UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

SECURITIES AND EXCHANGE COMMISSION, **Plaintiff,** **v.** **MAURIZIO CHIRIVA-INTERNATI,** **Defendant.**	**Cause No.: 4:24-cv-4729**

COMPLAINT

Plaintiff Securities and Exchange Commission ("Commission" or "SEC") files this Complaint against Defendant Maurizio Chiriva-Internati ("Chiriva" or "Defendant") and alleges as follows:

SUMMARY

1. Kiromic BioPharma, Inc. ("Kiromic") is a publicly traded biotherapeutics company in Houston that aims to develop and commercialize cell therapies that focus on immuno-oncology. Approximately two weeks before Kiromic raised $40 million through a public offering of company stock on July 2, 2021 (the "Offering"), the U.S. Food and Drug Administration ("FDA") notified Kiromic that it had placed clinical holds on two Investigational New Drug ("IND") applications that Kiromic filed in May 2021. However, in public statements and reports filed with the SEC both before and after the Offering, Kiromic made materially false and misleading statements and omissions concerning the status of the FDA's review of the INDs and the existence of the clinical holds.

2. On June 25, 2021, Chiriva, as Kiromic's Chief Executive Officer ("CEO"), signed and approved an SEC filing—registering the shares Kiromic sold through the Offering—that contained materially false and misleading statements and omissions. In addition, Chiriva failed to correct misstatements to investors Kiromic officers made on investor roadshow calls prior to the Offering. Finally, Chiriva signed and certified a materially misleading Form 10-Q that Kiromic filed on August 13, 2021 for the fiscal quarter ended June 30, 2021.

3. Based on the foregoing conduct, and the conduct described herein below, Chiriva violated Sections 17(a)(2) and 17(a)(3) of the Securities Act of 1933 ("Securities Act") and Rule 13a-14 of the Securities Exchange Act of 1934 ("Exchange Act"), and aided and abetted Kiromic's violations of Section 13(a) of the Exchange Act and Rules 12b-20, 13a-13, and 13a-15(a) thereunder.

JURISDICTION AND VENUE

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

5. Venue is proper in this district pursuant to Section 22(a) of the Securities Act [15 U.S.C. § 77v(a)] and Section 27(a) of the Exchange Act [15 U.S.C. § 78aa(a)]. Certain of the transactions, acts, practices, and courses of business constituting violations of the federal securities laws alleged herein occurred within this district.

DEFENDANT

6. **Chiriva**, age 56, resides in Manvel, Texas. Chiriva was born in Italy and speaks English as a second language. He is the co-founder and former CEO and Board Chairman of Kiromic, and prior to those roles was Kiromic's Chief Scientific Officer. Chiriva holds a Ph.D. in morphological sciences and a PH.D. in immunology.

RELATED ENTITY

7. **Kiromic BioPharma, Inc.** is a Delaware corporation formed in 2016 with its principal place of business in Houston, Texas. Kiromic's common stock was previously registered with the Commission under Section 12(b) of the Exchange Act and is currently registered under Section 12(g) of the Exchange Act.

FACTUAL ALLEGATIONS

I. The ALEXIS INDs and FDA Clinical Holds

8. At all times between May 2021 and February 2022, Kiromic was a pre-revenue company with no approved, commercial products for sale. In May 2021, Kiromic announced via press releases that it had submitted novel Investigational New Drug ("IND") applications to the FDA for its cancer product candidates, ALEXIS-PRO-1 and ALEXIS-ISO-1 (collectively, the "ALEXIS INDs"). Other than the ALEXIS INDs, Kiromic had no other product candidates in its pipeline. In its May 2021 press releases, Kiromic stated that "FDA feedback [was] expected within 30 days" before the company could begin clinical trials in "Q3 2021."

9. Per FDA regulations, "[a]n IND goes into effect: Thirty days after FDA receives the IND, unless FDA notifies the sponsor that the investigations described in the IND are subject to a clinical hold . . . ." 21 C.F.R. § 312.40(b)(1). "A clinical hold is an order issued by FDA to the [IND] sponsor to delay a proposed clinical investigation." 21 C.F.R. § 312.42(a). "The

clinical hold order may be made by telephone or other means of rapid communication [such as email] or in writing." 21 C.F.R. § 312.42(d). Once an IND is placed on clinical hold, an IND sponsor must first correct the deficiencies that the FDA cited before the agency will remove a clinical hold. 21 C.F.R. § 312.42(e).

