UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

RONALD H. KARP, Individually and On Behalf of All Others Similarly Situated, Plaintiff, vs. KIROMIC BIOPHARMA, INC., MAURIZIO CHIRIVA-INTERNATI, TONY TONTAT, GIANLUCA ROTINO, PIETRO BERSANI, AMERICO CICCHETTI, MICHAEL NAGEL, JERRY SCHNEIDER and THINKEQUITY LLC, Defendants.	**Case No.:** 22-6690 **JURY DEMANDED**

COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

Plaintiff Ronald H. Karp ("Plaintiff"), individually and on behalf of all others similarly situated, by and through his attorneys, alleges the following upon information and belief, except as to those allegations concerning Plaintiff, which are alleged upon personal knowledge. Plaintiff's information and belief is based upon, among other things, his counsel's investigation, which includes without limitation: (a) review and analysis of regulatory filings made by Kiromic BioPharma, Inc. ("Kiromic" or the "Company") with the United States ("U.S.") Securities and Exchange Commission ("SEC"); (b) review and analysis of press releases and media reports issued by and disseminated by Kiromic; and (c) review of other publicly available information concerning Kiromic.

I. NATURE OF THE ACTION AND OVERVIEW

1. This is a federal securities class action on behalf of a class consisting of all persons and entities (other than Defendants) that purchased or otherwise acquired: (a) Kiromic common stock pursuant to the Offering Documents (defined below) and/or (b) Kiromic common stock between June 25, 2021 and August 13, 2021, both dates inclusive (the "Class Period").

2. The Company's public offering closed on July 2, 2021 (the "Offering") and was conducted pursuant to a registration statement filed with the SEC on June 25, 2021 ("Registration Statement") and a final prospectus dated June 29, 2021 (the "Prospectus," with the Registration Statement, the "Offering Documents").

3. Plaintiff pursues claims against the Defendants under the Securities Act of 1933 (the "Securities Act") and the Securities Exchange Act of 1934 (the "Exchange Act").

4. Plaintiff purchased Kiromic shares priced at $5.00 per share on the Offering. At the time of the Offering, the Company presented itself as a target discovery and gene-editing company which utilized artificial intelligence to create immunotherapy products. While the Company had no immunotherapy products on the market at the time, it had applications to begin human clinical trials for two new drug candidates, known as Investigational New Drug ("IND") applications, pending with the Food and Drug Administration ("FDA"). The Offering Documents stated that the Company could commence clinical trials within thirty (30) days of those IND applications unless the FDA imposed a clinical hold.

5. A clinical hold is an order issued by the FDA to delay or suspend new or existing clinical trials with respect to an applicant's products. When a proposed study is placed on clinical hold, no new subjects may be recruited for testing the drug, and patients already testing the drug must be taken off. A clinical hold can be imposed, among other grounds, where "(i) [h]uman subjects are or would be exposed to an unreasonable and significant risk of illness or injury; (ii)

[t]he clinical investigators named in the IND are not qualified by reason of their scientific training and experience to conduct the investigation described in the IND; (iii) [t]he investigator brochure is misleading, erroneous, or materially incomplete. . . .” *See* https://www.fda.gov/drugs/investigational-new-drug-ind-application/ind-application-procedures-clinical-hold. (last visited 08/03/2022).

6. The Offering Documents failed to disclose that the FDA had, prior to the filing of the Registration Statement and Prospectus, imposed a ***clinical hold***, and in fact, contained statements indicating that it had not. Given that the Offering closed on July 2, 2021, more than thirty (30) days after the Company submitted the IND applications for its two immunotherapy product candidates, investors were assured that no clinical hold had been issued and clinical trials would commence.

7. The Company, however, had received communications from the FDA on June 16 and 17, 2021, informing it that the FDA was placing the IND applications for its two candidate products on ***clinical hold***. The Offering Documents failed to disclose this information, instead representing that clinical testing was expected to proceed in the third quarter of 2021. Clinical testing did not proceed in the third quarter of 2021, nor was it likely given the FDA’s imposition of a ***clinical hold***.

8. The Offering Documents contained untrue statements of material fact, omitted material facts necessary to make the statements contained in them not misleading, and/or failed to make adequate disclosures otherwise required regarding the status of those applications.

9. As a result of these untrue and misleading statements and omissions, and the resulting decline in the market value of the Company’s stock, Plaintiff and the putative class have suffered significant losses.

