UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
LEXINGTON DIVISION

SECURITIES AND EXCHANGE COMMISSION, **Plaintiff,** **v.** **CBA PHARMA, INC., WAYNE MICHAEL PUTNAM, and LOUIS A. CARMICHAEL,** **Defendants.**	Civil Action No. _____ Jury Trial Demanded

COMPLAINT

Plaintiff, Securities and Exchange Commission ("Commission" or "SEC") alleges as follows:

SUMMARY

1. From approximately April 2023 to approximately February 2024, CBA Pharma, Inc. ("CBA Pharma"), a private biopharmaceutical company based in Lexington, Kentucky, through its president, director, and chairman of the board, Wayne Michael Putnam ("Putnam"), and its vice president of capital markets, Louis "Buzz" Carmichael ("Carmichael") (collectively, "Defendants"), engaged in a scheme to deceive and defraud prospective investors by making materially false and misleading statements about a drug called CBT-1.

2. CBA Pharma was in the business of developing CBT-1 to treat cancer by purportedly preventing or reversing "multidrug resistance" to cancer treatments, such as chemotherapy. Multidrug resistance is the ability of certain types of cancers to become resistant to a variety of drug treatments.

3. According to Putnam, during CBA Pharma's existence, it raised approximately $130 million from several hundred investors in 43 states and seven countries. CBA Pharma's drug development activities were funded solely with investor money. This Complaint focuses on CBA Pharma's capital raise in connection with what it called the "Royalty Funding Program" or "Royalty Offering" (herein "Royalty Offering"), and, in particular, the period of the Royalty Offering between April 3, 2023, and February 28, 2024 (the "Royalty Offering Period"). During the Royalty Offering Period, CBA Pharma raised approximately $4.1 million from approximately 160 investors throughout the United States.

4. Prior to the Royalty Offering Period, in 2013, the United States Food and Drug Administration ("FDA") – the federal government agency responsible for, among other things, approving requests to market and sell new drug products in the United States – informed CBA Pharma that its application for FDA approval of CBT-1 had many deficiencies that prevented FDA approval. In particular, the FDA informed CBA Pharma in 2013 that its application for CBT-1 lacked evidence of efficacy and that CBA Pharma should conduct additional clinical trials to demonstrate whether CBT-1 was effective. CBA Pharma never completed those additional clinical trials or otherwise rectified these deficiencies. The FDA also warned CBA Pharma in 2013 that its website misleadingly claimed that CBT-1 was effective, when in fact it had not been approved by the FDA, and, among other things, had failed a clinical trial. By April 3, 2023, the FDA informed CBA Pharma that the FDA had withdrawn the company's application for approval of CBT-1.

5. Despite this information, CBA Pharma, through Putnam and Carmichael, deceived and defrauded prospective Royalty Offering investors by falsely and misleadingly representing to them during the Royalty Offering Period that CBA Pharma was in the final stages of obtaining FDA approval for CBT-1, even though Defendants knew that CBT-1 was never

close to obtaining FDA approval. Defendants made further misleading statements to prospective investors during the Royalty Offering Period about CBT-1's efficacy by omitting to disclose the substance of important communications and warnings from the FDA to CBA Pharma.

6. As a result of the fraudulent misconduct described herein, victims of Defendants' misconduct lost approximately $4.1 million by investing in the Royalty Offering.

7. Unless enjoined, Defendants are reasonably likely to engage in future violations of the federal securities laws alleged in this Complaint.

JURISDICTION AND VENUE

8. This Court has jurisdiction over this action pursuant to Sections 20(b) and 22(a) of the Securities Act of 1933 ("Securities Act") [15 U.S.C. §§ 77t(b), 77v(a)], and Sections 21(d), 21(e), and 27 of the Securities Exchange Act of 1934 ("Exchange Act") [15 U.S.C. §§ 78u(d), 78u(e), and 78aa]. Defendants have, directly or indirectly, made use of the means and instrumentalities of interstate commerce, or the mails, or of the facilities of a national securities exchange in connection with the acts, practices, and courses of business alleged in this Complaint.

9. Venue lies in this Court pursuant to Section 22(a) of the Securities Act [15 U.S.C. § 77v(a)] and Section 27 of the Exchange Act [15 U.S.C. § 78aa]. A substantial part of the acts, practices, transactions, and courses of business constituting the violations alleged in this Complaint occurred in Lexington, in Fayette County, Kentucky, within the Lexington Division of the Eastern District of Kentucky, and were effected, directly or indirectly, by making use of means or instrumentalities of transportation or communication in interstate commerce, or the mails. In addition, CBA Pharma was headquartered within the Lexington Division of the Eastern District of Kentucky, and Putnam and Carmichael are residents of the Lexington Division of the Eastern District of Kentucky.