A. The FDA imposed clinical holds on Kiromic's ALEXIS INDs in June 2021.

10. On June 16, 2021, the FDA contacted Kiromic's then-Chief Medical Officer ("CMO") via telephone to inform him that the FDA placed Kiromic's ALEXIS-PRO-1 IND on clinical hold. That same day, the FDA also sent Kiromic's CMO a confirmatory email stating that Kiromic's ALEXIS-PRO-1 had "been placed on clinical hold" because a section of the submission was "grossly deficient" and because the lack of information about certain factors, such as manufacturing and testing, prevented the FDA from assessing the risk of the product. The FDA also informed Kiromic in the email that a formal "clinical hold letter w[ould] be issued to [Kiromic] by July 16, 2021."

11. A formal clinical hold letter explains the FDA's basis and reasoning for the hold.

12. Later in the afternoon of June 16, 2021, the CMO informed Chiriva of the FDA's clinical hold on the ALEXIS-PRO-1. The CMO also forwarded to Chiriva the FDA's June 16, 2021 clinical hold email. Chiriva reviewed the FDA's June 16, 2021 email and understood that "clinical hold" meant that the FDA did not authorize the continuation of this IND.

13. The next day, on June 17, 2021, the FDA informed the CMO via telephone that the FDA had similarly placed Kiromic's second IND, the ALEXIS-ISO, on clinical hold. The CMO relayed to Chiriva the clinical hold on the ALEXIS-ISO IND via telephone that same day.

14. On June 17, 2021, the CMO sent Chiriva an email recommending that Kiromic promptly disclose the clinical holds.

15. In a reply email, Chiriva said that he agreed.

B. Chiriva updated Kiromic's Board about the FDA communications.

16. On June 18, 2021, a Kiromic Board member asked Chiriva via text message (in Italian): "[w]hat did the FDA say about the first IND? It's ok, it's not so bad, or did they raise issues?" Chiriva responded, "[w]e are waiting but [the FDA is] asking more information so at this moment we are not authorized to do anything until we will address secondary level of questions that will arrive by July 15."

17. The 30-day window the FDA had to review the INDs elapsed on June 16 for the ALEXIS PRO and June 20 for the ALEXIS ISO.

18. On June 22, 2021, Chiriva convened a virtual meeting of Kiromic's Board of Directors via conference call to discuss, among other things, Kiromic's communications with the FDA regarding the ALEXIS INDs. The CMO, a non-Board member, and Kiromic's legal counsel also attended the virtual meeting.

19. Chiriva is not a native English speaker, and his messaging to the Board about the FDA's communications about the status of the ALEXIS INDs was imprecise. Chiriva told the Board that: Kiromic had received communications from the FDA about the ALEXIS INDs; the FDA had requested an additional 30 days to conduct a secondary review; and the IND applications were on halt and administratively on hold until Kiromic received further questions from the FDA. While Chiriva told the Board that the CMO was involved in the meeting to give more specifics if there were any questions, the Board did not ask questions of Chiriva or anyone else on this issue, and Chiriva did not ask questions of the Board or anyone else.

20. Some attendees at the meeting, including members of the Board, did not understand from Chiriva's update that the FDA had already imposed clinical holds on the

ALEXIS INDs. Rather, they understood—from Chiriva's comments about the FDA's secondary review and further questions expected in another 30 days—that the FDA was still reviewing the ALEXIS INDs and had not made a determination about the ALEXIS INDs. Chiriva did not share the June 16 email from the FDA to the CMO documenting a clinical hold with key personnel, such as Kiromic's then-Controller or then-CFO, who were involved in Kiromic's filings and statements made during the Offering.

II. False and Misleading Statements and Omissions About the ALEXIS INDs in the Offering, SEC Filings, and other Public Statements.