II. JURISDICTION AND VENUE

10. The claims asserted herein arise under and pursuant to Sections 11, 12(a)(2), and 15 of the Securities Act (15 U.S.C. §§ 77k, 77l(a)(2), and 77o) and Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 22 of the Securities Act (15 U.S.C. § 77v) and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

12. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b). There are presumably hundreds, if not thousands, of investors in Kiromic's common stock located in the U.S., some of whom undoubtedly reside in this Judicial District. Further, Defendant ThinkEquity LLC's principal place of business is located at 17 State Street, New York, NY 10004.

13. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the United States mail, interstate telephone communications, and the facilities of a national securities exchange.

III. PARTIES

A. Plaintiff

14. Plaintiff Ronald H. Karp, as set forth in the accompanying certification, incorporated by reference herein, purchased Kiromic common stock on the Company's Offering, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein. Plaintiff Karp is a citizen of New York.

B. Defendants

15. Defendant Kiromic is a Delaware corporation with its principal place of business in Houston, Texas. Kiromic's shares trade on the Nasdaq Capital Market under the symbol "KRBP."

16. ***Defendant ThinkEquity LLC*** ("ThinkEquity") is a Delaware limited liability company with its principal place of business at 17 State Street, New York, NY 10004. Defendant ThinkEquity is successor to Fordham Financial Management Inc. ("FFA"), which was the underwriter, and was listed as such in the Offering Documents. FFA converted to a limited liability company and changed its name on August 21, 2021.

17. ***Defendant Maurizio Chiriva-Internati*** ("Chiriva-Internati") served as the Company's Chief Executive Officer ("CEO") and signed the Registration Statement. As of June 25, 2021, Defendant Chiriva-Internati beneficially owned 18.61% of the Company's common stock. Further, Defendant Chiriva-Internati served as the Company's Chief Scientific Officer from December 2012 to September 2019 and has PhDs in Immunology, Morphological Science, and Biological Sciences.

18. ***Defendant Tony Tontat*** ("Tontat") served as the Company's Chief Financial Officer ("CFO") and signed the Registration Statement. As of June 25, 2021, Defendant Tontat beneficially owned 6.10% of the Company's common stock. On September 29, 2021, Defendant Tontat notified the Company of his decision to resign from his positions at the Company effective immediately.

19. ***Defendant Gianluca Rotino*** ("Rotino") served as the Company's Chief Strategy and Innovation Officer and signed the Registration Statement. As of June 25, 2021, Defendant Rotino beneficially owned 6.21% of the Company's common stock.

20. ***Defendant Pietro Bersani*** ("Bersani') served as a Director of the Company and is the Chairman of the Company's Audit Committee. Defendant Bersani signed the Registration Statement. Defendant Bersani is currently the CEO of the Company.

21. ***Defendant Americo Cicchetti*** ("Cicchetti") served as a Director of the Company. Defendant Cicchetti signed the Registration Statement.

22. ***Defendant Michael Nagel*** ("Nagel") served as a Director of the Company and is a member of the Company's Audit Committee. Defendant Nagel signed the Registration Statement.

23. ***Defendant Jerry Schneider*** ("Schneider") served as a Director of the Company and is a member of the Company's Audit Committee. Defendant Schneider signed the Registration Statement. On December 3, 2021, Defendant Schneider informed the Board that he was resigning his position as director of the Company effective immediately.

24. Defendants Chiriva-Internati, Tontat, Rotino, Bersani, Cicchetti, Nagel, and Schneider are collectively referred as "Individual Defendants."

25. The Company, the Individual Defendants and ThinkEquity are collectively referred to as "Defendants."

IV. CLASS ACTION ALLEGATIONS

26. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class, consisting of all persons and entities that purchased Kiromic common stock issued in connection with the Company's Offering and/or purchased or otherwise acquired Kiromic securities between June 25, 2021 and August 13, 2021, both dates inclusive (the "Class Period"). Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal

representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

27. The members of the Class are so numerous that joinder of all members is impracticable. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are at least hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Kiromic or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

28. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

29. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

30. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether the Offering Documents omitted and/or misrepresented material facts about the business, operations, and prospects of the Company; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

31. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

V. SUBSTANTIVE ALLEGATIONS

32. Plaintiff participated in the Offering and received an allocation of 30,000 shares priced at $5.00 per share. Plaintiff's purchase of Kiromic stock was issued pursuant to the Offering because Plaintiff purchased his Kiromic stock directly in the Offering.