DEFENDANTS

10. **CBA Pharma, Inc.** was a Nevada corporation with its principal place of business in Lexington, in Fayette County, Kentucky. CBA Pharma was a private biopharmaceutical company that Putnam formed in 1999. CBA Pharma's primary business was trying to develop, and obtain FDA approval for, the drug CBT-1. In February 2024, the Federal Bureau of Investigation ("FBI") executed a search warrant at CBA Pharma's offices. CBA Pharma has since ceased operations, and it is in default as a Nevada corporation.

11. **Wayne Michael Putnam**, age 80, is a resident of Lexington, in Fayette County, Kentucky. He served as CBA Pharma's president, director, and chairman of the board since at least 1999. Putnam exercised ultimate control over CBA Pharma's operations, including overseeing all activities in drug development and having ultimate authority over the contents of the false and misleading marketing materials disseminated to investors as discussed herein. He also solicited and raised money from new investors with CBA Pharma. From 1983 through 1987, Putnam was associated with a SEC registered broker-dealer and passed the Series 7 and 63 exams.

12. **Louis A. Carmichael**, age 80, is a resident of Lexington, in Fayette County, Kentucky. From approximately 2006 through February 2024, he worked at CBA Pharma as its vice president of capital markets, where his primary responsibility was to solicit investors to invest in CBA Pharma. From 1974 to 2006, Carmichael was associated with SEC registered broker-dealers and investment advisers and held various securities licenses, including the Series 24, 63 and 65.

FACTS

I. CBT-1 And Its Significance to CBA Pharma

13. CBA Pharma's primary business was trying to develop and obtain FDA approval of CBT-1, which CBA Pharma described as a "major breakthrough" cancer drug. CBA Pharma was originally formed to exclusively manufacture, market, license and distribute CBT-1. The original developers of CBT-1 included three affiliates of CBA Pharma which, after a series of reorganizations between 2002 and 2011, transferred all rights relating to CBT-1 to CBA Pharma.

14. CBA Pharma claimed CBT-1 was formulated to treat cancer by purportedly reversing multidrug resistance to chemotherapies, targeted therapies, and immunotherapies in over 500 different cancer types.

15. CBA Pharma claimed that CBT-1, which is administered orally, reduced multidrug resistance by preventing chemotherapy drugs from being pumped out of the infected cell, thus re-establishing chemotherapeutic agent effectiveness. CBA Pharma also claimed that CBT-1 worked to shut down many of the problematic cell activities which create mutations. CBA Pharma claimed that CBT-1 was different from other targeted therapies in that CBT-1 worked in many cancer types, not just one.

II. The FDA's Drug Approval Process

16. Before a new drug can be marketed and sold in the United States, it must be approved by the FDA. Accordingly, CBA Pharma was required to obtain FDA approval of its application for CBT-1 before the company would be permitted to market and sell CBT-1 in the United States. The approval process is usually preceded by substantial pre-clinical testing (usually in animals), after which a new drug company submits an investigational new drug application ("IND") to the FDA to conduct human clinical trials. A company is not allowed to administer the investigational new drug in human clinical trials until the IND goes into effect.

Human clinical trials usually occur in three phases and are designed to test for safety and efficacy.

17. After the completion of clinical trials, a company may submit a new drug application ("NDA") to the FDA seeking approval to market and sell its product to the public.

III. CBA Pharma's Submissions and Communications with the FDA Regarding CBT-1

A. CBA Pharma Submitted and Filed Its NDA for CBT-1

18. On November 30, 2010, CBA Pharma, through CBA Research, Inc., submitted to the FDA an NDA for CBT-1 as an adjunct treatment for multidrug resistant cancer. The NDA included, among other things, results from eight clinical trials that CBA Pharma claimed to have completed between 1994 and 2009 to evaluate CBT-1's effectiveness in reducing multidrug resistance in cancer patients.

19. In 2011, the FDA issued two Refuse to File Letters to CBA Pharma. A Refuse to File Letter is a threshold determination by the FDA that an NDA is insufficiently complete to permit a substantive review. The first Refuse to File Letter, issued by the FDA in January 2011, stated that the NDA for CBT-1 was inadequately organized to permit even a "high-level review to assess its adequacy for filing." In September 2011, the FDA issued a second Refuse to File Letter, informing CBA Pharma, among other things, that the NDA was "too poorly organized to review and confirm drug product quality" and lacked evidence of CBT-1's efficacy in various clinical trials. The FDA informed CBA Pharma that if it were to perform a complete review of the NDA, "the deficiencies identified in our filing review are severe enough to render the application not approvable without major modification."

