
**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): November 7, 2018

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

Delaware
(State or other jurisdiction of
incorporation or organization)

001-36225
(Commission
File Number)

46-1160142
(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 November 7, 2018, Kindred Biosciences, Inc. (the “Company”) issued a press release announcing its financial results for the three months ended September 30, 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 November 7, 2018.

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: November 7, 2018

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release of Kindred Biosciences, Inc. issued on November 7, 2018.

Kindred Biosciences Announces Third Quarter 2018 Financial Results

San Francisco, CA (November 7, 2018) Kindred Biosciences, Inc. (NASDAQ: KIN), a commercial-stage biopharmaceutical company focused on saving and improving the lives of pets, today announced financial results for the third quarter ended September 30, 2018 and provided updates on its programs. For the third quarter 2018, KindredBio reported net product revenues of \$0.6 million and a net loss of \$13.0 million or \$0.39 per share.

“We are very pleased so far with our first product launch. Mirataz[®] was ordered by almost a quarter of all veterinary clinics in the United States during its first quarter on the market, reflecting continued strong growth in new accounts, and we are likewise encouraged by the re-orders, which have allowed us to recognize revenues already,” said Richard Chin, KindredBio CEO. “We are also pleased to have reported positive pilot effectiveness results for our lead canine atopic dermatitis biologic candidate last week. These promising data validate our broad portfolio of monoclonal antibodies for this and other diseases, and position KindredBio as a leader in companion animal biologics.”

Development and Corporate Milestones

- KindredBio recorded Mirataz[®] (mirtazapine transdermal ointment) net product revenues of \$0.6 million in the third quarter. The product became commercially available to U.S. veterinarians on July 9, 2018, resulting in a partial quarter, with initial stocking orders sent to the Company’s distribution partners through mid-August. Approximately 5,500 veterinary clinics in the United States ordered Mirataz during this partial quarter, resulting in market penetration of 22%, with approximately one-third of customers placing re-orders in the period.

On December 21, 2017, the European Medicines Agency (EMA) accepted KindredBio’s Mirataz submission for review. KindredBio is currently responding to the EMA’s questions.

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 October 30, 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. The study was a randomized, blinded, placebo-controlled, pilot laboratory study that enrolled 32 dogs to assess the effectiveness of KIND-016 at three doses. A single dose of KIND-016 was administered on day 0 and itching was induced at weeks 1, 2, 3, 4, 6, and 8 with an injection of canine IL-31. The Company’s IL-31 antibody resulted in statistically significant reductions in pruritus ($p < 0.0001$ to $p < 0.05$) across all dose groups and was sustained for 6 to 8 weeks, with a clear dose response. The reduction in the itching score was as high as 86.1%. Based on a preliminary review of the safety data, the drug appears to be well tolerated. In addition, the Company announced that the U.S. Patent and Trademark Office has issued a patent (Patent No. 10,093,731) for KindredBio’s anti-IL31 antibody. KindredBio is also currently conducting a pilot field effectiveness study for its IL-31 antibody. The Company is in the process of initiating pilot effectiveness studies for several other molecules for atopic dermatitis, including a caninized anti-IL17 antibody and canine anti-IL4/IL13 SINK molecule.

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 over \$500 million annually and

growing rapidly. KindredBio is pursuing a multi-pronged approach toward atopic dermatitis, with a portfolio of promising biologics.

- 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 KindredBio regarding the 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 has indicated it will conduct a reinspection of the API manufacturer. The approval timeline is now dependent on FDA's reinspection, and given the review timelines are not fixed, approval will likely be in 2019. Regulatory approval is subject to the typical risks inherent in such a process. Preparations for the commercial launch remain on track.
Zimeta IV 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 Zimeta™ (dipyron oral gel) has been completed with positive results. The target animal safety study is also complete, and Zimeta Oral 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.

Zimeta Oral, which is a proprietary oral gel, is expected to expand use of the drug and build upon the success of Zimeta IV.

- The pilot field effectiveness study of the enhanced version of epoCat™ (long-acting feline recombinant erythropoietin) for the control of non-regenerative anemia in cats is nearly completed, with top line data expected in 1Q 2019. The Company is in discussions with the FDA regarding the pivotal study design, assuming the pilot data are positive.
Anemia is a common condition in older cats which is often associated with chronic kidney disease, resulting in decreased levels of endogenous erythropoietin. Chronic kidney disease affects approximately half of older cats. epoCat is a recombinant protein that has been specially engineered by KindredBio with a prolonged half-life compared to endogenous feline erythropoietin. The PK data suggest that the molecule may have a sufficiently long half-life to allow for once-monthly dosing.
 - 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 encompasses primary and secondary erosive and ulcerative diseases of both the squamous and glandular parts of the stomach. It 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 is now in discussions with the FDA regarding the pivotal study design.
Sepsis in foals can cause up to 50% mortality and is an important unmet medical need. There is currently no FDA-approved therapy. KindredBio has optimized an equine anti-TNF monoclonal antibody and intends to continue field studies during the 2019 foaling season, following discussion with the FDA regarding the development plan.
 - Construction on the biologics manufacturing lines in the Elwood, Kansas facility which KindredBio acquired in August 2017 is progressing. The facility includes approximately 180,000 square feet with clean rooms, utility, equipment, and related quality documentation suitable for small molecule and biologics manufacturing. Construction to support KindredBio's initial production lines is expected to be completed by mid-2019.
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Third Quarter 2018 Financial Results

