UNITED STATES OF AMERICA
Before the
SECURITIES AND EXCHANGE COMMISSION

SECURITIES ACT OF 1933
Release No. 11311 / September 26, 2024

SECURITIES EXCHANGE ACT OF 1934
Release No. 101201 / September 26, 2024

ADMINISTRATIVE PROCEEDING
File No. 3-22210

In the Matter of **HOAU-YAN WANG,** **Respondent.**	**ORDER INSTITUTING CEASE-AND-DESIST PROCEEDINGS, PURSUANT TO SECTION 8A OF THE SECURITIES ACT OF 1933 AND SECTION 21C OF THE SECURITIES EXCHANGE ACT OF 1934, MAKING FINDINGS, AND IMPOSING A CEASE-AND-DESIST ORDER**

I.

The Securities and Exchange Commission ("Commission") deems it appropriate and in the public interest that cease-and-desist proceedings be, and hereby are, instituted pursuant to Section 8A of the Securities Act of 1933 ("Securities Act"), and 21C of the Securities Exchange Act of 1934 ("Exchange Act"), against Hoau-Yan Wang ("Dr. Wang" 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, except as to the Commission's jurisdiction over him and the subject matter of these proceedings, which are admitted, and except as provided herein in Section V, Respondent consents to the entry of this Order Instituting Cease-and-Desist Proceedings,

Pursuant to Section 8A of the Securities Act of 1933 and 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. This matter involves false and misleading statements about reported biomarker results from Cassava Sciences, Inc.'s ("Cassava") Phase 2b clinical trial for Cassava's drug candidate PTI-125,[2] a potential therapy for the treatment of Alzheimer's disease. In filings with the SEC, Cassava claimed that Phase 2b bioanalyses were conducted under blinded conditions and claimed that patients taking the drug showed significant improvement across every measured biomarker for Alzheimer's disease compared with patients who took a placebo. Because of the conduct of Dr. Wang described herein, those claims were false.

2. Dr. Wang conducted the analyses that Cassava announced as the final results of Phase 2b. Respondent used information provided by Cassava to partially unblind himself before performing those bioanalyses. By partially unblinding himself, Dr. Wang was able to manipulate the reported results to show that patients taking the placebo had little change in biomarkers on average while patients taking PTI-125 showed significant improvement on average.

3. After Cassava reported its Phase 2b trial results, the company raised more than $260 million in new funding, in part based on false biomarker results provided by Respondent.

Respondent

4. **Dr. Hoau-Yan Wang** is a tenured associate professor at the City University of New York's ("CUNY") School of Medicine. Dr. Wang served on Cassava's Scientific Advisory Board, and Cassava retained Dr. Wang as a paid consultant through June 2024. Dr. Wang co-invented PTI-125 along with Cassava's Senior Vice President of Neuroscience.

[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] PTI-125 is also known as simufilam.

Other Relevant Persons or Entities

5. **Cassava Sciences, Inc. ("Cassava")** is a Delaware corporation with its principal place of business in Austin, Texas. Cassava is a pharmaceutical company with one primary drug candidate, PTI-125, a potential therapeutic for Alzheimer's disease. Cassava's shares are registered with the Commission pursuant to Section 12(b) of the Exchange Act and are listed on the Nasdaq Capital Market under the symbol "SAVA."

Cassava's Initial PTI-125 Trials

6. Clinical trials for a new drug usually proceed through three phases before the FDA will consider a New Drug Application.

7. In 2017, the FDA cleared Cassava's Investigational New Drug application for PTI-125, which allowed Cassava to begin clinical trials of the drug in humans. That same year, Cassava completed a Phase 1 human safety trial of PTI-125.

8. In 2019, Cassava ran what it called a Phase 2a trial, consisting of 13 Alzheimer's patients who all took doses of PTI-125 for 28 days. There was no placebo group.