20. After receiving the two Refuse to File Letters from the FDA, in May 2012, CBA Pharma requested that its NDA for CBT-1 be filed over protest, resulting in its NDA ultimately being filed with the FDA in June 2012.

B. FDA Found CBA Pharma's NDA for CBT-1 to be Deficient

21. Upon a substantive review of CBA Pharma's NDA, the FDA found it to be deficient and not approvable in its current form, and, on April 19, 2013, issued a response to CBA Pharma called a Complete Response Letter. The Complete Response Letter specified 14 deficiencies that CBA Pharma needed to address in its NDA.

22. For example, the Complete Response Letter specified that the clinical trials conducted by CBA Pharma did not show substantial evidence of CBT-1's efficacy. The FDA informed CBA Pharma that it "should conduct additional clinical trials that demonstrate the safety and efficacy" of CBT-1.

23. Putnam received the Complete Response Letter at or around the time at which the FDA issued it in April 2013. Carmichael was aware of the Complete Response Letter at least by the time of the Royalty Offering Period.

24. Given Putnam's role as CBA Pharma's long-serving president, director, and chairman of the board, the fact he oversaw CBA Pharma's drug development operations, and his review of the Complete Response Letter, Putnam understood the significance of the Complete Response Letter, including that the FDA viewed CBT-1 as not ready for FDA approval for drug marketing and sale in the United States, that the FDA did not believe that CBA Pharma had demonstrated CBT-1's efficacy, and that CBA Pharma needed to address the many deficiencies in CBA Pharma's NDA for CBT-1 identified by the FDA in order to gain FDA approval of CBT-1 for marketing and sale in the United States.

25. Likewise, Carmichael, as CBA Pharma's vice president of capital markets for many years, also understood the significance of the Complete Response Letter, including that the FDA viewed CBT-1 as not ready for FDA approval for marketing and sale in the United States, that the FDA did not believe that CBA Pharma had demonstrated CBT-1's efficacy, and that

CBA Pharma needed to address the many deficiencies in CBA Pharma's NDA for CBT-1 identified by the FDA in order to gain FDA approval of CBT-1 for marketing and sale in the United States.

C. The FDA Warned CBA Pharma About its Misleading Promotion of CBT-1

26. On April 25, 2013, the FDA issued a warning letter to CBA Pharma (the "Warning Letter") informing the company that its website contained false or misleading statements regarding CBT-1. The FDA stated that CBA Pharma's website "misleadingly promotes CBT-1 as safe and effective" in violation of FDA regulations and statutes and "is false or misleading because it overstates the efficacy of CBT-1."

27. Among other things, in the FDA's Warning Letter, the FDA pointed to the following false or misleading claims on CBA Pharma's website that promoted CBT-1 as safe and/or effective:

- "ADMINISTERED ORALLY Oral delivery of CBT-1® prior to and during the administration of chemotherapy, achieves the required therapeutic concentration necessary to reverse multidrug resistance in the clinical setting."
- "NO SIGNIFICANT OR LASTING TOXIC SIDE EFFECTS CBT-1® demonstrated no significant or lasting side effects in the clinical setting, and had a very favorable adverse event profile."
- "MULTIPLE CANCERS Eight Phase I and II clinical trials, with patients that had failed conventional chemotherapy treatments, showed efficacy of CBT-1® in multiple cancers. Likewise, the targeted mechanism of action multidrug resistance of CBT-1® is found in the vast majority of all late stage human cancer types."
- "HIGH PATIENT BENEFIT IN PHASE I AND PHASE II CLINICAL TRIALS CBT-1® has demonstrated in Phase I and II clinical trials a high rate of patient benefit."

28. The FDA also pointed to claims made in a presentation that could be downloaded from CBA Pharma's website, including the following:

- "**CBT-1®** A Novel Multidrug Resistant Modulator for Cancer Chemotherapy" (Slide 1)
- "**CBT-1® Safety and Efficacy Profile**

  Preclinical and Clinical research has consistently demonstrated the potential for CBT-1® to be safe and effective.

