
**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 12, 2019

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))

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

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 12, 2019, Kindred Biosciences, Inc. (the “Company”) issued a press release announcing its financial results for the three months ended September 30, 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 November 12, 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: November 12, 2019

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

Kindred Biosciences Announces Third Quarter 2019 Financial Results

San Francisco, California (November 12, 2019) - 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, 2019 and provided updates on its programs. For the third quarter 2019, KindredBio reported net product revenues of \$1.1 million and a net loss of \$15.3 million, or \$0.39 per share.

“We are excited about the positive opinion in the European Union regarding the Mirataz submission and expect approval of the product candidate this year. By year-end, we anticipate multiple additional catalysts, including approval of dipyrone IV in the US,” stated Richard Chin, Chief Executive Officer of KindredBio.

“Our quarterly revenues are still subject to fluctuations in distributor ordering patterns. As such, the third quarter result is not reflective of underlying demand as sales from distributors to veterinary clinics grew in the double-digits quarter-over-quarter.”

Development and Corporate Updates

- KindredBio recorded Mirataz[®] (mirtazapine transdermal ointment) net product revenues of \$1.1 million in the third quarter. Net product revenues were lower on a sequential basis due to several factors, including fluctuations in the ordering pattern by distributors. Sales from distributors to veterinary clinics grew 20% versus the second quarter and have increased consistently quarter-over-quarter since Mirataz’s launch. Market penetration reached approximately 51% in the third quarter, positioning Mirataz ahead of most key feline therapeutics at an equivalent stage of launch. Approximately 68% of all purchasing veterinary clinics placed re-orders, and average order size grew quarter-over-quarter.

On October 10, 2019, KindredBio [announced](#) the European Medicines Agency's Committee for Medicinal Products for Veterinary Use adopted a positive opinion recommending marketing authorization of Mirataz[®] (mirtazapine transdermal ointment) for bodyweight gain in cats experiencing poor appetite and weight loss resulting from chronic medical conditions. A marketing authorization decision from the European Commission is anticipated by mid-December.

- The U.S. Food and Drug Administration has approved the safety and effectiveness technical sections for dipyrone injection for the control of pyrexia (fever) in horses. KindredBio expects approval of the product candidate by the end of November, dependent on satisfactory responses to outstanding Chemistry, Manufacturing, and Controls questions. 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 U.S. and currently more than one million are seen by a veterinarian for fever annually. Existing off-label treatments can have serious side effects.

- In July 2019, KindredBio [reported](#) positive topline results from its pilot field effectiveness study of KIND-016, a fully caninized, high-affinity monoclonal antibody targeting interleukin-31, for the treatment of atopic dermatitis in dogs. Due to changes and enhancements to the manufacturing process during scale-up, the pivotal effectiveness study is now expected to start in 2020.
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Almost all patients have been enrolled in the pilot effectiveness study for the company's canine anti-IL-4/IL-13 SINK molecule, with results expected in the first quarter of 2020.

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 fill & finish for KindredBio's feline recombinant erythropoietin was completed at the Elwood, Kansas biologics manufacturing facility in the third quarter of 2019, and the pivotal efficacy study has since been initiated. The product candidate is being developed for the management of non-regenerative anemia in cats. It has been engineered by the company 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.

- On August 1, 2019, KindredBio [announced](#) positive results from its pilot efficacy study of KIND-030, a monoclonal antibody targeting canine parvovirus (CPV). Pivotal studies for this molecule are expected to be completed in 2020. Approval is anticipated by late 2020 or early 2021.

CPV is the most significant cause of viral enteritis in dogs, especially puppies, with over 90% mortality rate if untreated. There are currently no approved or unapproved treatments for CPV. Currently, owners spend up to thousands of dollars for supportive care for dogs infected with CPV.

- The pilot field effectiveness study for KindredBio's anti-TNF antibody for canine inflammatory bowel disease (IBD) has been initiated with completion now expected in the first half of 2020, due to competing priorities for drug supply manufacturing.

The majority of canine IBD cases involve chronic states of diarrhea, vomiting, gastroenteritis, inappetence, and other symptoms, certain of which are cited as among the most frequent disorders impacting dogs. For certain dog breeds, the prevalence of diarrhea exceeds 5%. Existing treatments can have significant drawbacks, including limited diets and excessive antibiotic use, which can lead to owner frustration, lapses in treatment adherence, or poor quality of life for the affected animal.

- The pivotal field efficacy study for KIND-014 for the treatment of gastric ulcers in horses is scheduled to start in the fourth quarter of 2019.