9. One key objective of Cassava's Phase 2a trial was to measure changes in concentration of biomarkers—substances in cerebrospinal fluid ("CSF") believed to correspond with Alzheimer's disease pathology, neuroinflammation, and neurodegeneration. To measure changes in biomarkers, CSF was collected from patients before taking the drug and again after 28 days of treatment.

10. Cassava asked Dr. Wang to analyze the CSF samples collected from the Phase 2a participants. According to Dr. Wang's results, all 13 patients showed directional improvements in multiple biomarkers, suggesting that the drug may be causing changes in biomarker levels.

11. In public announcements and SEC filings, Cassava disclosed that Dr. Wang and his lab at CUNY performed the biomarker tests for Phase 2a.

Cassava's Phase 2b Trial

12. In 2019, Cassava designed and began its Phase 2b clinical trial. That trial ultimately included 64 patients separated into three groups—one placebo group, one group taking 50 mg doses of PTI-125, and another group taking 100 mg doses of PTI-125. Each patient in each group was to take their respective treatment for 28 days.

13. Phase 2b was to be conducted as a double-blinded clinical trial, which means neither the patient nor the tester is aware which patient received which treatment. Blinding is a standard practice in many clinical trials, in part because it helps reduce the potential impact of bias.

14. Participants in Phase 2b had CSF drawn before treatment began and again after 28 days of treatment. Pursuant to the testing protocol, Cassava directed each clinical site to send patient CSF samples to the CUNY laboratory in New York where Dr. Wang performed research to be stored before laboratory analysis. Laboratory results were to be sent directly to Cassava's Senior Vice President of Neuroscience who then was to forward them to a biostatistics company hired by Cassava to compile unblinded results.

Phase 2b Round 1 Biomarker Testing

15. Cassava initially hired a laboratory in Europe to test the Phase 2b CSF samples for nine biomarkers. However, there were two biomarkers that Cassava wanted tested that the European lab could not measure. Cassava asked Dr. Wang to test CSF samples for those two biomarkers. All biomarker testing by the European lab (seven tests) and Dr. Wang (two tests) (collectively, "Round 1") were completed by early May 2020. Results were sent to Cassava's Senior Vice President of Neuroscience, who forwarded them to the biostatistics company.

16. On May 15, 2020, Cassava filed a Form 8-K with the Commission, attaching a press release with the headline "Top-line Results from a Phase 2b Study of PTI-125 in Alzheimer's Disease Does Not Meet Primary Endpoint."

17. None of the tests performed by the European lab showed a meaningful effect of the drug treatment arms compared with the placebo. The Phase 2b Round 1 results also did not show a drug effect consistent with Dr. Wang's Phase 2a results.

Dr. Wang Partially Unblinds Himself to Certain Phase 2b Patients

18. On May 13, 2020, the biostatistics company sent Cassava's Senior Vice President of Neuroscience a document summarizing the statistics for each Round 1 biomarker. The document included, among other things, statistics for the lowest (min) and highest (max) sample levels in each treatment arm and in the placebo group for Day 0 (before the trial) and Day 28 (after the trial). The document also identified the largest and smallest "change from baseline" or change in biomarker levels in each treatment arm and placebo group.

19. On May 14, 2020, Cassava's Senior Vice President of Neuroscience sent this document with min, max, and change from baseline data to Dr. Wang.

20. That document had sufficient information to allow Dr. Wang to match the test results that he ran in Round 1 with specific reported statistics.

21. Ultimately, using the information he was provided, Dr. Wang was able to unblind himself to roughly a third of the patients in Phase 2b—eight patients in the placebo group; seven in the 50 mg group; and eight in the 100 mg group.

22. Dr. Wang recorded his process for unblinding certain patients in a set of spreadsheets that matched the individual patient identification numbers with known biomarker results from Round 1.