  The drug is safe, well tolerated, lacks harmful pharmacokinetic interactions when combined with chemotherapeutic agents, has specificity for P-gp and MDR-1, is stable, orally available, and has produced clinically objective responses in heavily pre-treated and/or late cancers." (Slide 16)
- "**Advantages of CBT-1®**
  - Reverses drug resistance in multiple cancer types.
  - Strong safety and tolerability profile: side effects are manageable and non-life threatening.
  - In advanced relapsed cancers clinical trials demonstrate a meaningful response rate.
  - Oral administration prior to chemotherapy achieves required concentration to reverse drug resistance.
  - Does not alter the pharmacokinetic profile of Doxorubicin and Paclitaxel (two MDR substrates).
  - Enhances most common chemotherapy agents in current oncology protocols." (Slide 17)

29. The FDA further warned CBA Pharma that its website was false or misleading because it did not mention "the failed clinical trial … submitted in your NDA, in which CBT-1 did not demonstrate substantial evidence of efficacy for its main efficacy outcomes … as described in the [FDA's] Complete Response Letter…."

30. Putnam was aware of the Warning Letter at or around the time at which the FDA issued it in April 2013. Carmichael was aware of the Warning Letter by at least December 2023.

D. CBA Pharma Failed to Address Deficiencies

31. After the FDA issued the Complete Response Letter and the Warning Letter to CBA Pharma in 2013, the FDA granted several lengthy extensions to CBA Pharma over a ten-

year period, giving the company additional time to submit updated information to address the deficiencies raised by the FDA in the Complete Response Letter.

32. During that time, CBA Pharma failed to correct the deficiencies, including the completion of additional clinical trials. While CBA Pharma started a clinical trial for CBT-1 in or about 2018, it was never completed.

33. By the time of the Royalty Offering Period, both Putnam and Carmichael knew that the clinical trial that CBA Pharma had launched for CBT-1 in or about 2018 had not been completed.

34. Further, as of the Royalty Offering Period, neither Putnam nor Carmichael were aware of any other clinical trials that CBA Pharma had commenced, beyond the never-completed clinical trial that began in or about 2018.

35. In February 2023, the FDA notified CBA Pharma that it was not inclined to grant another extension to the company to respond to the Complete Response Letter for its NDA for CBT-1. The FDA explained that CBA Pharma had 30 days to submit a detailed explanation for why the NDA for CBT-1 should not be withdrawn from consideration by the FDA for approval. In March 2023, CBA Pharma made another extension request to the FDA, seeking a three-year extension to respond to the Complete Response Letter.

E. FDA Withdrew CBA Pharma's NDA for CBT-1

36. On April 3, 2023, the FDA informed CBA Pharma that it was denying CBA Pharma's latest extension request and that it had withdrawn CBA Pharma's NDA for CBT-1 from consideration by the FDA for approval (the "FDA Withdrawal Letter"). The FDA Withdrawal Letter stated that "[t]he withdrawal does not prejudice any future filing of the application[,]" that CBA Pharma "may request that the information contained in the withdrawn application be

considered in conjunction with any future submission[,]" and that "[a] resubmitted application must address all deficiencies as listed in the [Complete Response Letter]."

37. Putnam was aware of the Withdrawal Letter at or around the time at which the FDA issued it in April 2023.

38. Shortly after receiving the FDA Withdrawal Letter, on or about April 25, 2023, CBA Pharma finally submitted a response to the FDA's Complete Response Letter, issued over 10 years earlier in April 2013. However, CBA Pharma's response did not provide adequate data to address the deficiencies in the Complete Response Letter.

39. In late April and early May 2023, the FDA responded to CBA Pharma that, given the Withdrawal Letter, (a) CBA Pharma needed to submit a new complete NDA; (b) the FDA would be reviewing CBA Pharma's response to the Complete Response Letter as a new NDA submission; (c) all documents applicable to the NDA would need to be submitted (or resubmitted) electronically and updated, as applicable; and (d) the "current review team will need to start from scratch" with its review.

F. CBA Pharma Resubmitted its NDA in Electronic Form in 2024

40. On February 14, 2024, CBA Pharma resubmitted in electronic form to the FDA the same NDA for CBT-1 that it had previously submitted on November 30, 2010, along with all amendments and CBA Pharma's response to the Complete Response Letter. This resubmission failed to address the deficiencies in CBA Pharma's NDA that the FDA had identified over ten years earlier and instead merely repeated CBA Pharma's previously rejected documents and arguments for FDA approval.

41. Two months later, in April 2024, the FDA issued a Refuse to File Letter to CBA Pharma, stating that a preliminary review showed that the electronically filed NDA was "not sufficiently complete to permit a substantive review." The FDA raised 24 deficiencies (some of

which repeated prior deficiencies) to be addressed by CBA Pharma, including the need to file comprehensive data reflecting the efficacy of CBT-1.

