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 9, 2019

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

Delaware	001-36225	46-1160142
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer 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. ☐

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.0001 par value	KIN	The NASDAQ Stock Market LLC
Preferred Stock Purchase Rights	KIN	The NASDAQ Stock Market LLC

Item 2.02 Results of Operations and Financial Condition.

On May 9, 2019, Kindred Biosciences, Inc. (the "Company") issued a press release announcing its financial results for the three months ended March 31, 2019 and recent business developments. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated herein by reference.

The information furnished under this Item 2.02, including the accompanying Exhibit 99.1, shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act"), or otherwise subject to the liability of such section, nor shall such information be deemed to be incorporated by reference in any subsequent filing by the Company under the Securities Act of 1933 or the Exchange Act, regardless of the general incorporation language of such filing, except as specifically stated in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of Kindred Biosciences, Inc. issued on May 9, 2019.

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: May 9, 2019

By: /s/ Wendy Wee
Wendy Wee
Chief Financial Officer

Kindred Biosciences Announces First Quarter 2019 Financial Results

San Francisco, CA (May 9, 2019) Kindred Biosciences, Inc. (NASDAQ: KIN), a biopharmaceutical company focused on saving and improving the lives of pets, today announced financial results for the first quarter ended March 31, 2019 and provided updates on its programs. For the first quarter 2019, KindredBio reported net product revenues of $0.5 million and a net loss of $16.1 million, or $0.42 per share.

“We are confident that Mirataz is on track to be a successful feline drug. We have seen strong growth in penetration and continued positive customer feedback, and expect the commencement of planned commercial initiatives to meaningfully expand sales this year,” said Richard Chin, CEO of KindredBio. “We believe 2019 will be a banner year for KindredBio. Already, we have successfully completed our first cGMP drug substance manufacturing runs at our plant in Burlingame, CA, representing a major accomplishment for KindredBio. With one of the deepest pipelines in animal health, we expect FDA approval of dipyrone IV, the commencement of three pivotal studies, readouts on several pilot studies, and the commissioning of our Kansas biologics manufacturing facility to further enhance our position as a leader in companion animal therapeutics in 2019.”

Development and Corporate Updates

- KindredBio recorded Mirataz® (mirtazapine transdermal ointment) net product revenues of $0.5 million in the first quarter. While net product revenues were lower versus the fourth quarter, sales of Mirataz from distributors to veterinary clinics increased quarter-over-quarter. Market penetration reached approximately 40%, positioning Mirataz ahead of most key feline therapeutics at an equivalent stage of launch, with approximately 61% of all purchasing veterinary clinics placing re-orders. KindredBio has seen a positive relationship between the number of veterinarian interactions (promotion by the Company’s sales specialists, professional service veterinarians, and educational events) and Mirataz sales. Accordingly, the Company expects a higher volume of promotional and educational events in the second quarter, alongside the commencement of a direct-to-consumer campaign, to further drive uptake.

  In April 2019, KindredBio received a request for further information from the European Medicines Agency (EMA) following their review of the Company’s responses to the first round of queries. The EMA’s response included a request to discuss the submission at an oral hearing, which has been scheduled for September 2019. The outcome of the oral hearing will determine the extent to which additional data may need to be generated to obtain European approval of Mirataz. KindredBio will update the market on the path forward for Mirataz EU pending communication from the EMA post the hearing. Regulatory approval is subject to the typical risks inherent in such a process.

  Mirataz is the first and only transdermal medication specifically developed, and Food and Drug Administration (FDA)-approved, for the management of weight loss in cats.

  Weight loss in cats is a serious and potentially fatal condition that represents a leading cause of visits to the veterinarian for cats. The Company's research estimates that U.S. veterinarians see as many as nine million cats each year with unintended weight loss caused by varying underlying conditions, such as chronic kidney disease, cancer or diabetes. Mirataz, which is formulated with KindredBio's proprietary Accusorb™ technology, is applied topically to the cat's inner ear (pinna) once a day, providing a more attractive application route compared to oral administration. The

product is classified as a weight gain drug and can be used in cats with various underlying diseases associated with unintended weight loss.

- The FDA has approved the safety and effectiveness technical sections for dipyrone injection for the control of pyrexia (fever) in horses. The Company has filed a New Animal Drug Application for dipyrone injection with the FDA. The FDA inspection of the contract manufacturer of the active pharmaceutical ingredient dipyrone took place in March 2019. Pending a positive outcome from the manufacturer's response to the findings, FDA approval of dipyrone injection is expected in mid-2019. Regulatory approval is subject to the typical risks inherent in such a process. Preparations for the commercial launch remain on track.

  Dipyrone injection is expected to be the first FDA-approved product for the control of fever in horses. There are eight to nine million horses in the United States and currently more than one million are seen by a veterinarian for fever annually. Existing off-label treatments can have serious side effects.

