, and further, any debt for disgorgement, prejudgment interest, civil penalty or other amounts due by Respondents under this Order or any other judgment, order, consent order, decree or settlement agreement entered in connection with this proceeding, is a

debt for the violation by Respondents of the federal securities laws or any regulation or order issued under such laws, as set forth in Section 523(a)(19) of the Bankruptcy Code, 11 U.S.C. §523(a)(19).

By the Commission.

Vanessa A. Countryman
Secretary