Dr. Wang Conducts Phase 2b Round 2 Biomarker Testing

23. On or around June 1, 2020, Cassava directed Dr. Wang to perform a reanalysis of the Phase 2b clinical samples for the seven biomarkers tested by the European lab during Round 1 using the CSF samples remaining in Dr. Wang's lab. Dr. Wang did not, as part of Round 2, re-run tests for the two biomarkers he analyzed in Round 1. Dr. Wang also agreed to run additional biomarker tests that had not been completed in Round 1. These combined tests constituted the Round 2 testing.

24. Dr. Wang was partially unblinded before he began running bioanalyses for Round 2.

25. By unblinding himself to a portion of the Phase 2b patients, Dr. Wang caused Cassava to make misleading statements that all analyses were "conducted under blinded conditions to eliminate the possibility of bias."

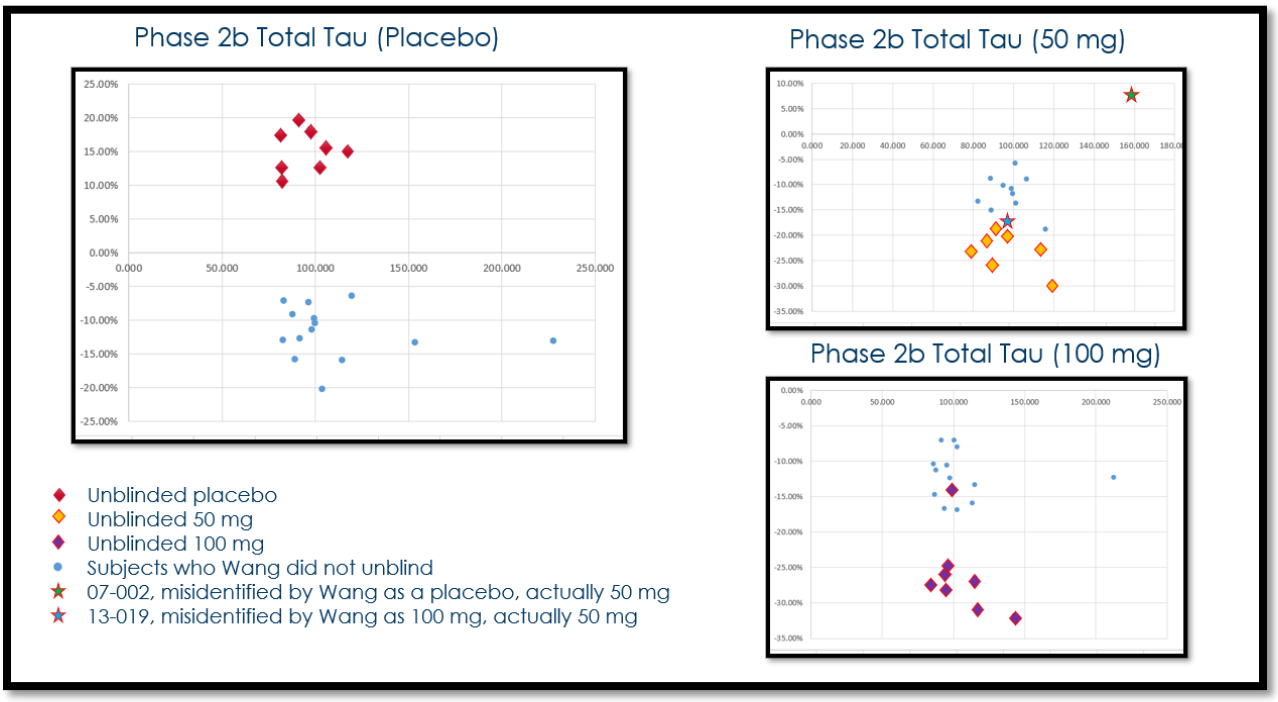
26. Dr. Wang manipulated the Phase 2b biomarker data, using the knowledge he gained through the unblinding process to show an exaggerated response to the treatment arms as compared to the placebo group.