IV. CBA Pharma's Securities Offering

42. In 2022, CBA Pharma launched the Royalty Offering, a securities offering through which CBA Pharma offered and sold unregistered securities to investors. During the Royalty Offering Period, from April 3, 2023 (when the FDA Withdrawal Letter was issued) to February 28, 2024 (when the FBI executed a search warrant on CBA Pharma's office), CBA Pharma raised approximately $4.1 million from approximately 160 investors throughout the United States.

43. CBA Pharma, through Putnam and Carmichael in meetings and phone calls with prospective investors, and also by Carmichael in emails with investors, solicited investments in the Royalty Offering from investors throughout the United States. At times, Putnam and Carmichael directed others at CBA Pharma to email information about the Royalty Offering to prospective investors.

44. CBA Pharma, through Putnam and Carmichael in meetings and phone calls with prospective Royalty Offering investors, and also by Carmichael in emails with investors, represented that their money would be pooled with other investor funds and used by CBA Pharma to take the necessary steps to obtain FDA approval for CBT-1 and to market, distribute, and sell CBT-1 upon approval.

45. CBA Pharma pooled funds from investors in the Royalty Offering in its bank accounts.

46. According to a Royalty Offering Certificate of Agreement ("Royalty Offering Agreement"), the company would share 50% of its net revenue with the investors, and the investors would receive a *pro rata* share of those net revenues up to a maximum of 40 times their

investment amount. For example, during the Royalty Offering Period, Putnam and Carmichael explained to some prospective investors that each $25,000 investment could generate as much as $1 million in returns once CBT-1 was approved by the FDA and brought to market.

47. Many, if not all versions of the Royalty Offering Agreement also provided that investors would receive two shares of CBA Pharma stock for every $1 that was invested, which CBA Pharma labeled as an "equity kicker stock grant." This offer of an "equity kicker" further involved the offer and sale of securities pursuant to the federal securities laws.

48. After the Royalty Offering Agreement was signed by the investor, Putnam typically would sign it on behalf of CBA Pharma. At times, CBA Pharma emailed the Royalty Offering Agreement to prospective investors, and once a decision to invest was made, the investor would at times mail or email a signed version of the agreement back to CBA Pharma.

49. Investors understood that they were investing in CBA Pharma in return for a share of the company's revenues once CBT-1 was approved by the FDA and sold to the market. Investors reasonably expected to profit from CBA Pharma's increased revenues from CBT-1. Similarly, investors reasonably expected to profit by the "equity kicker" shares of stock increasing in value once CBT-1 was approved by the FDA and sold to the market.

50. The Royalty Offering involved the offer and sale of stock (*i.e.* the "equity kicker stock grant") and investment contracts, both of which are securities within the meaning of Section 2(a)(1) of the Securities Act and Section 3(a)(10) of the Exchange Act.

51. The Royalty Offering involved the offer and sale of investment contracts because investors invested money with CBA Pharma through the Royalty Offering, their funds were pooled and used by CBA Pharma to fund its operations, the fortunes of each investor were tied to the overall success of CBA Pharma, and the investments were made with the expectation of profits derived from the efforts of CBA Pharma.

V. Defendants Made False and Misleading Statements to Prospective Royalty Offering Investors About CBT-1 and Engaged in Deceptive Conduct

A. CBA Pharma's False and Misleading Marketing Material

52. Putnam drafted by hand and then directed a CBA Pharma employee to type up and create offering and marketing materials that contained false and misleading statements about the status of FDA approval of CBT-1 and the efficacy of CBT-1 ("CBA Pharma Marketing Material").

53. At the direction of Putnam and Carmichael, a CBA Pharma employee distributed the CBA Pharma Marketing Material to prospective investors during the Royalty Offering Period. Carmichael also personally distributed the CBA Pharma Marketing Material to prospective investors during the Royalty Offering Period.

54. CBA Pharma employees, including Carmichael, distributed the materials to prospective Royalty Offering investors with Putnam's knowledge and oversight, and Putnam had ultimate control over the content of the CBA Pharma Marketing Material.

B. Defendants' False and Misleading Statements About the Status of FDA Approval

55. The CBA Pharma Marketing Material, distributed to investors during the Royalty Offering Period, falsely and misleadingly told prospective investors that (a) CBT-1 was "on course to be first-in-class as the first multi-drug resistance modulator ever approved by the FDA"; (b) CBT-1 was "in Its Final Stages" of "FDA Approval for Cancer"; (c) "CBT-1 is at the final stages of the drug development process with the FDA"; and (d) CBA Pharma's response to the FDA's Complete Response Letter was the "last milestone to get FDA approval" for CBT-1.

