

Kindred Biosciences, Inc.
Form 8-K
January 17, 2019

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 17, 2019

KINDRED BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

Delaware 001-36225 46-1160142
(State or other jurisdiction of (Commission (I.R.S. Employer
incorporation or organization) File Number) Identification No.)
1555 Bayshore Highway, Suite 200, Burlingame, California 94010
(Address of principal executive offices) (Zip Code)

(650) 701-7901
(Registrant's telephone number, include area code)
N/A
(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:

- 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))

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.

Preliminary Financial Information

Kindred Biosciences, Inc. (the “Company”) is currently finalizing its financial results for the fiscal year ended December 31, 2018. While complete financial information and operating data for this period are not yet available, based on the preliminary unaudited internal financial statements, the Company expects to record approximately \$2.0 million in net product revenues for the year ended December 31, 2018, and further expects that, as of December 31, 2018, its unaudited cash balances were approximately \$73.9 million.

The preliminary financial data above in this Current Report on Form 8-K is preliminary and may change, is based on information available to management as of the date of this Current Report on Form 8-K, and is subject to completion by management of the financial statements for the fiscal year ended December 31, 2018. There can be no assurance that the Company’s final net product revenues or cash position for this period will not differ from these estimates after the Company completes its year-end closing and review procedures. The preliminary financial data has been prepared by, and is the responsibility of, our management. KMJ Corbin & Company LLP has not audited, reviewed, compiled, or performed any procedures with respect to the preliminary financial data. Accordingly, KMJ Corbin & Company LLP does not express an opinion or any other form of assurance with respect thereto, and you should not draw any conclusions based on the foregoing estimates and should not place undue reliance on these preliminary estimates. The preliminary estimate of net product revenues for the fiscal year ended December 31, 2018 is not necessarily indicative of net product revenues to be achieved for any future period. Complete fiscal year results will be included in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2018. The Company assumes no duty to update these preliminary estimates except as required by law.

Item 8.01 Other Events.

On January 17, 2019, the Company issued a press release announcing that it intends to offer and sell shares of its common stock, subject to market and other conditions, in an underwritten public offering. A copy of the press release is attached hereto as Exhibit 99.1.

The Company recently updated its business information as follows:

Mirataz® (mirtazapine transdermal ointment), the Company’s transdermal drug for the management of unintended weight loss in cats, was approved by the Food and Drug Administration (“FDA”) in May 2018. The product became commercially available to U.S. veterinarians on July 9, 2018. Approximately 33% of veterinary clinics in the United States purchased Mirataz in the second half of 2018, with approximately 56% of veterinary clinics placing re-orders in that period.

The FDA has approved the safety and effectiveness technical sections for Zimeta™ (dipyron injection) for the control of pyrexia (fever) in horses. The FDA has indicated it does not have any additional questions or requests from the Company regarding the Chemistry, Manufacturing and Controls (“CMC”) technical section. The pre-approval inspection at the contract manufacturer of Zimeta IV took place in July 2018, which was successful. The responses to the findings identified during an inspection in April 2018 at the contract manufacturer of the active pharmaceutical ingredient (“API”) dipyron have been submitted to the FDA. The FDA indicated it would conduct a reinspection of the API manufacturer.

On December 21, 2017, the European Medicines Agency (the “EMA”) accepted the Company’s Mirataz submission for review, and the Company is currently responding to the EMA’s questions. The Company expects that Mirataz will be approved by the EMA in 2019. Regulatory approval is subject to the typical risks inherent in such a process.

Neither the disclosures on this Current Report on Form 8-K nor the attached press release shall constitute an offer to sell or the solicitation of an offer to buy these securities, nor shall there be any sale of these securities in any state or jurisdiction in which such an offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. All statements contained in this Current Report on Form 8-K that do not relate to matters of historical fact should be considered forward-looking statements, including, but not limited to, statements regarding our expectations about the trials, regulatory approval, manufacturing, distribution and commercialization of our current and future product candidates, and statements regarding our anticipated revenues, expenses, margins, profits and use of cash.

These forward-looking statements are based on our current expectations. These statements are not promises or guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results to be materially different from any future results expressed or implied by the forward-looking statements. These risks include, but are not limited to, the following: our limited operating history and expectations of losses for the foreseeable future; the absence of significant revenue from our product candidates for the foreseeable future; our potential inability to obtain any necessary additional financing; our substantial dependence on the success of our lead product candidates, which may not be successfully commercialized even if they are approved for marketing; the effect of competition; our potential inability to obtain regulatory approval for our existing or future product candidates; our dependence on third parties to conduct some of our development activities; our dependence upon third-party manufacturers for supplies of our product candidates; uncertainties regarding the outcomes of trials regarding our product candidates; our potential failure to attract and retain senior management and key scientific personnel; uncertainty about our ability to develop a satisfactory sales organization; our significant costs of operating as a public company; our potential inability to obtain patent protection and other intellectual property protection for our product candidates; potential claims by third parties alleging our infringement of their patents and other intellectual property rights; our potential failure to comply with regulatory requirements, which are subject to change on an ongoing basis; the potential volatility of our stock price; and the significant control over our business by our principal stockholders and management.

For a further description of these risks and other risks that we face, please see the risk factors described in our filings with the U.S. Securities and Exchange Commission (the SEC), including the risk factors discussed under the caption "Risk Factors" in our Annual Report on Form 10-K and any subsequent updates that may be contained in our Quarterly Reports on Form 10-Q filed with the SEC. As a result of the risks described above and in our filings with the SEC, actual results may differ materially from those indicated by the forward-looking statements made in this Current Report on Form 8-K. Forward-looking statements contained in this Current Report on Form 8-K speak only as of the date of this Current Report on Form 8-K, and we undertake no obligation to update or revise these statements, except as may be required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

| Exhibit No. | Description |
|-------------|-------------|
|-------------|-------------|

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| 99.1 | <u>Press Release of Kindred Biosciences, Inc. issued on January 17, 2019.</u> |
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SIGNATURE

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.

KINDRED BIOSCIENCES, INC.

Date: January 17, 2019 By: /s/ Richard Chin
Richard Chin
Chief Executive Officer