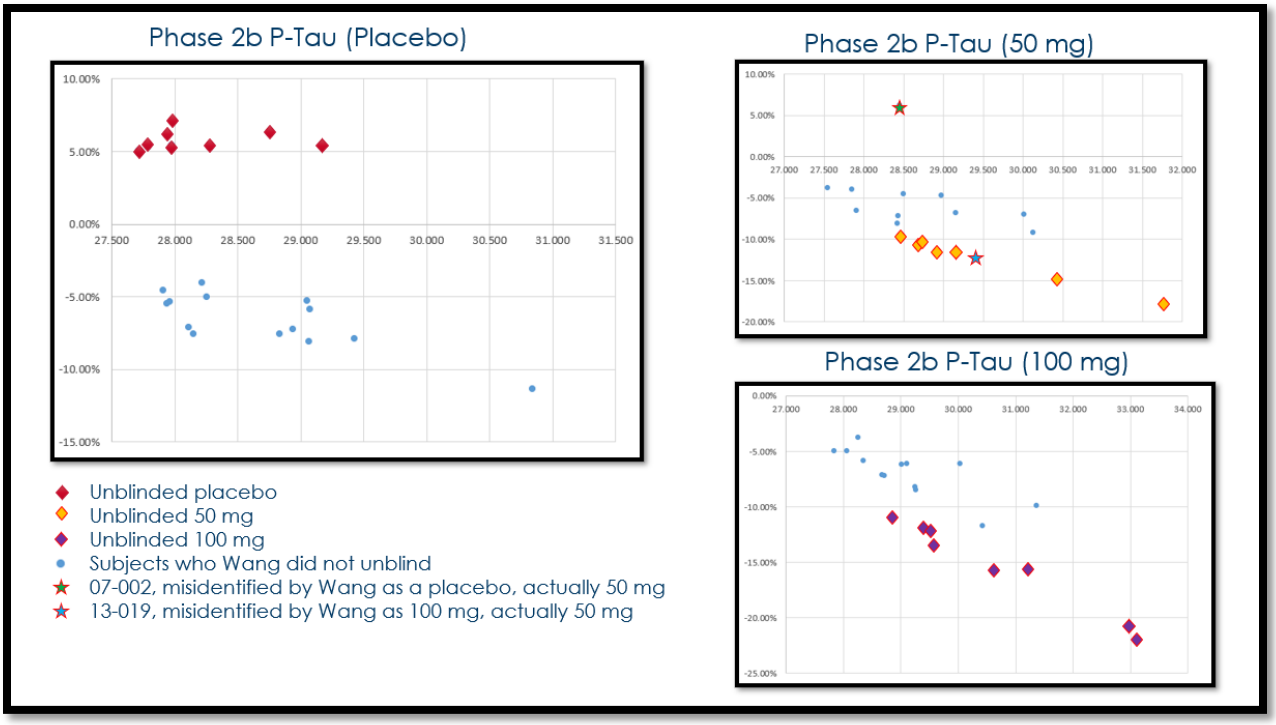
27. For every biomarker that Dr. Wang tested in Round 2, generally all patients showed improvements in biomarkers *except for* those patients who Dr. Wang had identified through his unblinding process as having taken the placebo.[3] Moreover, Dr. Wang reported results for unblinded 50 mg and 100 mg patients generally that reflected more improvement than patients who Dr. Wang did not

[3] Dr. Wang's spreadsheets that recorded his process of matching individual patient identification numbers to treatment groups contained two errors. Dr. Wang marked patient 07-002 as placebo when that patient was actually in the 50 mg group. Dr. Wang made this error on May 15, 2020, before he began any testing for Round 2. Second, Dr. Wang mistakenly identified patient 13-019 as part of the 100 mg group when that patient actually was in the 50 mg group because Dr. Wang's results showed two patients with the same value rounded to the nearest thousandth.

unblind. This pattern is evidenced in Dr. Wang's results for two tested biomarkers, Total Tau and Phosphorylated Tau.

