

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)
May 17, 2021

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.)

12707 High Bluff Drive, Suite 200
San Diego, CA 92130
(Address of principal executive offices, including zip code)

(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, \$0.0001 par value 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 2.02 Results of Operations and Financial Condition.

On May 17, 2021, Kinnate Biopharma Inc. issued a press release announcing its financial results for the quarter ended March 31, 2021. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

All of the information furnished in this Item 2.02 and Item 9.01 (including Exhibit 99.1) shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated May 17, 2021

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.

Date: May 17, 2021

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



Kinnate Biopharma Inc. Reports First Quarter 2021 Financial Results and Announces FDA Clearance of Investigational New Drug Application for KIN-2787

KIN-2787 is the company's RAF inhibitor candidate for patients with mutant BRAF-driven solid tumors

Planned initiation of Phase 1 clinical trial for KIN-2787 in mid-2021

Ended the quarter with cash and cash equivalents and investments of \$383.1 million

Closed \$35 million Series A financing of Chinese joint venture in May 2021

SAN FRANCISCO and SAN DIEGO, Calif. – May 17, 2021 – 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-2787 and also announced financial results for the quarter ended March 31, 2021. Kinnate expects to initiate a first-in-human Phase 1 clinical trial of KIN-2787 in patients with mutant BRAF-driven solid tumors in mid-2021.

“In the three years since our founding, Kinnate has consistently hit key milestones essential to our mission of delivering new therapies to patients with difficult-to-treat, genomically-defined cancers. The FDA’s clearance of our KIN-2787 IND marks another major achievement for the company and demonstrates the important progress we are making in our transition to becoming a clinical-stage company,” said Nima Farzan, Chief Executive Officer of Kinnate. “As we prepare for our first-in-human trial of KIN-2787 later this year, we are also pleased with the rapid advance of our lead FGFR inhibitor candidate, KIN-3248, which we believe may offer a new option for certain patients with cancers like urothelial tumors or intrahepatic cholangiocarcinoma. We anticipate a first half of 2022 IND filing for KIN-3248.”

The Phase 1 trial will evaluate the safety, tolerability, pharmacokinetics and anti-cancer activity of KIN-2787 in cancer patients with mutant BRAF-driven solid tumors. The dose escalation portion (Part A) of the trial will determine the recommended dose and schedule of KIN-2787 for further evaluation in patients with BRAF mutations. The dose expansion phase (Part B) of the trial will assess the safety and efficacy of KIN-2787 at the recommended dose and schedule in patients with cancers driven by BRAF Class II or III mutations, including lung cancer, melanoma and other selected adult solid tumors.

Recent Business Highlights and Corporate Update:

- In our RAF program, we filed an IND in April 2021 with the FDA to study KIN-2787 in patients with mutant BRAF-driven solid tumors. The FDA cleared the IND in May 2021 and we anticipate initiating a Phase 1 clinical trial for KIN-2787 in mid-2021. KIN-2787, our most advanced product candidate, is a RAF inhibitor we are developing for the treatment of patients with lung cancer, melanoma and other solid tumors. Unlike currently available treatments that target only Class I BRAF kinase mutations, we have designed KIN-2787 to target Class II and Class III BRAF mutations, where it would be a first-line targeted therapy, in addition to covering Class I BRAF mutations.
 - In May 2021 we closed a \$35 million Series A financing of a joint venture in China. Established with OrbiMed Asia Partners, OrbiMed Private Investments and Foresite Capital, the joint venture will be headquartered in Shanghai and the financing will enable the potential development and commercialization by the joint venture of certain Kinnate targeted oncology product candidates across Greater China (mainland China, Hong Kong, Taiwan, and Macau). Kinnate Biopharma will be the majority shareholder in the joint venture. The company has also announced that veteran biopharmaceutical industry executive Wenn Sun, Ph.D., has been appointed as the joint venture’s Executive Chair.
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- Data from pre-clinical studies of KIN-2787 have been selected for poster presentation at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting, which will be held virtually June 4-8, 2021. The data to be presented at the ASCO annual meeting was derived from pre-clinical studies evaluating the efficacy and tolerability of KIN-2787 in vitro and in vivo in BRAF mutation-driven human cancer models.
- In our FGFR program, we selected KIN-3248 as our lead FGFR inhibitor candidate for the treatment of intrahepatic cholangiocarcinoma and urothelial carcinoma and initiated GLP-toxicity studies of KIN-3248. Our FGFR candidates are designed to address clinically observed genomic alterations in FGFR2 and FGFR3 that drive resistance to current therapies. We anticipate filing an IND for KIN-3248 with the FDA in the first half of 2022 and, subject to our planned IND submission taking effect, initiating a Phase 1 clinical trial for KIN-3248 in the first half of 2022.
- We continued to advance a number of other small molecule research programs, including a CDK12 inhibitor in our KIN004 program to target the treatment of ovarian carcinoma, triple-negative breast cancer and metastatic castration-resistant prostate cancer.
- We expanded our organization to 41 full-time employees at March 31, 2021, of which 30 were engaged in research and development activities.