- The pivotal field effectiveness study for dipyrone oral gel has been completed with positive results. The target animal safety study is also complete, and dipyrone oral gel was found to be well-tolerated. KindredBio has agreed on a path forward with the FDA and bridging studies will likely commence in 2020.

  Dipyrone oral gel, which is a proprietary oral gel, is intended as a leave behind for owners to administer to their horse for continued care following dipyrone injection. Accordingly, it is expected to expand use of the drug and build upon the success of dipyrone injection.

- The Company is currently conducting a pilot field effectiveness study of KIND-016, a fully caninized, high-affinity monoclonal antibody targeting interleukin-31 (IL-31), for the treatment of atopic dermatitis in dogs. Results from the study are expected in the third quarter, with a pivotal study expected to commence by year-end. In October 2018, KindredBio reported positive topline results from its pilot efficacy study of KIND-016.

  The Company also expects pilot effectiveness results for its canine anti-IL-4/IL-13 SINK molecule in 2H 2019 and is advancing other programs for atopic dermatitis.

  KindredBio is pursuing a multi-pronged approach toward atopic dermatitis, with a portfolio of promising biologics. Atopic dermatitis is an immune-mediated inflammatory skin condition in dogs. It is the leading reason owners take their dog to the veterinarian, and the current market size is more than $600 million annually and growing.

- cGMP manufacturing has been completed at the Company's Burlingame facility for KindredBio's feline recombinant erythropoietin that is being developed for the management of non-regenerative anemia in cats. cGMP fill & finish will be undertaken at the Company's biologics manufacturing facility in Elwood, Kansas, which is expected to be completed by mid-2019. Thereafter, a pivotal effectiveness study will commence before year-end. KindredBio announced positive topline results from a pilot field effectiveness study of its feline recombinant erythropoietin in January 2019. The product candidate has been engineered by KindredBio to have a prolonged half-life compared to endogenous erythropoietin, a protein that regulates and stimulates production of red blood cells.

  Anemia is a common condition that is estimated to afflict millions of older cats. It is often associated with chronic kidney disease, because kidneys produce erythropoietin and chronic kidney disease leads to decreased levels of endogenous erythropoietin. Chronic kidney disease

affects approximately half of older cats, making it a leading cause of feline mortality. Human erythropoietins, which are multi-billion dollar products in the human market, have been shown to be immunogenic in many cats.

- The pilot field effectiveness study for KindredBio's anti-TNF antibody for canine inflammatory bowel disease (IBD) has been initiated and is underway. Study results are expected by the end of 2019.

  IBD can affect dogs at any age, but is more common in middle-aged and older dogs.

- The pilot field effectiveness study of KIND-014 for the treatment of gastric ulcers in horses has been completed with positive results. The Company has selected a formulation for development and both the pivotal field and pivotal safety studies will begin in 2019.

  Equine gastric ulcer syndrome (EGUS) is a common condition in horses. Prevalence estimates have been reported to range from 60 to 90% in adult horses, depending on age, performance, and evaluated populations. A variety of clinical signs are associated with EGUS, including poor appetite, poor condition, colic, and behavioral issues.
- The pilot field effectiveness study of KindredBio's anti-TNF monoclonal antibody targeting sick or septic foals has been completed, with positive results. KindredBio will initiate the next field study in 2020.

  Sepsis in foals can cause up to 50% mortality and is an important unmet medical need. There is currently no FDA-approved therapy.
- Construction to support initial production lines on KindredBio's biologics manufacturing facility in Elwood, Kansas is expected to be completed by mid-2019. The facility includes approximately 180,000 square feet with clean rooms, utility, equipment, and related quality documentation suitable for small molecule and biologics manufacturing. KindredBio acquired the facility in August 2017.

First Quarter 2019 Financial Results

For the quarter ended March 31, 2019, KindredBio reported a net loss of $16.1 million or $0.42 per share, as compared to a net loss of $10.0 million or $0.36 per share, for the same period in 2018.

The Company recorded $0.5 million in net product revenues for Mirataz for the quarter ended March 31, 2019. There were no net product revenues for the same period in 2018 as Mirataz became commercially available in July 2018.

The cost of product sales totaled $92,000 in the first quarter of 2019, resulting in a gross margin of 82%.

Research and development expenses for the quarter ended March 31, 2019 were $7.2 million, compared to $5.3 million for the same period in 2018. The $1.8 million year-over-year increase in research and development expenses was primarily due to higher headcount and related expenses as the Company focuses on advancing its biologics programs and higher consulting expenses for quality assurance programs. Stock based compensation expense for the first quarter of 2019 was $0.4 million, as compared to $0.5 million for the same period in 2018.