Third Quarter 2019 Financial Results

For the quarter ended September 30, 2019, KindredBio reported a net loss of \$15.3 million or \$0.39 per share, as compared to a net loss of \$13.0 million or \$0.39 per share for the same period in 2018. For the nine months ended September 30, 2019, the net loss was \$45.7 million or \$1.18 per share, as compared to a net loss of \$34.2 million or \$1.14 per share for the same period in 2018.

The company recorded \$1.1 million in net product revenues for Mirataz for the third quarter and \$2.9 million for the first nine months of 2019. Net product revenues for the same period in 2018 were \$0.6 million. Mirataz became commercially available in July 2018.

The cost of product sales totaled \$0.1 million in the third quarter and \$0.4 million for the first nine months in 2019, resulting in a gross margin of 87% and 86%, respectively.

Total research and development expenses for the three and nine months ended September 30, 2019 were \$7.3 million and \$21.2 million, respectively, compared to \$7.5 million and \$18.6 million for the same periods in 2018. Stock-based compensation expense included in research and development expense was \$0.5 million and \$1.4 million for the three and nine months ended September 30, 2019 compared to \$0.4 million and \$1.3 million for the same periods in 2018. The \$2.5 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, higher consulting expenses for quality assurance programs and increased capital equipment depreciation expense.

Selling, general and administrative expenses totaled \$9.4 million and \$28.3 million for the three and nine months ended September 30, 2019, compared to \$6.6 million and \$17.3 million for the same periods in 2018. The \$11.1 million year-over-year increase is the result of being a commercial company, as well as increased expenses incurred by the Elwood, 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 included in selling, general and administrative expense was \$1.4 million and \$4.2 million for the three and nine months ended September 30, 2019, as compared to \$1.2 million and \$3.3 million for the same periods in 2018.

As of September 30, 2019, KindredBio had \$87.6 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 nine months of 2019 was approximately \$42.6 million, offset by \$43.1 million of net cash proceeds from an underwritten public offering of common stock in the first quarter of 2019 and \$19.2 million from a debt financing in the third quarter of 2019, net of closing fees and expenses. The company also invested approximately \$7.3 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 October 2, 2019, KindredBio [announced](#) the closing of a \$50 million senior secured debt facility with investment affiliates managed by Solar Capital Partners, LLC. The non-dilutive financing agreement provides KindredBio with up to \$50 million of borrowing capacity available in three tranches, each bearing interest at 1-Month LIBOR + 6.75% with a floor of 2.17%. The entire debt facility will mature on September 30, 2024.

With respect to spending in 2019, the company continues to expect operating expenses of between \$57 million and \$59 million, excluding the impact of stock-based compensation expense and the impact of acquisitions, if any. In addition, the company is on track with its \$8.0 million to \$10.0 million investment in capital expenditures for the year. KindredBio believes its existing cash, cash equivalents, restricted cash, short-term investments and additional draw down of \$30 million from its debt facility, contingent on the achievement of certain milestones, will be sufficient to fund the current operating plan through 2021. Furthermore, the company plans to reduce both operating expenses and capital expenditures in 2020.

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 8153966. 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. KindredBio has a deep pipeline of novel drugs and biologics in development across many therapeutic classes. Its 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 our products 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 our products 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 our products 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 our products 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.

The results stated in this press release have not been reviewed by the Food and Drug Administration or the United States Department of Agriculture Center for Veterinary Biologics, as applicable.

Contacts

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Kindred Biosciences, Inc.
Consolidated Statements of Operations

(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2019	2018	2019	2018
Revenue	\$ 1,104	\$ 640	\$ 2,855	\$ 640
Cost and expenses:				
Cost of revenue	139	110	400	110
Research and development	7,290	7,477	21,176	18,643
Selling, general and administrative	9,382	6,608	28,348	17,280
Total costs and expenses	<u>16,811</u>	<u>14,195</u>	<u>49,924</u>	<u>36,033</u>
Loss from operations	(15,707)	(13,555)	(47,069)	(35,393)
Interest and other income, net	414	518	1,414	1,144
Net loss	<u>\$ (15,293)</u>	<u>\$ (13,037)</u>	<u>\$ (45,655)</u>	<u>\$ (34,249)</u>
Basic and diluted net loss per share	<u>\$ (0.39)</u>	<u>\$ (0.39)</u>	<u>\$ (1.18)</u>	<u>\$ (1.14)</u>
Weighted-average number of common shares used to calculate basic diluted net loss per share	<u>38,940</u>	<u>33,601</u>	<u>38,542</u>	<u>30,089</u>

Selected Consolidated Balance Sheet Data
(In thousands)

	September 30, 2019 (unaudited)	December 31, 2018
Cash, cash equivalents and investments	\$ 87,644	\$ 73,932
Total assets	125,335	106,482
Total stockholders' equity	95,230	91,207