21. By July 2021, Kiromic was running out of money. Without a capital infusion, Kiromic only had enough cash on hand for about three and a half months before the company would be forced to shut down. Consequently, on July 2, 2021, Kiromic raised $40 million by selling common stock through the Offering for the purpose of funding the company's clinical trials of its ALEXIS INDs. However, Kiromic did not disclose in Kiromic's SEC filings, investor roadshow calls, and due diligence calls that the FDA had placed the ALEXIS INDs on clinical hold, despite being aware of this information approximately two weeks before the Offering began.

A. Kiromic made material omissions related to the FDA clinical holds in its Form S-1 and final prospectus.

22. Kiromic filed a Form S-1 on June 25, 2021, and a final prospectus on June 30, 2021, both of which were materially false and misleading because they discussed the clinical trial plan for the ALEXIS INDs and the hypothetical risk that the FDA *could* issue a clinical hold but omitted that the FDA had *actually* placed the ALEXIS INDs on clinical holds. This information was important to, among other things, the company's projected clinical trial timeline of "third quarter of 2021."

23. Instead, Kiromic stated in both filings only that its "two product candidates . . . ALEXIS-ISO-1 and ALEXIS-PRO-1 . . . are in the pre-initial new drug ('IND') stages of the [FDA] clinical trial process. We are currently going through the IND enabling trials process and we expect that first in human dosing in Phase I of clinical trials will commence in the third quarter of 2021."

24. In its risk factors in both the Form S-1 and the final prospectus, Kiromic stated (emphasis added):

> *If* the FDA imposes a *clinical hold*, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such trials.

25. Despite disclosing the hypothetical risk of a clinical hold and the potential negative consequences on Kiromic's business, Kiromic failed to disclose the material information that the FDA had already issued clinical holds on the ALEXIS INDs.

26. Chiriva reviewed, signed, and contributed content to the Form S-1, including information about the FDA clinical trials timelines.

27. As CEO and Board Chairman, and as someone who knew of the FDA clinical holds, Chiriva knew or should have known that Kiromic omitted the FDA clinical holds before he signed Kiromic's Form S-1.

B. Kiromic made false and misleading statements and omissions related to the FDA clinical holds to prospective investors during its investor roadshow calls.

28. On June 28 and 29, 2021, just days before the Offering, Kiromic's officers participated in at least ten investor roadshow calls and failed to inform potential investors that the FDA had placed the ALEXIS INDs on clinical holds. Chiriva participated in some but not all of these investor roadshow calls. Kiromic's CFO was primarily responsible for speaking during

these calls. During one investor call, the CFO stated the following about the FDA's review of Kiromic's INDs:

> So the two INDs were filed on the 24th of May, and now we are at the end of June. The normal calendar is 30 to 60 days to get a reply back from the FDA, and they tell us that we are authorized to begin our first in human [trials]. So I do believe that within July we should be any days being able to hear back. Our confidence in it going through is very high…[S]o we do believe that our chances of getting FDA authorization is very good. Within this July we will hear about that.

29. Chiriva attended this June 29, 2021 investor call, and he knew that the FDA had placed the ALEXIS INDs on clinical holds nearly two weeks earlier. Despite this knowledge, Chiriva did not correct the CFO's misstatement by disclosing the clinical holds. On certain other investor calls on June 28 and 29, the CFO made similar false and misleading statements or omissions, and Chiriva did not correct the CFO's statements by disclosing the clinical holds.

C. Kiromic made false and misleading statements and omissions related to the FDA clinical holds during due diligence calls with its underwriters, lawyers, and auditors.

30. In preparation for the Offering, Kiromic participated in due diligence calls with its underwriters, lawyers, and auditors ("external participants"), during which Kiromic did not disclose that the FDA had placed the INDs on clinical hold. Some due diligence questions asked about upcoming announcements and the timeline of the first in-human dosing for the ALEXIS INDs, indicating that Kiromic's underwriters viewed the FDA's response to Kiromic's IND applications—and the effect on the clinical trials timeline—as significant information.

31. For example, the underwriters were particularly interested in when Kiromic would receive the FDA's authorization to begin clinical trials, because this was considered a very strong selling point for the Offering. Kiromic's officers, including Chiriva on at least one occasion, participated in discussions in which the underwriters expressed that the clinical trials

timeline was the most important component of the Offering.