Selling, general and administrative expenses for the 2019 and 2018 first quarters were $9.9 million and $4.9 million, respectively. The $5.0 million year-over-year increase included higher payroll and related expenses, marketing, travel and conference expenses related to Mirataz, as well as increased expenses

incurred by the Kansas plant in the lead up to its commissioning. In addition, higher corporate infrastructure costs and stock-based compensation expense also contributed to the increase in expenses. Stock based compensation expense was $1.4 million for the 2019 first quarter, versus $1.0 million in the year-ago period.

As of March 31, 2019, KindredBio had $96.0 million in cash, cash equivalents and investments, compared with $73.9 million as of December 31, 2018. Net cash used in operating activities for the first quarter of 2019 was approximately $18.7 million. The Company also invested approximately $2.7 million in capital expenditures for the remaining portion of the build-out of its Elwood, Kansas manufacturing facility and the purchase of associated lab and manufacturing equipment for the facility.

On January 23, 2019, KindredBio closed its public offering of 4,847,250 shares of common stock at $9.50 per share. The gross proceeds are approximately $46 million before deducting underwriting discounts and commissions and offering expenses payable by KindredBio. The net proceeds will be used for the development of KindredBio's therapeutic candidates, the expansion of its commercial infrastructure, and for other general corporate and working capital purposes.

With respect to spending in 2019, the Company remains focused on advancing its core pipeline and programs, including the commencement of multiple pivotal studies, increasing adoption of Mirataz and preparing for the commercial launch of dipyrone injection. Given approval of Mirataz EU is no longer expected in 2019, the Company is revising its expectations for 2019 operating expenses. KindredBio now anticipates operating expenses of between $57 million and $59 million, excluding the impact of stock-based compensation expense and the impact of acquisitions, if any. The Company continues to plan to invest $8.0 million to $10.0 million in capital expenditures on lab and manufacturing equipment for its biologics programs and the remaining portion of the build-out of its Elwood, Kansas facility. KindredBio believes its existing cash, cash equivalents, restricted cash and short-term investments will be sufficient to fund the current operating plan through early 2021.

Webcast and Conference Call

KindredBio will host a conference call and webcast today at 4:30 p.m. Eastern Time / 1:30 p.m. Pacific Time. Interested parties may access the call by dialing toll-free (855) 433-0927 from the US, or (484) 756-4262 internationally, and using conference ID 5176808. The call will be webcast live here, with a replay available at that link for 30 days.

Important Safety Information

Mirataz® (mirtazapine transdermal ointment) is for topical use in cats only under veterinary supervision. Do not use in cats with a known hypersensitivity to mirtazapine or any of the excipients or in cats treated with monoamine oxidase inhibitors (MAOIs). Not for human use. Keep out of reach of children. Wear gloves to apply and wash hands after. Avoid contact with treated cat for 2 hours following application. The most common adverse reactions include application site reactions, behavioral abnormalities (vocalization and hyperactivity) and vomiting. Please see the full Prescribing Information.

About Kindred Biosciences

Kindred Biosciences is a commercial-stage biopharmaceutical company focused on saving and improving the lives of pets. Its mission is to bring to pets the same kinds of safe and effective medicines that human family members enjoy. The Company's strategy is to identify compounds and targets that have already demonstrated safety and effectiveness in humans and to develop therapeutics based on these validated compounds and targets for dogs, cats and horses. The Company has a deep pipeline of novel drugs and biologics in development across many therapeutic classes. KindredBio's first approved drug is Mirataz® (mirtazapine transdermal ointment) for the management of weight loss in cats.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. All statements contained in this press release 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 Mirataz® (mirtazapine transdermal ointment) and our product candidates for the foreseeable future; the likelihood that our revenue will vary from quarter to quarter; our potential inability to obtain any necessary additional financing; our substantial dependence on the success of Mirataz and 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 Mirataz and 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 and maintain patent protection and other intellectual property protection for Mirataz and 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 press release. Forward-looking statements contained in this press release speak only as of the date of this press release and we undertake no obligation to update or revise these statements, except as may be required by law.

Contacts

For investor inquiries:
Katja Buhrer
Katja.buhrer@kindredbio.com
(917) 969-3438

Kindred Biosciences, Inc.
Condensed Consolidated Statements of Operations
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2019	2018
Net product revenues	$ 515	$ -
Operating costs and expenses:		
Cost of product revenues	92	-
Research and development	7,152	5,346
Selling, general and administrative	9,901	4,902
Total operating costs and expenses	17,145	10,248
Loss from operations	(16,630)	(10,248)
Interest and other income, net	575	277
Net loss	$ (16,055)	$ (9,971)
Basic and diluted net loss per share	$ (0.42)	$ (0.36)
Weighted average shares used to calculate basic and diluted net loss per share	37,786	27,986

Selected Balance Sheet Data
(In thousands)

	March 31, 2019 (unaudited)	December 31, 2018
Cash, cash equivalents and investments	$ 95,988	$ 73,932
Total assets	132,681	106,482
Stockholders' equity	120,294	91,207