28. The following scatterplots are representative of Dr. Wang's manipulation across each of the seven Phase 2b biomarkers tested in Round 2. These scatterplots portray patient data in the placebo, 50 mg, and 100 mg groups for Total Tau and Phosphorylated Tau, two neurodegeneration biomarkers. As seen below, the patients unblinded by Dr. Wang (those marked by red diamonds) move anomalously to the rest of the blinded subjects (those marked by blue dots). The plots also illustrate the two incorrectly identified patients.





29. The same general pattern occurred for the remaining biomarkers that Dr. Wang analyzed in Round 2 of Phase 2b testing.

30. This pattern *does not* exist in the two biomarkers that Dr. Wang analyzed in Round 1, prior to his unblinding.

31. When unblinded patients are removed from the analysis of each Round 2 biomarker, the results no longer show a significant difference between placebo, 50 mg, and 100 mg.

32. The results from the subjects unblinded by Dr. Wang appear to drive the Phase 2b Round 2 results reported by Cassava.

33. Dr. Wang knew these manipulated results would be reported to the market.

Cassava Publicizes Results from Dr. Wang's Phase 2b Results

34. On September 14, 2020, Cassava publicized Dr. Wang's results which showed statistically significant improvement in all biomarkers in the treatment groups as compared with the placebo group. The company issued a press release and provided an investor presentation with an accompanying slide deck, all of which were filed with the Commission under Form 8-K.

35. The September 14, 2020, press release stated that "Bioanalyses were conducted under blinded conditions to eliminate any possibility of bias. An academic lab generated final results." Cassava further announced that "Alzheimer's patients treated with 50 mg or 100 mg of [PTI-125] twice-daily for 28 days showed statistically significant ($p<0.05$) improvements in biomarkers of disease pathology, neurodegeneration and neuroinflammation, versus Alzheimer's patients who took placebo."

36. Shortly after Cassava's announcements regarding its Round 2 Phase 2b results, the company's stock more than doubled, from $3.40 to $8.41 on September 14, 2020.

Investors Purchase Cassava Shares Based on Phase 2b Results Manipulated by Dr. Wang

37. On November 16, 2020, Cassava filed an updated prospectus supplement to sell more than 9 million shares at $8 per share, netting Cassava around $70 million after underwriting fees. The prospectus incorporated by reference certain documents, including the Form 8-K filed September 14, 2020.

38. Cassava subsequently filed a new shelf registration statement in February 2021 to register sales of approximately $200 million, which it executed on, netting more than $190 million after paying underwriter fees. Cassava incorporated documents into the shelf registration and subsequent prospectus, including the Form 8-K filed September 14, 2020.

39. Dr. Wang owned Cassava stock and unexercised options. He also qualified to participate in Cassava's Cash Incentive Plan, which allowed Cassava's Board of Directors discretion to authorize cash payments from a pool based on meeting valuation benchmarks and other triggers. Dr. Wang also was a long-term consultant for Cassava, for which he received a monthly payment.

Dr. Wang Violated Securities Act Sections 17(a)(1) and (3) and Exchange Act Section 10(b) and Rules 10b-5(a) and (c)

40. Securities Act Section 17(a)(1) makes it unlawful for any person, in the offer or sale of a security, to "employ any device, scheme, or artifice to defraud." Securities Act Sections 17(a)(2) and 17(a)(3) make 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, or to "engage in any transaction, practice, or course of business which operates or would operate as a fraud or deceit upon the purchaser."

41. Section 10(b) of the Exchange and Rules 10b-5(a) and (c) prohibit, in connection with the purchase or sale of a security, employing any device, scheme,

or artifice to defraud, and engaging in any transaction, practice, or course of business which operates or would operate as a fraud or deceit upon any person.

42. Securities Act Section 17(a)(1), Exchange Act Section 10(b), and Rules 10b-5(a) and (c) require a showing that the defendant acted with scienter. Reckless conduct generally satisfies the scienter requirement.