33. Kiromic described itself to investors as a "target discovery and gene-editing company utilizing artificial intelligence and our proprietary neural network platform with a therapeutic focus on immuno-oncology." To generate revenue, the Company is dependent on the successful "development, regulatory approval and commercialization" of immunotherapy product candidates. As of June 29, 2021, the Company had no approved products, had not generated any revenue, and continued to incur significant product and development expenses related to its ongoing operations.

A. The ALEXIS Products

34. As of June 29, 2021, the Company's only product candidates were a brand of immunotherapy products called ALEXIS-ISO-1 and ALEXIS-PRO-1 (collectively "ALEXIS"). As explained in the Offering Documents, the ALEXIS products are chimeric antigen receptor T cell (CAR-T) therapies "designed to treat cancer by capitalizing on the immune system's ability to destroy cancer cells." Such therapies have "recently emerged as a revolutionary and potentially curative therapy for patients with hematologic cancers, including refractory cancers."

35. Before the ALEXIS products could be sold, the Company needed to obtain regulatory approval from the FDA. In the Offering Documents, the Company explained to investors that the process required by the FDA before a biological product could be marketed in the United States generally involved. The Offering Documents state:

- completion of nonclinical laboratory tests and animal studies according to good laboratory practices, or GLPs, and applicable requirements for the humane use of laboratory animals or other applicable regulations;

- submission to the FDA of an IND, which must become effective before human clinical trials may begin;

- approval by an independent IRB or ethics committee at each clinical site before the trial is commenced;

- performance of adequate and well-controlled human clinical trials according to the FDA's GCPs, and any additional requirements for the protection of human research patients and their health information, to establish the safety and efficacy of the proposed biological product for its intended use;

- submission to the FDA of a BLA for marketing approval that includes substantial evidence of safety, purity, and potency from results of nonclinical testing and clinical trials;

- satisfactory completion of an FDA Advisory Committee review, if applicable;

- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced to assess compliance with cGMP, to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity and, if applicable, the FDA's current good tissue practices, or GTPs, for the use of human cellular and tissue products;

- potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA; and

- FDA review and approval, or licensure, of the BLA.

36. Thus, before human clinical trials could commence, an applicant had to complete nonclinical laboratory tests and animal studies and submit to the FDA an IND application.

37. The Company stated in the Offering Documents that the IND application "automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the trial on a clinical hold within that 30-day time period." In that event, the "IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin." If the FDA imposes a clinical hold, "trials may not recommence without FDA authorization and then only under terms authorized by the FDA."

38. On December 17, 2020, the Company submitted two IND applications with the FDA for the ALEXIS products. After communicating with the FDA, the Company resubmitted these applications on May 14 and May 17, 2021. The revised IND applications were for human clinical trials of the ALEXIS products. The Offering Documents were otherwise silent regarding the status of the IND applications.

B. <u>The FDA Communications</u>

39. On June 16 and 17, 2021, the Company received communications from the FDA that the FDA was placing the Company's IND applications on clinical hold (the "FDA Communications"). The Offering Documents did not disclose this highly material information. The clinical hold had broad-ranging implications for the IND applications, raising the possibility that clinical trials could be delayed indefinitely with substantial costs required to address FDA issues, or that the clinical hold might never be lifted.

40. The FDA IND Application Procedures explain that a "clinical hold order may be made by telephone or other means of rapid communication."

41. The FDA Communications were undoubtedly material to investors, had they been disclosed prior to the Offering. Sale of ALEXIS products, which would be impossible without FDA approval, provided the Company's only prospect for continuing to advance product candidates and for potentially generating revenue. The FDA Communications gave notice that the Company could not commence clinical trials as planned and might never do so. Indeed, clinical holds are rarely issued and the most common reasons for clinical holds are clinical and product quality issues. Many IND applications which are put on clinical hold remain on clinical hold for over a year. Addressing the issues raised by the FDA may come at great financial expense. A delay in clinical trials is, of course, detrimental to business operations by delaying access to much needed revenue with ever mounting expenses. The Company recognized this risk in the discussion of risk factors in the Offering Documents:

> If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

42. The Offering Documents' discussion of risk factors emphasized that "[t]he clinical and commercial success of our current and any future product candidates will depend on a number of factors, including . . . timely completion of our preclinical studies and clinical trials. . . ." Indeed, the Company listed four "principal factors" that might affect its financial performance, two of which were "slow or delayed IND applications," and "slow or delayed clinical trial enrollment."

