

UNITED STATES OF AMERICA
Before the
SECURITIES AND EXCHANGE COMMISSION

SECURITIES ACT OF 1933
Release No. 11332 / December 3, 2024

SECURITIES EXCHANGE ACT OF 1934
Release No. 101797

ADMINISTRATIVE PROCEEDING
File No. 3-22337

In the Matter of

**KIROMIC BIOPHARMA,
INC.,**

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” and “SEC”) 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”) and Section 21C of the Securities Exchange Act of 1934 (“Exchange Act”), against Kiromic BioPharma, Inc. (“Kiromic” 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 herein, except as to the Commission’s jurisdiction over it and the subject matter of these proceedings, which are admitted, 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 finds¹ that:

Summary

1. This matter involves violations of the federal securities laws by Kiromic BioPharma, Inc., a publicly traded biotherapeutics company in Houston, Texas 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 Commission 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. In addition, Kiromic and its officers made misstatements and omissions to investors on investor roadshow calls prior to the Offering. Kiromic's conduct violated the antifraud and reporting provisions of the federal securities laws.

Respondent

2. **Kiromic BioPharma, Inc.** is a Delaware corporation formed in 2016 with its principal place of business in Houston, Texas. It is a clinical-stage, fully integrated biotherapeutics company that develops and commercializes cell therapies that focus on immuno-oncology. Kiromic's stock previously traded on the Nasdaq Stock Market exchange and now trades on the OTCQB Venture Market under the ticker symbol "KRBP." Kiromic's common stock was previously registered under Section 12(b) of the Exchange Act and is currently registered under Section 12(g) of the Exchange Act. Kiromic is required to file periodic reports, including quarterly reports on Form 10-Q, with the Commission under Section 13(a) of the Exchange Act and related rules thereunder.

Facts

The ALEXIS INDs and FDA Clinical Holds

3. 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

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.

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.”

4. 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).

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

5. 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.” A formal clinical hold letter explains the FDA’s basis and reasoning for the hold.

6. Later in the afternoon of June 16, 2021, the CMO informed Kiromic’s then-CEO, Maurizio Chiriva-Internati (“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.

7. 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 that the FDA had placed a clinical hold on the ALEXIS-ISO IND via telephone that same day.

8. On June 17, 2021, the CMO sent Chiriva an email recommending that Kiromic promptly disclose the clinical holds. In a reply email, Chiriva said that he agreed.

Chiriva updated Kiromic’s Board about the FDA communications.

9. 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.”

10. 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.

11. 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.

12. 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.

13. 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 documenting a clinical hold with key personnel, such as Kiromic's then-Controller or Kiromic's then-CFO, Tony Tontat, who were involved in Kiromic's filings and statements made during the Offering.

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

14. 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 its SEC filings, investor roadshow calls, or 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.

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

15. 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.”

16. 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.”

17. In its risk factors in both the Form S-1 and the final prospectus, Kiromic stated:

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. (emphasis added).

18. 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.

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

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

20. 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. Tontat was primarily responsible for speaking during these calls. During one investor call, Tontat 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.

21. 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, Tontat made similar false and misleading statements or omissions, and Chiriva did not correct Tontat's statements by disclosing the clinical holds.

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

22. 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.

23. 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 and Tontat, participated in discussions in which the underwriters expressed that the clinical trials timeline was the most important component of the Offering.

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

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

The FDA's July 13 Clinical Hold Letters.

25. 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, Tontat reviewed the letters. The next day, Tontat urged Kiromic to make prompt disclosure of the clinical holds. The Kiromic Board subsequently discussed the letters and approved a press release.

26. 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."

27. 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.

Kiromic's False and Misleading Form 10-Q.

28. 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."

29. 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.

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

31. 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.

Kiromic's Subsequent Actions

32. 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.

33. Thereafter, 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.

34. Following the Investigation, the Special Committee proposed, and Kiromic's Board adopted, several remedial measures to improve the effectiveness of the company's disclosure controls and procedures, including: (a) appointing an interim CEO who received training on appropriate disclosure controls and procedures; (b) establishing a Disclosure Committee comprised of management; and (c) appointing two new independent directors to the Board.

Kiromic also filed a Form 8-K in which it acknowledged that it had failed to timely disclose the FDA communications. The Form 8-K also stated that the company terminated Chiriva for cause.

35. Kiromic also voluntarily self-reported to the SEC's Division of Enforcement ("Division") regarding its failure to disclose the FDA's clinical-hold communications and cooperated with the Division's investigation. Kiromic's cooperation included facilitating the submissions of sworn declarations and testimony of foreign-based witnesses.

Violations

36. As a result of the conduct described above, Kiromic violated Sections 17(a)(2) and 17(a)(3) of the Securities Act. Section 17(a)(2) prohibits any person from obtaining money or property in the offer or sale of a security "by means of any untrue statement of a material fact or 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." Section 17(a)(3) of the Securities Act prohibits any person from engaging "in any transaction, practice, or course of business which operates or would operate as a fraud or deceit upon the purchaser."

37. Also as a result of the conduct described above, Kiromic violated Section 13(a) of the Exchange Act and Rules 12b-20 and 13a-13 thereunder, which require every issuer of a security registered pursuant to Section 12 of the Exchange Act to file with the Commission quarterly reports containing such information as the Commission's rules may require and such further material information as may be necessary to make the required statements, in light of the circumstances under which they were made, not misleading.

38. Also as a result of the conduct described above, Kiromic violated Exchange Act Rule 13a-15(a), which requires every issuer with a security registered pursuant to Section 12 of the Exchange Act to maintain disclosure controls and procedures designed to ensure that information required to be disclosed by an issuer in reports it files or submits under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the Commission's rules and forms.

Kiromic's Cooperation and Remedial Efforts

39. In determining to accept the Offer, the Commission considered Kiromic's self-report, remedial acts promptly undertaken, and cooperation afforded the Commission staff.

IV.

In view of the foregoing, the Commission deems it appropriate to impose the sanctions agreed to in Kiromic's Offer.

Accordingly, it is hereby ORDERED that:

A. Pursuant to Section 8A of the Securities Act and Section 21C of the Exchange Act, Respondent cease and desist from committing or causing any violations and any future violations of

Sections 17(a)(2) and 17(a)(3) of the Securities Act and Section 13(a) of the Exchange Act and Rules 12b-20, 13a-13, and 13a-15(a) thereunder.

B. Respondent acknowledges that the Commission is not imposing a civil penalty based upon, among other things, its cooperation in a Commission investigation and/or related enforcement action. If at any time following the entry of the Order, the Division obtains information indicating that Respondent knowingly provided materially false or misleading information or materials to the Commission, or in a related proceeding, the Division may, at its sole discretion and with prior notice to the Respondent, petition the Commission to reopen this matter and seek an order directing that the Respondent pay a civil money penalty. Respondent may contest by way of defense in any resulting administrative proceeding whether it knowingly provided materially false or misleading information but may not: (1) contest the findings in the Order; or (2) assert any defense to liability or remedy, including, but not limited to, any statute of limitations defense.

By the Commission.

Vanessa A. Countryman
Secretary