56. The CBA Pharma Marketing Material was materially false and deceived and defrauded investors because the FDA had withdrawn the NDA for CBT-1 and because CBA

Pharma had failed to address or correct many of the deficiencies which the FDA had outlined in 2013 in its Complete Response Letter to CBA Pharma.

57. Therefore, during the Royalty Offering Period, CBT-1 was ***not*** "on course" to be the first multi-drug resistance modulator ever approved by the FDA, CBT-1 was ***not*** "in its final stages" of FDA approval or "at the final stages of the drug development process with the FDA," as represented by CBA Pharma, and the response to the FDA's Complete Response Letter was ***not*** "the last milestone to get FDA approval."

58. Further, the statements in the CBA Pharma Marketing Material that CBT-1 was "on course to be first-in-class as the first multi-drug resistance modulator ever approved by the FDA," that CBT-1 was "in Its Final Stages" of "FDA Approval for Cancer," and "CBT-1 is at the final stages of the drug development process with the FDA," all were materially misleading because the CBA Pharma Marketing Material omitted to state that the FDA had issued the Warning Letter in 2013, that CBA Pharma had not completed clinical trials for CBT-1 or otherwise addressed the deficiencies identified by the FDA in the 2013 Complete Response Letter, that the FDA had told CBA Pharma in 2013 that the company had not demonstrated CBT-1's efficacy, and that the FDA had issued the Withdrawal Letter in April 2023.

59. In creating and distributing the CBA Pharma Marketing Material that contained false and misleading statements about the status of FDA approval of CBT-1, CBA Pharma, Putnam, and Carmichael acted knowingly, recklessly, or negligently.

60. At least one former CBA Pharma employee familiar with the Complete Response Letter warned Putnam prior to 2021 that CBA Pharma could not make claims about when it expected FDA approval in documents provided to investors, but Putnam ignored the warnings. Another CBA Pharma employee warned Putnam that the communications in the CBA Pharma

Marketing Material about FDA approval were unrealistic, but Putnam also ignored those warnings.

61. Putnam made similar false and misleading statements orally about the status of FDA approval to prospective Royalty Offering investors.

62. Specifically, during the Royalty Offering Period, Putnam orally told certain prospective investors words to the effect that: (a) the company was very close to obtaining FDA approval for CBT-1; and (b) CBA Pharma was in the final stages of the FDA approval process for CBT-1. Putnam also mentioned the pending resubmission in electronic form of the NDA to at least some prospective investors, misleadingly suggesting that the pending resubmission made it likely that the FDA would soon approve CBT-1.

63. Putnam made these oral statements despite knowing of the FDA Warning Letter, the FDA Withdrawal Letter, and CBA Pharma's failure to address or correct many of the deficiencies which the FDA had outlined in its 2013 Complete Response Letter to CBA Pharma.

64. Putnam made these false and misleading oral statements knowingly, recklessly, or negligently.

65. Carmichael made some of the same oral false and misleading statements, and written false and misleading statements in emails, while soliciting investors during the Royalty Offering Period. The false and misleading oral and written statements Carmichael made to prospective investors, after CBA Pharma received the FDA Withdrawal Letter, included words to the effect that: (a) CBA Pharma was in the final stages, or final phase, of the FDA approval process for CBT-1; and (b) CBA Pharma expected FDA approval within 6 to 12 months. Carmichael also mentioned the pending resubmission in electronic form of the NDA to at least some prospective investors, misleadingly suggesting that the pending resubmission made it likely that the FDA would soon approve CBT-1.

66. Carmichael made these oral and written statements despite knowing that CBA Pharma had not completed additional clinical trials for CBT-1 and that the FDA had never informed CBA Pharma that it had successfully addressed or corrected the deficiencies which the FDA had outlined in its 2013 Complete Response Letter to CBA Pharma.

67. Prior to 2021, at least one former CBA Pharma employee familiar with the Complete Response Letter overheard Carmichael making oral false and misleading claims to investors about FDA approval and warned him he could not say that.

68. Carmichael made these false and misleading written and oral statements knowingly, recklessly, or negligently.

69. Defendants' false and misleading statements were material. Reasonable investors making investment decisions related to the Royalty Offering would find the information regarding the status of FDA approval important as part of the total mix of information available.