For the quarter ended September 30, 2018, KindredBio reported a net loss of \$13.0 million or \$0.39 per share, as compared to a net loss of \$7.9 million or \$0.29 per share for the same period in 2017. For the nine months ended September 30, 2018, the net loss was \$34.2 million or \$1.14 per share, as compared to a net loss of \$21.1 million or \$0.88 per share for the same period in 2017. In the third quarter of 2018, the Company recognized \$0.6 million in net product revenues of Mirataz.

The cost of product revenues totaled \$0.1 million in the third quarter of 2018, resulting in a gross margin of 83%.

Total research and development expenses for the three and nine months ended September 30, 2018 were \$7.5 million and \$18.6 million, respectively, compared to \$4.9 million and \$12.5 million for the same periods in 2017. Stock-based compensation expense included in research and development expense was \$0.4 million and \$1.3 million for the three and nine months ended September 30, 2018, which is in line with the same periods in 2017. The increase in year-to-date research and development expenses was due to higher field trial and material costs, including formulation development costs associated with the advancement of the Company's pipeline, as well as consulting and other operating expenses.

Selling, general and administrative expenses totaled \$6.6 million and \$17.3 million for the three and nine months ended September 30, 2018, compared to \$3.3 million and \$9.2 million for the same periods in 2017. The increase in general and administrative expenses in 2018 was due to higher headcount and related expenses as KindredBio transitioned to a commercial stage company, as well as higher stock-based compensation expense and other corporate expenses. Stock-based compensation expense included in selling, general and administrative expense was \$1.2 million and \$3.3 million for the three and nine months ended September 30, 2018, as compared to \$0.9 million and \$2.6 million for the same periods in 2017.

As of September 30, 2018, KindredBio had \$91.6 million in cash, cash equivalents and investments, compared with \$82.5 million as of December 31, 2017. Net cash used in operating activities for the first nine months of 2018 was approximately \$32.2 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 \$8.5 million in capital expenditures for the build-out of its Elwood, Kansas manufacturing facility.

For the 2018 calendar year, the Company expects operating expenses to be closer to \$48 million, excluding the impact of stock-based compensation expense and the impact of acquisitions, if any. The Company is scaling up the commercial team and continuing to focus on the development of its core pipeline candidates and programs. Additionally, KindredBio plans to invest \$14.0 to \$16.0 million in capital expenditures on the construction and build-out of its Elwood, Kansas facility for its biologics programs, of which \$10.0 to \$12.0 million is expected in 2018, with the balance in 2019.

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 5790907. The call will be webcast live [here](#), with a replay available at that link for 30 days.

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.

For more information or to download the corporate presentation, visit www.KindredBio.com/LearnMore. Stay connected with KindredBio on Facebook at www.Facebook.com/KindredBio.

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](#).

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 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 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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenue	\$ 640	\$ -	\$ 640	\$ -
Cost and expenses:				
Cost of revenue	110	-	110	-
Research and development	7,477	4,877	18,643	12,523
Selling, general and administrative	6,608	3,269	17,280	9,168
Total costs and expenses	14,195	8,146	36,033	21,691
Loss from operations	(13,555)	(8,146)	(35,393)	(21,691)
Interest and other income, net	518	256	1,144	542
Net loss	<u>\$ (13,037)</u>	<u>\$ (7,890)</u>	<u>\$ (34,249)</u>	<u>\$ (21,149)</u>
Basic and diluted net loss per share	<u>\$ (0.39)</u>	<u>\$ (0.29)</u>	<u>\$ (1.14)</u>	<u>\$ (0.88)</u>
Weighted-average number of common shares used to calculate basic diluted net loss per share	<u>33,601</u>	<u>27,400</u>	<u>30,089</u>	<u>24,130</u>

Selected Consolidated Balance Sheet Data
(In thousands)

	September 30, 2018 (unaudited)	December 31, 2017
Cash, cash equivalents and investments	\$ 91,626	\$ 82,519
Total assets	113,388	90,822
Total stockholders' equity	104,431	84,680