32. On June 17, 2021, one day after the FDA informed Kiromic about the clinical hold on the ALEXIS-PRO-1, Chiriva and the CFO participated in a "Management Due Diligence Call." On behalf of Kiromic, the CFO answered questions regarding the clinical trials timeline and did not disclose the clinical holds. Instead, the CFO told the external participants that Kiromic was waiting on the FDA's authorization to begin clinical trials. During the call, Chiriva did not correct the CFO's misleading statements or omissions by disclosing the clinical holds.

III. False and Misleading Statements Related to the Clinical-Hold Communications in Kiromic's Form 10-Q.

A. The FDA's July 13 Clinical Hold Letters

33. On July 13, 2021, Kiromic received the detailed FDA clinical-hold letters for the ALEXIS INDs, which explained the FDA's reasons for issuing the June 16 and 17 clinical holds. Further, the letters made clear that the FDA originally communicated the clinical holds by telephone on June 16 and 17. That same day, the CFO reviewed the letters. The next day, the CFO urged Kiromic to make prompt disclosure of the clinical holds. The Kiromic Board subsequently discussed the letters and approved a press release.

34. On July 16, 2021, Kiromic issued a press release (but not a Form 8-K) stating that the "FDA returned with *comments*" (emphasis added) regarding the INDs and that Kiromic still expected to meet its third quarter 2021 clinical trials timeline. Kiromic's July 16 press release did not use the term "clinical hold."

35. This July 16 press release was associated with Kiromic's stock price dropping by an abnormal 16.36%, eliminating roughly $9.7M in market capitalization.

B. Kiromic's False and Misleading Form 10-Q

36. On August 13, 2021, Kiromic filed its Form 10-Q for the period ended June 30,

2021, which failed to disclose that the FDA had placed the ALEXIS INDs on clinical holds. The Form 10-Q stated that the ALEXIS INDs "are in the pre-initial new drug ("IND") stages of the [FDA] clinical trial process. We are currently going through the IND enabling trials process and we expect that first in human dosing in Phase I of clinical trials will commence in the first quarter of 2022."

37. Under the heading "Recent Developments" in the Form 10-Q, Kiromic discussed the submission of the INDs to the FDA in May 2021, but omitted the FDA's June and July clinical-hold communications.

38. As CEO, Chiriva signed and certified Kiromic's Form 10-Q, despite these false and misleading statements and omissions.

39. On August 13, 2021, Kiromic issued a press release (and a Form 8-K), announcing that it had applied for "a Type A meeting with the FDA…[to] address the *clinical hold* issues and…discuss [a] path toward our first-in-human dosing" (emphasis added). This was Kiromic's first public reference to the FDA's "clinical hold[s]" on the ALEXIS INDs.

IV. Kiromic's Subsequent Actions

40. In August 2021, after Kiromic filed its Form 10-Q, the company received two complaints, via the company's anonymous hotline, alleging risks associated with Kiromic's public disclosures in its SEC filings and statements made to the public related to the anticipated timing of FDA authorization of Kiromic's INDs and projected clinical trials start date.

41. Kiromic's Board of Directors formed a Special Committee comprised only of independent directors of the Board and engaged outside counsel to conduct an internal investigation into the anonymous complaints (the "Investigation"). The Investigation found that Kiromic had received FDA clinical-hold communications on June 16 and 17, 2021, and that

Kiromic raised $40 million in the Offering without disclosing the June FDA clinical-hold communications in its Form S-1, final prospectus, or Form 10-Q for the period ended June 30, 2021.

42. Following the Investigation, Kiromic undertook several remedial measures to improve the effectiveness of the company's disclosure controls and procedures and filed a Form 8-K in which it acknowledged that it had failed to timely disclose the FDA communications. The 8-K also stated that the company terminated Chiriva for cause.

CLAIMS FOR RELIEF

First Claim

Chiriva Violated Sections 17(a)(2) and 17(a)(3) of the Securities Act [15 U.S.C. §§ 77q(a)(2) and (a)(3)]

43. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the paragraphs above.