43. The Offering Documents' discussion of risk factors emphasized the materiality of a clinical hold. It warned investors that:

- Clinical trials "may be suspended or terminated by . . . the FDA . . . due to

a number of factors . . . resulting in the imposition of a clinical hold[;]"

- "[F]ailure to comply with regulatory requirements" may result in "holds on clinical trials;

- "[T]he FDA can place an IND application on clinical hold even if such other [regulatory] entities have provided a favorable review[.]"

44. Moreover, information about the FDA Communications was also material to investors by signaling the FDA's likelihood to ultimately grant approval for commercialization of the ALEXIS products. As the Company recognized in the Offering Documents "[m]any of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates."

45. If the ALEXIS products were unable to obtain regulatory approval, the Company recognized that the Company "may not be able to continue" operations.

C. The Offering

46. On June 29, 2021, the Company announced the pricing terms of a public offering to be closed on July 2, 2021. The offering resulted in the sale of 8,000,000 shares of Kiromic common stock at a price of $5.00 per share, for gross proceeds of $40 million. The Company announced the pricing of the Offering through a June 29, 2021 press release which listed the amount of shares offered, the price, directed the reader where to find the final prospectus, and explained that the shares of common stock "are being offered by" the Company. The press release also explained that the Company planned to use net proceeds "primarily for clinical trials for its ALEXIS-ISO-1 and ALEXIS-PRO-1 product candidates, GMP facility expansion, intellectual property protection and reinforcement, IND applications and IND enabling trials and working capital and the remainder for general corporate purposes." In light of the clinical holds, however, the proceeds of the Offering would have to be used to remedy the concerns expressed by the FDA.

In fact, many of the uses listed would not be possible unless the Company was able to promptly resolve the clinical hold issues with the FDA.

47. The Offering was underwritten by ThinkEquity on a firm commitment basis. The Offering Documents explained that "[t]he underwriters are committed to purchase all shares offered by us" other than those covered by an over-allotment option.

48. The primary purpose of the offering was to generate cash to fund upcoming human clinical trials for the ALEXIS products.

49. The Offering was conducted pursuant to a registration statement filed with the SEC on June 25, 2021 and a final prospectus dated June 29, 2021. The Offering Documents became effective on June 29, 2021.

D. False And Misleading Statements In The Offering Documents

50. The Offering Documents contained untrue statements of material fact, omitted material facts necessary to make the statements contained in them not misleading, and omitted to state material facts required under the statute, rules, and regulations governing the preparation of public offering documents for securities.

51. In relevant part, the Offering Documents described the status of the ALEXIS products' applications to the FDA as follows:

> These products are in the pre-initial new drug ("IND") stages of the US Food and Drug Administration (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.

52. Disclosure of the FDA Communications informing Kiromic that their IND applications were put on clinical hold was necessary to make this statement not misleading because the imposition of a clinical hold is material information that a reasonable investor would have

expected to be included in a description of the status of the ALEXIS IND applications. However, this information was not made public until after the Offering had closed.

53. Omission of the FDA Communications rendered this statement especially misleading in light of the Offering Documents' ambitious statement that human dosing in Phase I of clinical trials was expected to commence in the third quarter of 2021. With such an optimistic estimate, a reasonable investor would have been misled to believe that the FDA had not issued a clinical hold.

54. This is especially true given that the Offering Documents disclosed that when the ALEXIS IND applications were originally submitted on December 17, 2020, it took five (5) months of communication with the FDA and consults with its scientific board and clinical advisors before the Company was able to resubmit those applications on May 14 and May 17, 2021. A reasonable investor would have concluded that the FDA had not provided further comments given that the commencement of clinical trials by the third quarter of 2021 would otherwise have been unrealistic or even impossible.

55. Moreover, by June 29, 2021, the requisite thirty (30) day period for the FDA to provide comments before the IND applications would have become effective had elapsed, and a reasonable investor would have concluded that the clinical trials should have been able to commence. As the Company explained in the Offering Documents, the "IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the trial on a clinical hold within that 30-day time period." This statement, combined with the timing of the Offering, lead investors to conclude that there was no clinical hold, that the IND had become effective, that clinical trials were able to commence, and that their investment would be used for clinical trials.

56. Thus, failure to disclose the FDA Communications in the Offering Documents constitutes an omission of material information necessary to make the statements in the Offering Documents not untrue and misleading, when made.

57. Disclosure of the FDA Communications was also necessary to make statements in the Offering Documents not misleading, which discuss the possibility of a clinical hold as something that "may" or "could" occur, not something that the Company had already been informed by the FDA had occurred:

- "The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance. 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."