43. Dr. Wang retained information provided by Cassava to unblind himself as to a portion of Phase 2b clinical trial patients. Dr. Wang used his knowledge about certain unblinded patients to manipulate the results of Phase 2b biomarker results, which he transmitted to Cassava to be used for public disclosures about the Phase 2b trial's purported success.

44. Dr. Wang obtained money or property in the form of stock option awards from Cassava.

45. As a result of Dr. Wang's conduct described above, he violated Securities Act Sections 17(a)(1) and (3) and Exchange Act Section 10(b)(5) and Rules 10b-5(a) and (c).

Dr. Wang Caused Cassava's Violations of Securities Act Sections 17(a)(2) and (3)

46. Securities Act Sections 17(a)(2) and 17(a)(3) make 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, or to "engage in any transaction, practice, or course of business which operates or would operate as a fraud or deceit upon the purchaser."

47. In administrative proceedings, the Commission may impose sanctions upon any person that is, was, or would be a cause of a violation, due to an act or omission the person knew or should have known would contribute to such violation. In order to establish that a person caused a non-scienter based violation, a showing of negligence will suffice.

48. Cassava falsely disclosed to the public that all its bioanalyses related to Phase 2b were "conducted under blinded conditions to eliminate the possibility of bias." By unblinding himself as to a portion of Cassava's Phase 2b patients, Dr. Wang caused Cassava's violations of Securities Act Sections 17(a)(2) and (3).

Findings

49. As a result of the conduct described above, the Commission finds that Respondent violated Section 17(a) of the Securities Act, and Section 10(b)

and Rules 10b-5(a) & (c) of the Exchange Act. Respondent caused Cassava's violations of Securities Act Sections 17(a)(2) and 17(3).

IV.

In view of the foregoing, the Commission deems it appropriate, in the public interest, and for the protection of investors to impose the sanctions agreed to in Respondent Wang's Offer.

Accordingly, pursuant to Section 8A of the Securities Act, and 21C of the Exchange Act, it is hereby ORDERED that:

A. Respondent Wang shall cease and desist from committing or causing any violations and any future violations of Section 17(a) of the Securities Act, Section 10(b) of the Exchange Act and Rule 10b-5 thereunder.

B. Respondent Wang shall pay civil penalties of $50,000.00 to the Securities and Exchange Commission. If timely payment is not made, additional interest shall accrue pursuant to 31 U.S.C. §3717.

Payment shall be made in the following installments:

- Within 30 days of the entry of the Order, Respondent shall pay $30,000;
- Respondent shall make a second payment of $5,000 within 120 days of the entry of the Order;
- Respondent shall make a third payment of $5,000 within 210 days of the entry of the Order;
- Respondent shall make a fourth payment of $5,000 within 300 days of the entry of the Order; and
- Respondent shall make a final payment within 364 days of the entry of the Order.

Prior to making the final payment set forth herein, Respondent shall contact the staff of the Commission for the amount due. Payments shall be applied first to post order interest, which accrues pursuant to pursuant to 31 U.S.C. 3717. If Respondent fails to make any payment by the date agreed and/or in the amount agreed according to the schedule set forth above, all outstanding payments under this Order, including post-order interest, minus any payments made, shall become due and payable immediately at the discretion of the staff of the Commission without further application to the Commission.

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 Hoau-Yan Wang 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 Mark Cave, Division of Enforcement, Securities and Exchange Commission, 100 F St., NE, Washington, DC 20549.

C. Pursuant to Section 308(a) of the Sarbanes-Oxley Act of 2002, a Fair Fund is created for penalties referenced in paragraphs IV.B. above. 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, he shall not argue that he is entitled to, nor shall he 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 he 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.

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 Respondent, and further, any debt for disgorgement, prejudgment interest, civil penalty or other amounts due by Respondent 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 Respondent 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