44. By engaging in the conduct described herein, Chiriva, directly or indirectly, in the offer or sale of a security, by the use of the means or instruments of transportation or communication in interstate commerce or by use of the mails: obtained money or property by means of an untrue statement of a material fact or an 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/or engaged in a transaction, practice, or course of business which operated or would operate as a fraud or deceit upon the purchaser.

45. Chiriva was at least negligent in his conduct alleged herein.

46. For these reasons, Chiriva violated, and unless enjoined will continue to violate, Sections 17(a)(2) and (3) of the Securities Act [15 U.S.C. §§ 77q(a)(2) and (3)].

Second Claim

Chiriva Violated Exchange Act Rule 13a-14
[17 C.F.R. § 240.13a-14]

47. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the paragraphs above.

48. On August 13, 2021, acting under Section 302 of the Sarbanes-Oxley Act of 2002 and Exchange Act Rule 13a-14, Chiriva certified a quarterly report filed with the SEC by Kiromic.

49. By engaging in the acts and conduct alleged herein, Chiriva filed or caused to be filed on Kiromic's behalf a quarterly report on Form 10-Q that contained certifications signed by Chiriva as Kiromic's principal executive officer pursuant to Exchange Act Rule 13a-14 and included untrue statements of material fact, or failed to include, in addition to the information required to be stated in such certification, such further material information as was necessary to make the required statements, in light of the circumstances under which they were made, not misleading, or failed to disclose information required to be disclosed therein..

50. By reason of the foregoing, Chiriva violated, and unless enjoined will continue to violate, Exchange Act Rule 13a-14.

Third Claim

Chiriva Aided and Abetted Kiromic's Violations of Section 13(a) of the Exchange Act [15 U.S.C. § 78m(a)] and Rules 12b-20, 13a-13, and 13a-15(a) thereunder [17 C.F.R. §§ 240.12b-20, 240.13a-13, and 13a-15(a)]

51. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the paragraphs above.

52. Kiromic is an issuer of securities registered under Section 12 of the Exchange Act that filed required reports with the SEC under Section 13(a) of the Exchange Act and related

rules and regulations.

53. By engaging in the conduct described above, Kiromic: failed to file a quarterly report with the SEC that was true and correct; failed to include material information in its required report as was necessary to make the statements made, in light of the circumstances under which they were made, not misleading; and failed to maintain disclosure controls and procedures.

54. By engaging in the acts and conduct alleged herein, Kiromic violated Section 13(a) of the Exchange Act and Exchange Act Rules 12b-20, 13a-13, and 13a-15(a) thereunder. Kiromic has consented to the entry of an SEC 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 ("OIP"), finding, among other things, that Kiromic violated Section 13(a) of the Exchange Act and Exchange Act Rules 12b-20, 13a-13, and 13a-15(a) thereunder.

55. Chiriva, acting with the requisite state of mind, provided substantial assistance to Kiromic in committing its violations of Section 13(a) of the Exchange Act and Exchange Act Rules 12b-20, 13a-13, and 13a-15(a) thereunder.

56. By reason of the foregoing, Chiriva aided and abetted Kiromic's violations of Section 13(a) of the Exchange Act and Exchange Act Rules 12b-20, 13a-13, and 13a-15(a) thereunder and, unless enjoined, will continue to aid and abet such violations.

PRAYER FOR RELIEF

THEREFORE, the SEC respectfully requests that the Court:

(1) Permanently enjoin Chiriva from violating Sections 17(a)(2) and (3) of the Securities Act and Rule 13a-14 of the Exchange Act, and from aiding and abetting violations of

Section 13(a) of the Exchange Act and Rules 12b-20, 13a-13, and 13a-15(a) thereunder;

(2) Order Chiriva to pay a civil penalty 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)(3)];

(3) Bar Chiriva from acting as an officer or director of any issuer that has a class of securities registered pursuant to Section 12 of the Exchange Act [15 U.S.C. § 78l] or that is required to file reports pursuant to Section 15(d) of the Exchange Act [15 U.S.C. § 78o(d)]; and

(4) Grant such other and further relief as the Court may deem just and proper.

Dated: December 3, 2024

Respectfully submitted,

s/ Jennifer D. Reece

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