- "We may also experience delays in completing planned clinical trials for a variety of reasons, including delays related to: obtaining regulatory authorization to begin a trial, if applicable. . . ."

- "Further, a clinical trial may be suspended or terminated by . . . the FDA . . . due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold. . . ."

- "The FDA's review of our data of our ongoing clinical trials may, depending on the data, also result in the delay, suspension or termination of one or more clinical trials, which would also delay or prevent the initiation of our other planned clinical trials."

- "Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party suppliers or manufacturing processes, or failure to

> comply with regulatory requirements, may result in . . . fines, warning letters or holds on clinical trials. . .”

- “Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include, among other actions, . . . a clinical hold. . . .”

58. Discussion of a clinical hold as a mere possibility without disclosure of the FDA Communications is also untrue or misleading given that such a clinical hold had already actually occurred. While framed as cautionary language, the statements above only served to further mislead investors by communicating that a clinical hold had not been imposed. Disclosure of the FDA Communications were necessary to make these statements not untrue or misleading.

59. The failure to disclose the FDA Communications also rendered misleading the Offering Documents’ disclosure relating to the Company’s contemplated use of proceeds. The Offering Documents stated:

> We plan to use the net proceeds of this offering primarily for clinical trials for our ALEXIS-ISO-1 and ALEXIS-PRO-1 product candidates, GMP facility expansion, intellectual property protection and reinforcement, IND applications and IND enabling trials and working capital and the remainder for general corporate purposes.

60. This statement was misleading because the FDA had already given notice that clinical trials of the ALEXIS products were placed on clinical hold. The Offering Documents fail to disclose that some of the proceeds would be needed to remedy the concerns expressed by the FDA. Moreover, many of the uses listed would not be possible unless the Company was able to promptly resolve the clinical hold issues with the FDA. Given that the Company remains subject to the clinical hold to this day, the issues underlying the clinical hold are significant and therefore difficult, costly, or impossible to fix.

61. Moreover, the Offering Documents omitted material information that was otherwise required to be disclosed. Item 303(b)(2)(ii) of SEC Regulation S-K, 17 C.F.R. § 229.303(b)(2)(ii), required Defendants to describe in the Offering Documents "any known trends or uncertainties that have had or that are reasonably likely to have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations." Similarly, Item 105 of SEC Regulation S-K, 17 CFR § 229.105, required the Offering Documents to describe "the material factors that make an investment in the registrant or offering speculative or risky." Defendants violated both Items 303 and 105 by failing to disclose the FDA Communications because a clinical hold undoubtedly constitutes an uncertainty that is reasonably likely to have a material unfavorable impact on revenues, or alternatively, a material factor which makes investment speculative or risky.

62. In addition, the Offering Documents omitted to disclose that as of June 30, 2021, the Company had deficiencies in its disclosure controls and procedures regarding the identification of information for disclosure during the second and third quarters of 2021. While the Company did disclose that it had "identified material weaknesses in our internal control over financial reporting", the discussion of this risk factor was specifically tailored to its financial reporting internal controls. In reality, the deficiencies in the Company's disclosure controls that existed at the time were far broader than its financial reporting and should have been represented as such. This represents material information that was otherwise required to be disclosed, as well as material information required to make its disclosure not misleading.

63. On July 16, 2021, two weeks after the closing of the Offering, the Company announced through a press release that it had received "comments" from the FDA regarding the ALEXIS products including "[t]racing of all reagents used in manufacturing," "[f]low chart of

manufacturing processes," and "Certificate of Analysis (COA) for the Company's CAR-T products (allogeneic CAR-T)."

64. On August 13, 2021, the Company issued a press release which made passing reference to "clinical hold issues" but did not otherwise expand on what those issues were. The press release stated, in relevant part, under the heading *Events occurring after June 30, 2021 until August 13, 2021*:

> Communications with the FDA -- Supported by IQVIA, instead of simply addressing the FDA's questions with a written response only (WRO), we took the decision to apply for a Type A meeting with the FDA. The Type A meeting will address the clinical hold issues and will allow us to discuss path toward our first-in-human dosing.

65. A Type A meeting is a meeting needed to help an otherwise stalled product development program proceed. According to FDA guidance, it includes "[m]eetings to discuss clinical holds in which a response to hold issues has been submitted, but the FDA and the sponsor or applicant agree that the development is stalled and a new path forward should be discussed."