C. Defendants' Misleading Statements About the Efficacy of CBT-1

70. The CBA Pharma Marketing Material, distributed by CBA Pharma at Putnam's and Carmichael's direction during the Royalty Offering Period, also contained misleading statements about the efficacy of CBT-1 in treating multidrug resistance in cancer patients.

71. The CBA Pharma Marketing Material misleadingly stated that CBT-1: (a) was "effective"; (b) "is a viable commercial product"; and (c) is the "biggest breakthrough drug in history for successfully treating multidrug resistance in cancer patients."

72. These statements were materially misleading because they omitted to state that the FDA had issued the Warning Letter in 2013, that CBA Pharma had not completed additional clinical trials for CBT-1 or otherwise addressed the deficiencies identified by the FDA in the 2013 Complete Response Letter, that the FDA had told CBA Pharma in 2013 that the company

had not demonstrated CBT-1's efficacy, and that the FDA had issued the Withdrawal Letter in April 2023.

73. In creating and distributing the CBA Pharma Marketing Material that contained misleading statements about the efficacy of CBT-1, CBA Pharma, Putnam, and Carmichael acted knowingly, recklessly, or negligently.

74. Putnam and Carmichael also made similar misleading statements orally about the efficacy of CBT-1 to prospective Royalty Offering investors.

75. Specifically, Putnam and Carmichael orally told certain prospective investors during the Royalty Offering Period words to the effect that CBT-1: (a) was very effective; (b) had a high efficacy rate; and (c) performed well in clinical trials. They made these statements despite knowing about the status of clinical trials and certain communications with the FDA and CBA Pharma's responses.

76. At least one former CBA Pharma employee who overheard Carmichael making misleading claims to investors that CBT-1 was effective warned him he could not say that. The former employee also informed Putnam about Carmichael's misleading statements.

77. Putnam and Carmichael made these misleading statements knowingly, recklessly, or negligently.

78. Defendants' misleading statements were material. Reasonable investors making investment decisions related to the Royalty Offering would find the information regarding the efficacy of CBT-1 important as part of the total mix of information available.

D. Defendants Obtained Money as a Result of Their False and Misleading Statements

79. As a result of their false and misleading statements regarding CBT-1, investors were duped into investing approximately $4.1 million with CBA Pharma through the Royalty Offering, and Putnam and Carmichael were paid their salaries from those proceeds.

COUNT I

Violations of Section 17(a) of the Securities Act
[15 U.S.C. § 77q(a)]

(Against All Defendants)

80. The SEC repeats and realleges Paragraphs 1 through 79 of its Complaint, as though fully set forth herein.

81. By engaging in the conduct described above, including without limitation the conduct described in Paragraphs 23 through 25, 30, 33 through 34, 37, and 52 through 79 above, Defendants, knowingly, recklessly or negligently, directly or indirectly, in the offer or sale of securities, by use of the means and instruments of transportation or communication in interstate commerce or by use of the mails: (a) employed devices, schemes, and artifices to defraud; (b) obtained money or property by means of any untrue statement of a material fact and any omission to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and (c) engaged in transactions, practices, and courses of business which operated or would operate as a fraud or deceit upon the purchasers of such securities.

82. By reason of the foregoing, Defendants, directly or indirectly, violated, and, unless enjoined, will continue to violate Section 17(a) of the Securities Act [15 U.S.C. § 77q(a)].

COUNT II

Fraud in Violation of Section 10(b) and Rule 10b-5 of the Exchange Act [15 U.S.C. § 78j(b) and 17 C.F.R. § 240.10b-5]

(Against All Defendants)

83. The SEC repeats and realleges Paragraphs 1 through 79 of its Complaint, as though fully set forth herein.

84. By engaging in the conduct described above, including without limitation the conduct described in Paragraphs 23 through 25, 30, 33 through 34, 37, and 52 through 78 above, Defendants, knowingly or recklessly, in connection with the purchase or sale of securities, by the use of any means or instrumentalities of interstate commerce or by the use of the mails, or any national securities exchange, directly or indirectly: (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and omitted to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and (c) engaged in acts, practices, and courses of business which operated or would have operated as a fraud or deceit upon sellers and purchasers and prospective purchasers of securities.

85. By reason of the foregoing, Defendants, directly or indirectly, violated, and, unless enjoined, will continue to violate Section 10(b) and Rule 10b-5 of the Exchange Act, 15 U.S.C. § 78j(b) and 17 C.F.R. § 240.10b-5.

