

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported)
January 18, 2022

KINNATE BIOPHARMA INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-39743
(Commission File Number)

82-4566526
(IRS Employer Identification No.)

3611 Valley Centre Drive, Suite 175
San Diego, CA 92130
(Address, including zip code, of Registrant's principal executive offices)

(858) 299-4699
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	KNTE	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01. Other Events.

On January 18, 2022, Kinnate Biopharma Inc. issued a press release announcing that the U.S Food and Drug Administration has cleared the company's Investigational New Drug application for KIN-3248, a next-generation pan-FGFR inhibitor being developed for intrahepatic cholangiocarcinoma and urothelial carcinoma. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.**(d) Exhibits.**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated January 18, 2022.
104	Cover page interactive data file (embedded within the inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

KINNATE BIOPHARMA INC.

By: /s/ Nima Farzan
Nima Farzan
President and Chief Executive Officer

Date: January 18, 2022



Kinnate Biopharma Inc. Announces FDA Clearance of Investigational Drug Application for KIN-3248

Planned initiation of Phase 1 clinical trial for KIN-3248 in 1H2022

SAN FRANCISCO and SAN DIEGO, January 18, 2022 -- Kinnate Biopharma Inc. (Nasdaq: KNTE) ("Kinnate"), a biopharmaceutical company focused on the discovery and development of small molecule kinase inhibitors for difficult-to-treat, genomically defined cancers, today announced that the U.S Food and Drug Administration (FDA) has cleared the company's Investigational New Drug (IND) application for KIN-3248, a next-generation pan-FGFR inhibitor being developed for intrahepatic cholangiocarcinoma (ICC) and urothelial carcinoma (UC).

"The IND clearance for KIN-3248 is another important validation of our Kinnate Discovery Engine and an exciting step forward in our mission to deliver new therapies to patients with difficult-to-treat, genomically-defined cancers," said Nima Farzan, Chief Executive Officer of Kinnate. "By targeting clinically relevant primary FGFR driver alterations and secondary resistance mutations, including FGFR2 and FGFR3 gatekeeper, molecular brake, and activation loop mutations, we believe that KIN-3248 is unique among FGFR inhibitors and has the potential to extend the clinical response of cancer patients with FGFR-altered tumors."

KIN-3248 is an irreversible, small molecule pan-FGFR inhibitor that has been developed to address both primary FGFR2 and FGFR3 oncogenic alterations and those predicted to drive acquired resistance to current FGFR-targeted therapies, including gatekeeper, molecular brake, and activation loop mutations observed in cancers such as ICC and other gastrointestinal cancers. In preclinical studies, KIN-3248 demonstrated inhibitory activity across a wide range of clinically relevant mutations that drive primary disease and acquired resistance.

The Phase 1 trial is expected to initiate in the first half of 2022 and will evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and anti-cancer activity of KIN-3248 in FGFR inhibitor naïve and pretreated cancer patients with FGFR2 and/or FGFR3 gene alterations. The dose escalation portion (Part A) of the trial will determine the recommended dose and schedule of KIN-3248 for further evaluation in patients with FGFR2 and/or FGFR3 gene alterations. The dose expansion phase (Part B) of the trial will assess the safety and efficacy of KIN-3248 at the recommended dose and schedule in FGFR inhibitor naïve and pretreated patients with cancers driven by FGFR2 and/or FGFR3 gene alterations, including ICC, UC and other selected adult solid tumors.

Oncogenic FGFR (FGFR1, FGFR2, FGFR3, and FGFR4) gene alterations are observed in approximately 7% of all human cancers. FGFR2 gene fusions and FGFR3 activating alterations are predicted oncogenic drivers in approximately 10-20% of cholangiocarcinoma and 20-35% of urothelial cancers, respectively. While currently approved FGFR inhibitors and those in development provide clinical benefit in these cancer indications, disease progression typically occurs within 6-12 months of starting treatment and is often associated with the emergence of on-target resistance mutations within the FGFR kinase domain.

For more information about Kinnate's pipeline of targeted oncology therapeutics, please visit: www.kinnate.com/science-and-pipeline.

About Kinnate

Kinnate is focused on the discovery and development of small molecule kinase inhibitors for difficult-to-treat, genomically defined cancers. Kinnate's mission is to expand the reach of targeted therapeutics by developing products that are designed to address significant unmet need. Kinnate utilizes its deep expertise in structure-based drug discovery, translational research, and patient-driven precision medicine, which it refers to as the Kinnate Discovery Engine, to develop targeted therapies. Based in San Francisco and San Diego, California, the Kinnate team is composed of drug discovery experts supported by a distinguished group of scientific advisors. For more information, please visit www.kinnate.com.

Forward Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. These forward-looking statements include, without limitation, statements regarding the potential benefits of the Kinnate Discovery Engine, KIN-3248 and our other product candidates; and the planned initiation and conduct of a Phase 1 clinical trial for KIN-3248. Words such as “believes,” “anticipates,” “plans,” “expects,” “intends,” “will,” “goal,” “potential” and similar expressions are also intended to identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and trends. Such expectations and projections may never materialize or may prove to be incorrect. These forward-looking statements are subject to a number of risks, uncertainties, assumptions and other factors, including risks related to recently transitioning to operating as a clinical-stage biopharmaceutical company with a limited operating history; our ability to raise additional capital to finance our operations; our ability to discover, advance through the preclinical and clinical development of, obtain regulatory approval for and commercialize our product candidates; the novel approach we are taking to discover and develop drugs; our ability to timely file and obtain approval of investigational new drug applications for our planned clinical trials; the potential for any clinical trial results to differ from our preclinical study results; negative impacts of the COVID-19 pandemic on our business, including ongoing and planned clinical trials and ongoing and planned preclinical studies; competition in our industry; regulatory developments in the United States and other countries; our ability to attract, hire and retain highly skilled executive officers and employees; difficulties in managing our growth; our ability to protect our intellectual property; reliance on third parties to conduct our preclinical studies and any ongoing or planned future clinical trials, and to manufacture our product candidates; general economic and market conditions; and other risks. These and other risks, uncertainties, assumptions and other factors are further described under the heading “Risk Factors” in our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2021 that we have filed with the Securities and Exchange Commission (the “SEC”), as well as in our subsequent filings we make with the SEC. New risk factors emerge from time to time and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements. Investors should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Our forward-looking statements speak only as of the date of this release, and except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason in the future.

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