66. On November 18, 2021, the "Company received a written notice from the Listing Qualifications Department of The Nasdaq Stock Market ("Nasdaq") advising the Company that it was not in compliance with Nasdaq's continued listing requirements under the Nasdaq Listing Rule 5250(c)(1) (the "Rule") as a result of its failure to file its Quarterly Report on Form 10-Q for the quarter ended September 30, 2021 (the "Form 10-Q") in a timely manner.

67. On January 27, 2022, the Company terminated Defendant Chiriva-Internati as CEO for cause after finding evidence of "conduct that the Board believed was inconsistent with the Company's policies." The details of his conduct have not been publicly revealed.

FIRST CLAIM

(Against The Company And The Individual Defendants For Violations Of Section 11 Of The Securities Act)

68. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein, except any allegation of fraud, recklessness or intentional misconduct.

69. This Count is brought by Plaintiff under Section 11 of the Securities Act, 15 U.S.C. § 77k. For purposes of this Section 11 claim, Plaintiff is not required to allege that any Defendant acted with scienter or fraudulent intent, as those are not elements of a Section 11 claim. Plaintiff disclaims any allegations of fraud, scienter, or recklessness.

70. The Offering Documents contained untrue statements of material fact and omitted to state material facts required to be stated therein or necessary to make the statements therein not misleading, as alleged above.

71. The Company is the issuer for the Offering. As issuer of Kiromic stock, the Company is strictly liable to Plaintiff (and the Class) for the misstatements and omissions in the Offering Documents.

72. As signatories of the Offering Documents, directors of the issuer, or a person performing similar functions as to a director, the Individual Defendants were responsible for their contents and dissemination.

73. The Individual Defendants did not act with reasonable care to ensure there were no untrue statements of material fact or omissions to state material facts required to be stated therein or necessary to make the statements therein not misleading in the Offering Documents.

74. The Company and the Individual Defendants issued, caused to be issued, and participated in the issuance of materially untrue and misleading written statements to the investing public that were contained in the Offering Documents. By reasons of the conduct alleged, the Company and the Individual Defendants violated Section 11 of the Securities Act.

75. Plaintiff's purchase of Kiromic common stock was issued pursuant to, and traceable to the Offering because Plaintiff purchased his shares directly in the Offering.

76. Plaintiff has sustained damages. The value of the Company's common stock has declined substantially after and as a result of the alleged violations.

77. At the time when he purchased the Company common stock, Plaintiff (and the Class) was without knowledge of the facts concerning the wrongful conduct alleged in this Complaint and could not have reasonably discovered those facts before the Company's subsequent admissions.

SECOND CLAIM

(Violation of Section 11 of the Securities Act Against Defendant ThinkEquity)

78. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein, except any allegation of fraud, recklessness or intentional misconduct.

79. This Count is brought by Plaintiff under Section 11 of the Securities Act, 15 U.S.C. § 77k. For purposes of this Section 11 claim, Plaintiff is not required to allege that Defendant ThinkEquity acted with scienter or fraudulent intent, as those are not elements of a Section 11 claim. Plaintiff disclaims any allegations of fraud, scienter, or recklessness.

80. The Offering Documents contained untrue statements of material fact and omitted to state material facts required to be stated therein or necessary to make the statements therein not misleading, as alleged above.

81. Defendant ThinkEquity was the underwriter for the Offering. As the underwriter, Defendant ThinkEquity was responsible for the contents and dissemination of the Offering Documents.

82. Defendant ThinkEquity did not act with reasonable care to ensure there were no untrue statements of material fact or omissions to state material facts required to be stated therein or necessary to make the statements therein not misleading in the Offering Documents. Among other things, Defendant ThinkEquity failed to conduct adequate due diligence on the adequacy of the internal controls for the Company.

83. Defendant ThinkEquity issued, caused to be issued, and participated in the issuance of materially untrue and misleading written statements to the investing public that were contained in the Offering Documents, which misrepresented or failed to disclose, *inter alia*, the facts alleged above. By reasons of the conduct alleged, Defendant ThinkEquity violated Section 11 of the Securities Act.

84. Plaintiff's purchase of Company common stock was issued pursuant to, and traceable to the Offering because Plaintiff purchased their shares directly in the Offering.

85. Plaintiff has sustained damages. The value of the Company's common stock has declined substantially after and as a result of the alleged violations.

86. At the time when Plaintiff purchased the Company common stock, Plaintiff was without knowledge of the facts concerning the wrongful conduct alleged in this Complaint and could not have reasonably discovered those facts before the Company's subsequent admissions.