First Quarter 2021 Financial Results

- First quarter net loss for 2021 was \$17.5 million, compared to \$3.9 million for the same period in 2020.
- First quarter research and development expenses for 2021 were \$12.7 million, compared to \$3.2 million for the same period in 2020.
- First quarter general and administrative expenses for 2021 were \$4.8 million, compared to \$1.0 million for the same period in 2020.
- As of March 31, 2021, the total of cash and cash equivalents and investments was \$383.1 million.

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 for underserved populations. 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 our drug discovery activities, the expected timing for our regulatory filings and initiation of our clinical trials and the potential benefits and treatment indications of our product candidates. 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 operating as a preclinical-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 trial results; negative impacts of the COVID-19 pandemic on our business, including planned clinical trials and ongoing and planned preclinical trials; 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 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 March 31, 2021 that we are concurrently filing 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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Kinnate Biopharma Inc.
Condensed Balance Sheets
(in thousands, except share and par value amounts)
(Unaudited)

	<u>March 31, 2021</u>	<u>December 31, 2020</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 182,389	\$ 365,462
Short-term investments	65,808	31,398
Prepaid expenses and other current assets	2,975	3,343
Total current assets	251,172	400,203
Property and equipment, net	283	368
Long-term investments	134,910	-
Total assets	\$ 386,365	\$ 400,571
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 3,212	\$ 3,940
Accrued expenses	4,581	3,364
Total current liabilities	7,793	7,304
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 200,000,000 shares authorized at March 31, 2021 and December 31, 2020; 0 shares outstanding at March 31, 2021 and December 31, 2020	-	-
Common stock, \$0.0001 par value; 1,000,000,000 shares authorized at March 31, 2021 and December 31, 2020; 43,477,439 shares issued and outstanding at March 31, 2021 and December 31, 2020	4	4
Additional paid-in capital	449,394	446,601
Accumulated other comprehensive loss	(40)	(9)
Accumulated deficit	(70,786)	(53,329)
Total stockholders' equity	378,572	393,267
Total liabilities and stockholders' equity	\$ 386,365	\$ 400,571

Kinnate Biopharma Inc.
Condensed Statements of Operations and Comprehensive Loss
(Unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2021	2020
Operating expenses:		
Research and development	\$ 12,666	\$ 3,198
General and administrative (includes related party amounts of \$0 and \$92, respectively)	4,815	955
Total operating expenses	<u>17,481</u>	<u>4,153</u>
Loss from operations	(17,481)	(4,153)
Other income:		
Interest income	403	212
Other (expense) income, net	(379)	-
Total other income, net	<u>24</u>	<u>212</u>
Net loss	(17,457)	(3,941)
Unrealized loss on investments	(31)	-
Comprehensive loss	<u>\$ (17,488)</u>	<u>\$ (3,941)</u>
Weighted-average shares outstanding, basic and diluted	43,477,439	3,672,446
Net loss per share, basic and diluted	<u>\$ (0.40)</u>	<u>\$ (1.07)</u>