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): March 6, 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. ☐

Item 2.02 Results of Operations and Financial Condition.

On March 6, 2019, Kindred Biosciences, Inc. (the "Company") issued a press release announcing its financial results for the fiscal year ended December 31, 2018 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 March 6, 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: March 6, 2019

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

Kindred Biosciences Announces Fourth Quarter and Full Year 2018 Financial Results

San Francisco, CA (March 6, 2019) Kindred Biosciences, Inc. (NASDAQ: KIN), a biopharmaceutical company focused on saving and improving the lives of pets, today announced financial results for the fourth quarter and full year ended December 31, 2018 and provided updates on its programs. For the fourth quarter 2018, KindredBio reported net product revenues of $1.3 million and a net loss of $15.4 million, or $0.46 per share. For the full year 2018, net product revenues were $2.0 million and the net loss was $49.7 million, or $1.60 per share.

“2018 was a transformational year for KindredBio marked by the approval of our first product, our transition to a commercial-stage company and the announcement of positive data validating our industry leading biologics pipeline. We are pleased to have doubled fourth quarter Mirataz® revenues quarter-over-quarter, reflecting broad-based customer demand and increased re-order size. We also achieved our goal of having Mirataz stocked in one-third of all veterinary clinics in the United States within six months of launch. Year-to-date, the rollout of Mirataz remains on track, with sales responding favorably to our participation at key industry conferences and broader marketing efforts. We also reported positive topline results from our pilot field effectiveness study of our feline recombinant erythropoietin in January, representing our third consecutive positive efficacy study in our biologics pipeline,” said Richard Chin, KindredBio CEO. “Looking to the year ahead, we expect the expansion of Mirataz sales, study results across key pipeline candidates, additional approvals and the commissioning of our Kansas biologics manufacturing facility to drive continued positive momentum.”

Development and Corporate Updates

- KindredBio recorded Mirataz® (mirtazapine transdermal ointment) net product revenues of $1.3 million in the fourth quarter, which is more than double third quarter net product revenues of $0.6 million. The product became commercially available to U.S. veterinarians on July 9, 2018. During the second half of 2018, market penetration reached approximately 33%, with approximately 56% of participating veterinary clinics placing re-orders in that period.

  In December 2017, the European Medicines Agency (EMA) accepted KindredBio's Mirataz submission for review. The Company has responded to the EMA’s list of questions and expects that Mirataz will be approved by the EMA in 2019. 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.

- On January 14, 2019, KindredBio announced positive topline results from its pilot field effectiveness study of its feline recombinant erythropoietin that is being developed for the management of non-regenerative anemia in cats. 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 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. Pending a positive inspection of the contract manufacturer of the active pharmaceutical ingredient dipyrone, 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, a significant unmet medical condition that affects millions of horses each year.

- 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 is in discussions with the FDA regarding the data required for submission and is in the process of transferring the product to the commercial manufacturer.

  Dipyrone oral gel, which is a proprietary oral gel, is expected to expand use of the drug and build upon the success of dipyrone injection.

- In October 2018, KindredBio reported positive topline results from its pilot 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.

  KindredBio is currently conducting a pilot field effectiveness study for its IL-31 antibody, with a pivotal study expected to commence in 2019. The Company continues to expect pilot efficacy results for its canine anti-IL-4/IL-13 SINK molecule in 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 almost $600 million annually and growing rapidly.
- The pilot field efficacy study for KindredBio's anti-TNF antibody for canine inflammatory bowel disease (IBD) has been initiated and is currently enrolling.

  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 anticipates moving into a pivotal field study in 2019.

  Equine gastric ulcer syndrome (EGUS) is a common condition in horses which affects approximately half of all horses. A variety of clinical signs are associated with EGUS, including poor appetite, poor condition, colic, and behavioral issues.
- The pilot field efficacy study of KindredBio's anti-TNF monoclonal antibody targeting sick or septic foals has been completed, with positive results. KindredBio intends to continue field studies during the 2020 foaling season, following discussion with the FDA regarding the development plan.

  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.

Fourth Quarter and Year-End 2018 Financial Results

For the quarter ended December 31, 2018, KindredBio reported a net loss of $15.4 million, or $0.46 per share, compared to a net loss of $9.7 million, or $0.35 per share, for the same period in 2017. For the year ended December 31, 2018, the net loss was $49.7 million or $1.60 per share as compared to a net loss of $30.9 million, or $1.23 per share in 2017.

The Company recorded $1.3 million and $2.0 million in net product revenues for Mirataz for the quarter and year ended December 31, 2018, respectively. Mirataz became commercially available in July 2018.

The cost of product sales totaled $0.2 million in the fourth quarter of 2018 and $0.3 million for the year, resulting in a gross margin of 84% for both periods.

Research and development expenses totaled $7.8 million for the fourth quarter ended December 31, 2018 compared to $5.1 million for the same period in 2017. For the full year 2018, research and development expenses were $26.4 million, compared to $17.7 million in 2017. Stock-based compensation expense related to research and development was $1.7 million for both years. The $8.7 million increase in full year research and development expenses was primarily due to higher headcount and related expenses as the Company advances its biologics programs. In addition, increased clinical trial costs and expanded biologics manufacturing, as well as lab supplies expenses (including other operations expenses), drove research and development expenses higher.

Selling, general and administrative expenses totaled $9.2 million for the fourth quarter ended December 31, 2018 compared to $4.8

million for the same period in 2017. For the full year 2018, selling, general and administrative expenses were $26.5 million, compared to $14.0 million for 2017. The $12.5 million increase in full year selling, general and administrative expenses was due to higher headcount and related expenses as KindredBio transitioned to a commercial stage Company, as well as higher corporate and administrative, and stock-based compensation expenses. Stock-based compensation expense included in selling, general and administrative was $4.5 million in 2018, versus $3.6 million in 2017.

As of December 31, 2018, KindredBio had $73.9 million in cash, cash equivalents and investments, compared to $82.5 million at December 31, 2017. Net cash used in operating activities in 2018 was approximately $45.0 million, offset by a total of $49.2 million of net cash proceeds from an underwritten public offering of the Company's common stock and an At-the-Market equity offering program. The Company also invested approximately $13.9 million in capital expenditures for the build-out of its Elwood, Kansas manufacturing facility, including equipment purchases.

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 will focus 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. Accordingly, for 2019 the Company expects operating expenses of between $64.0 million and $68.0 million, excluding the impact of stock-based compensation expense and the impact of acquisitions, if any. Additionally, KindredBio plans 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.

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 6089328. 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 efficacy 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; 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.

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2018	2017	2018	2017
	(Unaudited)			
Net product revenues	$ 1,326	$ -	$ 1,966	$ -
Operating costs and expenses:				
Cost of product sales	214	-	324	-
Research and development	7,756	5,142	26,399	17,665
General and administrative	9,219	4,820	26,499	13,988
Total operating costs and expenses	17,189	9,962	53,222	31,653
Loss from operations	(15,863)	(9,962)	(51,256)	(31,653)
Interest and other income, net	422	232	1,566	774
Net loss	$ (15,441)	$ (9,730)	$ (49,690)	$ (30,879)
Basic and diluted net loss per common share	$ (0.46)	$ (0.35)	$ (1.60)	$ (1.23)
Shares used to calculate basic and diluted net loss per common share	33,708	27,915	31,001	25,084

Selected Balance Sheet Data
(In thousands)
(Unaudited)

	December 31,	
	2018	2017
Cash, cash equivalents and investments	$ 73,932	$ 82,519
Total assets	106,482	90,822
Stockholders' equity	91,207	84,680