THIRD CLAIM

(Violation Of Section 12(a)(2) Of The Securities Act
Against The Company)

87. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein, except any allegation of fraud, recklessness or intentional misconduct.

88. This Count is brought by Plaintiff under Section 12(a)(2) of the Securities Act, 15 U.S.C. § 771(a)(2). For purposes of this Section 12(a)(2) claim, Plaintiff is not required to allege

that any Defendant acted with scienter or fraudulent intent, as those are not elements of a Section 12(a)(2) claim. Plaintiff disclaims any allegations of fraud, scienter, or recklessness.

89. By means of the defective Offering Documents—which include the Prospectus—the Company promoted and sold Company stock to Plaintiff for its own financial interests.

90. The Offering Documents were required pursuant to a public offering and contained untrue statements of material facts, omitted to state other facts necessary to make the statements made not misleading, and omitted to state material facts required to be stated therein, as alleged above.

91. The Company successfully solicited the sale of its securities by participating in the preparation and distribution of the untrue and misleading Offering Documents, which included signing the Registration Statement.

92. The Company did not act with reasonable care to ensure there were no untrue statements of material fact or omissions to state material facts required to be stated therein or necessary to make the statements therein not misleading in the Offering Documents. In the exercise of reasonable care, the Company would have known of such untruth or omission.

93. Plaintiff's purchase of the Company common stock was issued pursuant to, and traceable to the Offering because Plaintiff purchased his shares directly in the Offering.

94. By reason of the conduct alleged in this Complaint, the Company violated Section 12(a)(2) of the Securities Act. As a direct and proximate result of such violations, Plaintiff purchased the Company common stock pursuant to the Offering Documents and sustained substantial damages in connection with his purchases of the Company stock. Accordingly, Plaintiff has the right to rescind and recover the consideration paid for his Kiromic shares.

95. At the times when he purchased the Company common stock, Plaintiff was without knowledge of the facts concerning the wrongful conduct alleged in this Complaint and could not have reasonably discovered those facts before the Company's subsequent admissions.

FOURTH CLAIM

(Against Defendant ThinkEquity For Violations Of Section 12(a)(2) Of The Securities Act)

96. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein, except any allegation of fraud, recklessness or intentional misconduct.

97. This Count is brought by Plaintiff under Section 12(a)(2) of the Securities Act, 15 U.S.C. § 771(a)(2). For purposes of this Section 12(a)(2) claim, Plaintiff is not required to allege that Defendant ThinkEquity acted with scienter or fraudulent intent, as those are not elements of a Section 12(a)(2) claim. Plaintiff disclaims any allegations of fraud, scienter, or recklessness.

98. By means of the defective Offering Documents—which include the Prospectus—Defendant ThinkEquity sold and passed title of the Company common stock to Plaintiff for value.

99. The Offering Documents were required pursuant to a public offering and contained untrue statements of material facts, omitted to state other facts necessary to make the statements made not misleading, and omitted to state material facts required to be stated therein, as alleged above.

100. Defendant ThinkEquity did not act with reasonable care to ensure there were no untrue statements of material fact or omissions to state material facts required to be stated therein or necessary to make the statements therein not misleading in the Offering Documents. In the exercise of reasonable care, Defendant ThinkEquity would have known of such untruth or omission.

101. Plaintiff's purchase of the Company common stock was issued pursuant to, and traceable to the Offering because Plaintiff purchased his shares directly in the Offering.

102. By reason of the conduct alleged in this Complaint, Defendant ThinkEquity violated Section 12(a)(2) of the Securities Act. As a direct and proximate result of such violations, Plaintiff purchased the Company common stock pursuant to the Offering Documents and sustained substantial damages in connection with its purchases of the Company stock. Accordingly, Plaintiff has the right to rescind and recover the consideration paid for his Kiromic shares.

103. At the times when he purchased the Company common stock, Plaintiff was without knowledge of the facts concerning the wrongful conduct alleged in this Complaint and could not have reasonably discovered those facts before the Company's subsequent admissions.

FIFTH CLAIM

(Against the Individual Defendants For Violations Of Section 15 Of The Securities Act)

104. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein, except any allegation of fraud, recklessness or intentional misconduct.

105. This Count is brought by Plaintiff under Section 15 of the Securities Act, 15 U.S.C. § 77o. For the purposes of this Section 15 claim, Plaintiff is not required to allege that the Individual Defendants acted with scienter or fraudulent intent, as those are not elements of a Section 15 claim.