COUNT III

Aiding and Abetting Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Thereunder
[15 U.S.C. § 78t(e)]

(Against Defendant Putnam in the Alternative)

86. The SEC repeats and realleges Paragraphs 1 through 79 of its Complaint, as though fully set forth herein.

87. As alleged above in paragraphs 83 through 85, CBA Pharma committed primary violations of Section 10(b) of the Exchange Act and Rule 10b-5 thereunder.

88. By engaging in the conduct described above, including without limitation the conduct described in Paragraphs 23 through 24, 30, 33 through 34, 37, 43, and 52 through 78 above, and pursuant to Section 20(e) of the Exchange Act [15 U.S.C. § 78t(e)], Putnam aided and abetted, and is therefore liable for, the primary violations committed by CBA Pharma of Section 10(b) of the Exchange Act [15 U.S.C. §78j(b)] and Rule l0b-5 thereunder [17 C.F.R. § 240.10b-5], because Putnam knowingly or recklessly provided substantial assistance to CBA Pharma's violations of these provisions.

COUNT IV

Control Person Liability in Connection with CBA Pharma's Violations
[15 U.S.C. § 78t(a)]

(Against Defendant Putnam in the Alternative)

89. The SEC repeats and realleges Paragraphs 1 through 79 of its Complaint, as though fully set forth herein.

90. CBA Pharma violated Section 10(b) of the Exchange Act [15 U.S.C. § 78j(b)] and Rule 10b-5 thereunder [17 C.F.R. § 240.10b-5], as alleged in paragraphs 83 through 85 above.

91. When CBA Pharma violated Section 10(b) of the Exchange Act and Rule 10b-5 thereunder, Putnam was CBA Pharma's president, director, and chairman of the board, and exercised control over CBA Pharma and its misconduct, including having sole authority over the contents of the CBA Pharma Marketing Material which were disseminated to the Royal Offering investors. As such, Putnam was a "control person" with regard to CBA Pharma within the meaning of Section 20(a) of the Exchange Act [15 U.S.C. § 78t(a)].

92. By engaging in the conduct described above, including without limitation the conduct described in Paragraphs 11, 24, 43, and 52 through 79 above, and pursuant to Section 20(a) of the Exchange Act [15 U.S.C. § 78t(a)], Putnam is liable, jointly and severally with CBA Pharma and to the same extent as CBA Pharma, for CBA Pharma's violations of Section 10(b) of the Exchange Act and Rule 10b-5 thereunder.

RELIEF REQUESTED

WHEREFORE, the SEC respectfully requests that this Court grant the following relief:

I.

Grant an order of permanent injunction, in a form consistent with Rule 65(d) of the Federal Rules of Civil Procedure, permanently restraining and enjoining all Defendants and their agents, servants, employees and attorneys, and those persons in active concert or participation with them who receive actual notice of the injunction by personal service or otherwise, and each of them, from violating Section 17(a) of the Securities Act [15 U.S.C. § 77q(a)] and Section 10(b) of the Exchange Act [15 U.S.C. § 78j(b)] and Rule 10b-5 thereunder [17 C.F.R. § 240.10b-5].

II.

Issue an Order directing Defendant CBA Pharma, pursuant to Sections 21(d)(3), 21(d)(5), and 21(d)(7) of the Exchange Act [15 U.S.C. § 78u(d)], to disgorge, with prejudgment interest, all ill-gotten gains obtained by reason of the unlawful conduct alleged in this Complaint.

III.

Issue an Order directing all Defendants to pay civil monetary penalties pursuant to Section 20(d) of the Securities Act [15 U.S.C. § 77t(d)] and Section 21(d)(3) of the Exchange Act [15 U.S.C. § 78u(d)].

IV.

Issue an Order containing a conduct-based injunction prohibiting Defendants Putnam and Carmichael from, directly or indirectly, including, but not limited to, through any entity owned or controlled by each of them, participating in any issuance, purchase, offer or sale of any security, or engaging in activities for the purpose of inducing or attempting to induce the purchase or sale of any security, provided that such injunctions would not prevent Defendants from purchasing or selling securities for their own personal accounts.

V.

Grant such other and further relief as this Court may deem just and proper.

JURY DEMAND

The Commission demands a jury in this matter for all claims so triable.

Dated: February 5, 2026

Respectfully submitted,

By: s/ Timothy J. Stockwell
Timothy J. Stockwell
Eric M. Phillips
Tracy W. Lo
UNITED STATES SECURITIES AND EXCHANGE COMMISSION

175 West Jackson Boulevard, Suite 1450
Chicago, Illinois 60604
Telephone: (312) 596-6049
Facsimile: (312) 353-7398
Email: stockwellt@sec.gov