106. Each of the Individual Defendants was a control person of the Company by virtue of his or her position as a director or senior officer of the company, and by reason of his or her own involvement in the daily business of the Company. The Individual Defendants, at the time they held positions with the Company, were able to, and did, exercise substantial control over the

Company's operations, including control of the materially untrue and misleading statements, omissions, and course of conduct complained of in this action.

107. Indeed, the Individual Defendants were touted in the Offering Documents as "key executives," the loss of which would impede business operations. Moreover, each of the Individual Defendants signed the Registration Statement.

108. Each of the Individual Defendants exercised control over the violations of Sections 11 and 12(a)(2) of the Securities Act alleged in Counts I and II above, based on having signed the Offering Documents or having otherwise participated in the process that allowed the Offering to be completed.

SIXTH CLAIM

(Violations Of Section 10(b) Of The Exchange Act And Rule 10b-5 Promulgated Thereunder Against the Company and The Individual Defendants)

109. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

110. This Count is asserted against the Company and the Individual Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

111. During the Class Period, the Company and the Individual Defendants engaged in a course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading. This was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially

inflate and maintain the market price of the Company's securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire the Company's securities at artificially inflated prices. In furtherance of this unlawful course of conduct, the Company and the Individual Defendants took the actions set forth herein.

112. Pursuant to the above course of conduct, the Company and the Individual Defendants participated directly or indirectly in the preparation and/or issuance of the Offering Documents, SEC filings, press releases and other statements and documents described above, that were designed to influence the market for Kiromic securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about the Company's business prospects.

113. By virtue of their positions at the Company, the Individual Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, the Individual Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to the Individual Defendants. Said acts and omissions of the Individual Defendants were committed willfully or with reckless disregard for the truth. In addition, the Individual Defendants knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

114. Information showing that the Individual Defendants acted knowingly or with reckless disregard for the truth is peculiarly within the Individual Defendants' knowledge and control. As the senior managers and/or directors of the Company, the Individual Defendants had knowledge of the details of the Company's internal affairs.

115. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of the Company. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to the Company's businesses, operations, future financial condition, and future prospects. As a result of the dissemination of the aforementioned false and misleading public statements, the market price of the Company's securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning the Company's business and financial condition which were concealed by the Individual Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired the Company securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by the Individual Defendants and were damaged thereby.

116. During the Class Period, the Company's securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Company and the Individual Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of the Company's securities at prices artificially inflated by the Company and Individual Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of the Company's securities was substantially lower than the prices paid by Plaintiff and the other

members of the Class. The market price of the Company's securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

117. By reason of the conduct alleged herein, the Company and the Individual Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

SEVENTH CLAIM

(Violations Of Section 20(a) Of The Exchange Act Against Defendant Chiriva-Internati)

118. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

119. During the Class Period, Defendant Chiriva-Internati participated in the operation and management of the Company, and conducted and participated, directly and indirectly, in the conduct of the Company's business affairs. Because of his senior position, Defendant Chiriva-Internati knew the adverse non-public information about the clinical hold.

120. As an officer and/or director of a publicly owned company, Defendant Chiriva-Internati had a duty to disseminate accurate and truthful information with respect to the Company's results of operations, and to correct promptly any public statements issued by the Company, which had become materially false or misleading.

121. Because of his position of control and authority as senior officer, Defendant Chiriva-Internati was able to, and did, control the contents of the various reports, press releases and public filings which the Company disseminated in the marketplace during the Class Period, concerning the Company's results of operations. Throughout the Class Period, Defendant Chiriva-Internati exercised his power and authority to cause the Company to engage in the wrongful acts complained of herein. Defendant Chiriva-Internati, therefore, was a "controlling person" of the

Company within the meaning of Section 20(a) of the Exchange Act. In this capacity, he participated in the unlawful conduct alleged which artificially inflated the market price of Kiromic securities.

122. Defendant Chiriva-Internati, therefore, acted as a controlling person of the Company. By reason of his senior management positions and/or being director of the Company, Defendant Chiriva-Internati had the power to direct the actions of, and exercised the same to cause, the Company to engage in the unlawful acts and conduct complained of herein. Defendant Chiriva-Internati exercised control over the general operations of the Company and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

123. By reason of the above conduct, Defendant Chiriva-Internati is liable pursuant to Section 20(a) of the Exchange Act for the violations committed by the Company.

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

(A) Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

(B) Awarding compensatory damages or recission (as appropriate) in favor of Plaintiff and the other Class members against Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(C) Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(D) Awarding any equitable, injunctive, or other further relief that the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury. Dated: