Kindred Biosciences, Inc.
Form 10-Q
November 09, 2015
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)
x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2015
OR
.. TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to
Commission File Number: 001-36225

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

Delaware	46-1160142
(State of incorporation)	(I.R.S. Employer Identification No.)

1555 Bayshore Highway, Suite 200
Burlingame, California 94010
(Address of principal executive office) (Zip code)
Registrant's telephone number: (650) 701-7901

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter time that the registrant was required to submit and post such files). Yes x No ¨
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

Indicate by checkmark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

As of October 30, 2015, Kindred Biosciences, Inc. had outstanding 19,809,380 shares of common stock, $0.0001 par value.

Table of Contents

Kindred Biosciences, Inc.

TABLE OF CONTENTS

Table of Contents

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Kindred Biosciences, Inc.
Condensed Balance Sheets
(In thousands, except share and per share amounts)

	September 30, 2015 (Unaudited)	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$4,539	$12,969
Short-term investments	79,047	88,058
Prepaid expenses and other	449	477
Total current assets	84,035	101,504
Property and equipment, net	608	394
Other assets	30	22
Total assets	$84,673	$101,920
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$285	$420
Accrued compensation	1,568	1,457
Accrued liabilities	1,120	975
Total current liabilities	2,973	2,852
Long-term liability	46	44
Total liabilities	3,019	2,896
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Common stock, $0.0001 par value; 100,000,000 shares authorized; 19,792,337 and 19,724,482 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	2	2
Additional paid-in capital	133,830	130,521
Accumulated other comprehensive income (loss)	4	(27)
Accumulated deficit	(52,182)	(31,472)
Total stockholders' equity	81,654	99,024
Total liabilities and stockholders' equity	$84,673	$101,920

The accompanying notes are an integral part of these condensed financial statements.

Table of Contents

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

	Three months ended September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
Operating expenses:				
Research and development	$5,033	$3,755	$14,833	$13,892
General and administrative	2,095	2,342	5,969	6,525
Total operating expenses	7,128	6,097	20,802	20,417
Loss from operations	(7,128)	(6,097)	(20,802)	(20,417)
Interest income	33	25	92	67
Net loss	(7,095)	(6,072)	(20,710)	(20,350)
Change in unrealized gains or losses on available-for-sale securities	5	24	31	10
Comprehensive loss	$(7,090)	$(6,048)	$(20,679)	$(20,340)
Net loss per share, basic and diluted	$(0.36)	$(0.31)	$(1.05)	$(1.10)
Weighted-average number of common shares outstanding, basic and diluted	19,792	19,713	19,758	18,467

The accompanying notes are an integral part of these condensed financial statements.

Table of Contents

Kindred Biosciences, Inc.
Condensed Statements of Cash Flows
(In thousands)
(Unaudited)

	Nine months ended September 30,	
	2015	2014
Cash Flows from Operating Activities		
Net loss	$(20,710)	$(20,350)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	3,103	3,518
Depreciation and amortization expense	108	29
Amortization of premium on marketable securities	128	49
Changes in operating assets and liabilities:		
Prepaid expenses and other	28	(540)
Other assets	(8)	(22)
Accounts payable	(135)	55
Accrued liabilities and accrued compensation	258	461
Net cash used in operating activities	(17,228)	(16,800)
Cash Flows from Investing Activities		
Purchase of short-term investments	(81,086)	(128,142)
Sale of short-term investments	3,000	—
Maturities of short-term investments	87,000	30,000
Purchase of property and equipment	(322)	(211)
Net cash provided by (used in) investing activities	8,592	(98,353)
Cash Flows from Financing Activities		
Exercise of stock options and purchase of ESPP shares	206	83
Net proceeds from sale of common stock	—	58,065
Net cash provided by financing activities	206	58,148
Net change in cash and cash equivalents	(8,430)	(57,005)
Cash and cash equivalents at beginning of period	12,969	65,329
Cash and cash equivalents at end of period	$4,539	$8,324
Supplemental disclosure of non-cash financing activities:		
Issuance of common stock and stock options for accrued consulting expenses	$—	$303

The accompanying notes are an integral part of these condensed financial statements.

Table of Contents

Kindred Biosciences, Inc.
Notes to Condensed Financial Statements
(Unaudited)

1. Description of Business, Basis of Presentation and Summary of Significant Accounting Policies

Kindred Biosciences, Inc. ("we", "us" or "our") was incorporated on September 25, 2012 (inception) in the State of Delaware. We are a biopharmaceutical company focused on saving and improving the lives of pets. Our activities since inception have consisted principally of raising capital, establishing facilities, recruiting management and technical staff and performing research and development and advancing our product candidates seeking regulatory approval. Our headquarters are in Burlingame, California.

We are subject to risks common to companies in the biotechnology and pharmaceutical industries. There can be no assurance that our research and development will be successfully completed, that adequate patent or other intellectual property protection for our technology will be obtained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. We operate in an environment of substantial competition from other animal health companies. In addition, we are dependent upon the services of our employees and consultants, as well as third-party contract research organizations and manufacturers.

The accompanying unaudited interim condensed financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (SEC). Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States ("U.S. GAAP") for complete financial statements. These unaudited interim condensed financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2014 included in our annual report on Form 10-K as filed with the SEC on March 13, 2015. In the opinion of management, all adjustments, consisting of a normal and recurring nature, considered necessary for a fair presentation, have been included in these unaudited interim condensed financial statements.

Liquidity

We have incurred losses and negative cash flows from operations and have not generated any revenue since our inception. We expect to continue to incur losses and negative cash flows, which will increase significantly from historical levels as we expand our product development activities, seek regulatory approvals for our product candidates, establish a biologics manufacturing capability, and begin to commercialize any approved products. To date, we have been funded primarily through sales of our former convertible preferred stock, the sale of our common stock in our initial public offering in December 2013 and the sale of our common stock in our April 2014 follow-on public offering. We believe that our cash, cash equivalents and short-term investments totaling $83,586,000 as of September 30, 2015, are sufficient to fund our planned operations for at least the next 24 months.

If we require additional funding for operations, we may seek such funding through public or private equity or debt financings or other sources, such as corporate collaborations and licensing arrangements. We may not be able to obtain financing on acceptable terms, or at all, and we may not be able to enter into corporate collaborations or licensing arrangements. The terms of any financing may result in dilution or otherwise adversely affect the holdings or the rights of our stockholders.

Use of Estimates

The preparation of financial statements and related disclosures in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting periods. Significant estimates and assumptions reflected in these condensed financial statements include, but are not limited to, the valuation of stock-based awards, the realization of deferred tax assets and the accrual of research and development expenses. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from those estimates.

Table of Contents

Comprehensive Loss

Our comprehensive loss includes the change in unrealized gains or losses on available-for-sale securities. The cumulative amount of gains or losses are reflected as a separate component of stockholders' equity in the condensed balance sheets as accumulated other comprehensive income (loss).

Recently Issued Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-15, Presentation of Financial Statements - Going Concern (Subtopic 205-40) - Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern, which provides guidance regarding management's responsibility to assess whether substantial doubt exists regarding the ability to continue as a going concern and to provide related footnote disclosures. In connection with preparing financial statements for each annual and interim reporting period, management should evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the company's ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable). This ASU is effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. We are currently evaluating the new guidance and have not determined the impact this standard may have on our condensed financial statements.

We do not believe there are any other recently issued standards not yet effective that will have a material impact on our financial statements when the standards become effective.

2. Fair Value Measurements

Certain assets and liabilities are carried at fair value. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. A fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last is considered unobservable, is used to measure fair value:

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Observable inputs (other than Level 1 quoted prices) such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

Level 3: Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The carrying amount of financial instruments, including cash and cash equivalents, accounts payable and accrued liabilities approximate fair value due to the short maturities of these financial instruments. Financial assets, which consist of money market funds and available-for-sale securities, are measured at fair value on a recurring basis.

Table of Contents

Financial assets, which consist of money market funds and available-for-sale securities, are measured at fair value on a recurring basis and are summarized as follows (in thousands):

	Fair Value Measurements as of September 30, 2015			
Description	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Cash equivalents:				
Money market funds	$4,344	$4,344	$—	$—
Short-term investments:				
U.S. treasury bills	34,147	—	34,147	—
U.S. federal agency notes	13,571	—	13,571	—
U.S. treasury bonds and notes	31,329	—	31,329	—
	$83,391	$4,344	$79,047	$—

	Fair Value Measurements as of December 31, 2014			
Description	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Cash equivalents:				
Money market funds	$834	$834	$—	$—
Short-term investments:				
U.S. treasury bills	5,998	—	5,998	—
U.S. treasury bonds and notes	82,060	—	82,060	—
	$88,892	$834	$88,058	$—

There were no transfers of assets between Level 1, Level 2 or Level 3 of the fair value hierarchy at September 30, 2015 or December 31, 2014.

At September 30, 2015 and December 31, 2014, we did not have any financial liabilities which were measured at fair value on a recurring basis.

3. Short-Term Investments

We classify all highly-liquid investments with stated maturities of greater than three months from the date of purchase and remaining maturities of less than one year as short-term investments. Investments with maturities beyond one year may be classified as short-term based on their highly liquid nature and because such investments are viewed as being available to support current operations. We classify and account for short-term investments as available-for-sale and reflect realized gains and losses using the specific identification method. Changes in market value if any, excluding other-than-temporary impairments, are reflected in other comprehensive income (loss).

Table of Contents

The fair value of available-for-sale short-term investments by type of security at September 30, 2015 were as follows (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. treasury bills	$34,133	$15	$(1)	$34,147
U.S. federal agency notes	13,571	1	(1)	13,571
U.S. treasury bonds and notes	31,339	24	(34)	31,329
	$79,043	$40	$(36)	$79,047

The fair value of available-for-sale short-term investments by type of security at December 31, 2014 were as follows (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. treasury bills	$5,994	$4	$—	$5,998
U.S. treasury bonds and notes	82,091	—	(31)	82,060
	$88,085	$4	$(31)	$88,058

4. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	September 30, 2015	December 31, 2014
Research and development costs	$793	$715
Other expenses	317	247
Deferred rent	56	57
	1,166	1,019
Less current portion	(1,120)	(975)
Long-term liability (deferred rent)	$46	$44

Table of Contents

5. Stock-Based Awards and Common Stock

The table below shows the number of shares of common stock underlying options granted to employees, directors and consultants, the assumptions used in the Black-Scholes option pricing model used to value those options and the resulting weighted-average grant date fair value per share:

Stock Option Plan	Three months ended September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
Shares underlying options granted	32,500	117,500	844,733	1,064,463
Weighted-average exercise price	$6.37	$16.60	$6.67	$16.63
Weighted average risk- free interest rate	1.78 %	1.90 %	1.50%	1.71%
Weighted average expected term (years)	6.3	6.1	6.1	6.3
Weighted average expected volatility	90%	90%	96%	90%
Expected dividend yield	—	—	—	—
Weighted-average grant date fair value per share	$4.80	$12.42	$5.14	$12.37

Our Employee Stock Purchase Plan (the "Stock Purchase Plan"), adopted in December 2014, permits eligible employees to purchase common stock at a discount through payroll deductions during defined six-month consecutive offering periods beginning December 1 with the exception of our first offering period which commenced on January 1, 2015 for a five month duration. The price at which the stock is purchased is equal to the lower of 85% of the fair market value of the common stock on the first day of the offering or 85% of the fair market value of our common stock on the purchase date. A total of 200,000 shares of common stock are authorized for issuance under the Stock Purchase Plan. A participant may purchase a maximum of 2,000 shares of common stock during each offering period, not to exceed $25,000 worth of common stock on the offering date during each calendar year. We use the Black-Scholes option pricing model, in combination with the discounted employee price, in determining the value of the Stock Purchase Plan expense to be recognized during each offering period. The following assumptions were used in the Black-Scholes option pricing model to calculate employee stock-based compensation:

Stock Purchase Plan	Three months ended September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
Weighted average risk-free interest rate	—	—	0.07%	—
Weighted average expected term (years)	—	—	0.5	—
Weighted average expected volatility	—	—	73%	—
Expected dividend yield	—	—	—	—
Weighted-average grant date fair value per share	—	—	$2.14	—

Under the Stock Purchase Plan, employees purchased 26,772 shares of common stock for $147,000 during the nine months ended September 30, 2015. At September 30, 2015, we had an outstanding liability of $97,000, which is included in accrued compensation on the condensed balance sheet, for employee contributions to the Stock Purchase Plan for shares pending issuance at the end of the next offering period.

We recorded stock-based compensation expense as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
Research and development	$439	$376	$1,371	$1,065
General and administrative	567	889	1,732	2,453
	$1,006	$1,265	$3,103	$3,518

We had an aggregate of approximately $9,302,000 of unrecognized stock-based compensation expense for options outstanding and the Stock Purchase Plan as of September 30, 2015 which is expected to be recognized over a weighted-average period of 2.7 years.

10

Table of Contents

6. Commitments and Contingencies

In March 2014, we entered into a license agreement under which we made an up-front payment and were obligated to make annual payments and, subject to certain terms and conditions, milestone payments upon achievement of development milestones and a royalty based on sales of products developed under the agreement. We terminated this agreement in January 2015.

In April 2014, we entered into new noncancelable operating leases for laboratory space and office space through November 2017. In January 2015, we amended a lease to expand the laboratory space for an additional 2,431 square feet and in July 2015, we expanded the laboratory space by an additional 131 square feet. In June 2015, we entered into a new noncancelable operating lease for 3,126 square feet of office space in San Diego, California. In addition, we have three equipment leases, expiring in July 2017, July 2019 and July 2020, respectively.

As of September 30, 2015, we are obligated to make minimum lease payments under noncancelable operating leases as follows (in thousands):

Year ending December 31,	Lease Payments
2015 (remaining of year)	$104
2016	417
2017	341
2018	103
2019 and beyond	82
Total	$1,047

7. Net Loss Per Share

Basic and diluted net loss per share was calculated as follows (in thousands, except per share amounts):

	Three months ended September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
Basic and diluted net loss per share:				
Numerator:				
Net loss	$(7,095)	$(6,072)	$(20,710)	$(20,350)
Denominator:				
Weighted-average number of common shares outstanding, basic and diluted	19,792	19,713	19,758	18,467
Net loss per share, basic and diluted	$(0.36)	$(0.31)	$(1.05)	$(1.10)

There was no difference between the Company’s net loss and the net loss attributable to common stockholders for all periods presented.

Stock options to purchase 3,078,065 shares of common stock as of September 30, 2015, were excluded from the computation of diluted net loss per share attributable to common stockholders for the three and nine months ended September 30, 2015, because their effect was anti-dilutive.

Stock options and unvested restricted stock awards to purchase 2,390,090 shares of common stock were excluded from the computation of diluted net loss per share attributable to common stockholders for the three and nine months ended September 30, 2014, because their effect was anti-dilutive.

Table of Contents

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

In this section, "Kindred," "we," "our," "ours," "us" and the "Company" refer to Kindred Biosciences, Inc. You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes and other financial information included elsewhere in this Quarterly Report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q consists of forward-looking statements such as 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. In this Quarterly Report on Form 10-Q, the words "anticipates," "believes," "expects," "intends," "future," "could," "estimates," "plans," "would," "sho "potential," "continues" and similar words or expressions (as well as other words or expressions referencing future events, conditions or circumstances) often identify forward-looking statements.

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 and uncertainties include, but are not limited to, the following: our limited operating history and expectations of losses for the foreseeable future; the absence of 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 pertaining to 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 uncertainties and other risks and uncertainties that we face, please see the "Risk Factors" sections that are contained in our filings with the U.S. Securities and Exchange Commission (the SEC), including the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2014, which was filed with the SEC on March 13, 2015, and any subsequent updates that may be contained in the "Risk Factors" sections of this Quarterly Report on Form 10-Q and our other Quarterly Reports on Form 10-Q filed with the SEC. As a result of the risks and uncertainties 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 Quarterly Report on Form 10-Q. Forward-looking statements contained in this Quarterly Report on Form 10-Q speak only as of the date of this report and we undertake no obligation to update or revise these statements, except as may be required by law.

Table of Contents

Overview

We are an early stage biopharmaceutical company focused on saving and improving the lives of pets. Our mission is to bring to our pets the same kinds of safe and effective medicines that our human family members enjoy. Our core 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 pets, primarily dogs, cats and horses. We believe this approach will lead to shorter development times and higher approval rates than pursuing new, non-validated compounds and targets. We have three product candidates that are currently in a pivotal field efficacy trial, or pivotal trial. In addition, we have multiple other product candidates, including several biologics, in various stages of development. We believe there are significant unmet medical needs for pets, and that the pet therapeutics segment of the animal health industry is likely to grow substantially as new therapeutics are identified, developed and marketed specifically for pets.

In 2014, we initiated a pivotal trial of SentiKind (flupirtine), our lead product candidate, for the treatment of post-operative pain in dogs. Enrollment for the study has been completed and we are preparing for data readout and plans to report topline results in the coming weeks. The Chemical, Manufacturing, and Controls, or CMC, and Target Animal Safety Study technical sections of the New Animal Drug Application, or NADA, have been submitted for this product. We continue to conduct pilot studies of the active ingredient in SentiKind in several other indications across multiple species.

In March 2015, we announced a positive randomized, blinded, placebo-controlled pilot study investigating KIND-012 for fever in horses. In April 2015, we received a protocol concurrence from the U.S. Food and Drug Administration, or FDA, on the pivotal field study for KIND-012. The study is now fully enrolled and topline results for the pivotal trial are expected in the coming weeks. We have completed the in-life portion of the Target Animal Safety Study and is currently preparing the CMC technical section of the NADA.

The Pharmacokinetic, or PK, study of KIND-010 for management of weight loss in cats has been completed, with positive efficacy signal, as evidenced by increase in weight. A randomized, placebo-controlled pilot study of KIND-010 was ended early due to positive efficacy signal and we have initiated the pivotal field study in October 2015. Topline results for the pivotal field study are expected in the fourth quarter of 2016.

The initial pilot study of KIND-011 for metabolic syndrome in horses has been completed and confirmed activity with the active ingredient. Based on the results, we have advanced formulation development for of an analog of KIND-011. We believe that the analog, KIND-015, will have substantially lower cost of goods than KIND-011, with similar efficacy and safety profile.

Our feline erythropoietin program is advancing rapidly. The initial laboratory study has been completed, with a positive efficacy signal, as evidenced by increased reticulocyte formation. Preparations for Good Manufacturing Practice, or GMP, manufacturing activities are underway to allow us to proceed to GMP manufacturing in early 2016.

The PK study for the anti-TNF antibody has been completed with favorable pharmacokinetics and we expect to initiate GMP manufacturing activities shortly.

The checkpoint inhibitor programs are making strong progress, as well as multiple other biologics programs that are in early-stage development.

Some of our pivotal trials, such as KIND-012 for treatment of fever in horses, may be conducted under Protocol Concurrences granted by the FDA while other studies, such as SentiKind for postoperative pain in dogs, are performed without a Protocol Concurrence. Protocol Concurrences are not required, but where they are granted by the FDA, they demonstrate that the FDA agrees that the design and analyses proposed in a protocol are acceptable to

support regulatory approval of the product candidate with respect to effectiveness of the indication studied. Although the FDA's Center for Veterinary Medicine, or the CVM, has not concurred with our proposed SentiKind protocol, we have modified the SentiKind pivotal trial protocol in accordance with comments provided by the CVM on our Protocol Concurrence request and have proceeded with the trial without obtaining a formal FDA Protocol Concurrence. Nonetheless, the CVM may not accept the pivotal study.

Table of Contents

In addition to the product candidates discussed above, we are in the early stages of development for multiple additional indications, with the potential to attain approval for two or more products annually for several years. We plan to commercialize our products in the United States through a direct sales force complemented by selected distributor relationships, and in the EU through distributors and other third parties. Because we seek to identify product candidates that are not protected by third-party patents, we typically do not need to obtain licenses or make any upfront, milestone or royalty payments in connection with our product candidates.

We are an early stage company with no products approved for marketing and sale, and we have not generated any revenue. We have incurred significant net losses since our inception. We incurred cumulative net losses of $52,182,000 through September 30, 2015. These losses have resulted principally from costs incurred in connection with investigating and developing our product candidates, research and development activities and general and administrative costs associated with our operations.

Historically, our funding has been a combination of private and public offerings, most recently our initial public offering in December 2013 provided us with net proceeds of $54,871,000 and a follow-on public offering in April 2014 provided us with net proceeds of $58,065,000. As of September 30, 2015, we had cash, cash equivalents and short-term investments of $83,586,000.

For the foreseeable future, we expect to continue to incur losses, which will increase significantly from historical levels as we expand our product development activities, seek regulatory approvals for our product candidates and begin to commercialize them if they are approved by the CVM branch of the FDA, the U.S. Department of Agriculture, or USDA, or the European Medicines Agency, or EMA. If we are required to further fund our operations, we expect to do so through public or private equity offerings, debt financings, corporate collaborations and licensing arrangements. We cannot assure you that such funds will be available on terms favorable to us, if at all. Arrangements with collaborators or others may require us to relinquish rights to certain of our technologies or product candidates. In addition, we may never successfully complete development of, obtain adequate patent protection for, obtain necessary regulatory approval, or achieve commercial viability for any product candidate. If we are not able to raise additional capital on terms acceptable to us, or at all, as and when needed, we may be required to curtail our operations, and we may be unable to continue as a going concern.

Critical Accounting Policies and Significant Judgments and Estimates

Our management’s discussion and analysis of financial condition and results of operations is based on our condensed financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or U.S. GAAP. The preparation of our condensed financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, and revenue, costs and expenses and related disclosures during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments, including those described below. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

There have been no significant changes to our critical accounting policies since the beginning of our fiscal year. Our critical accounting policies are described in the “Management’s Discussion and Analysis of Financial Condition and Result of Operations” section of our Annual Report on Form 10-K for the year ended December 31, 2014, which was filed with SEC on March 13, 2015.

Table of Contents

Results of Operations

The following table summarizes the results of our operations for the periods indicated (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
Operating expenses:				
Research and development	$5,033	$3,755	$14,833	$13,892
General and administrative	2,095	2,342	5,969	6,525
Total operating expenses	7,128	6,097	20,802	20,417
Loss from operations	(7,128)	(6,097)	(20,802)	(20,417)
Interest income	33	25	92	67
Net loss	$(7,095)	$(6,072)	$(20,710)	$(20,350)

Revenue

We do not have any products approved for sale, have not generated any revenue since our inception and do not expect to generate any material revenue in the near future. If our development efforts result in clinical success and regulatory approval or collaboration agreements with third parties for any of our product candidates, we may generate revenue from those product candidates.

Research and Development Expense

All costs of research and development are expensed in the period incurred. Research and development costs consist primarily of salaries and related expenses for personnel, stock-based compensation expense, fees paid to consultants, outside service providers, professional services, travel costs and materials used in clinical trials and research and development. We are currently pursuing multiple product candidates for over a dozen indications. We typically use our employee and infrastructure resources across multiple development programs.

Research and development expense was as follows for the periods indicated (in thousands, except for percentages):

	Three months ended September 30,			Nine months ended September 30,		
	2015	2014	% Change	2015	2014	% Change
Payroll and related	$2,324	$1,423	63 %	6,149	3,109	98 %
Consulting	259	418	(38)%	1,019	1,397	(27)%
Field trial costs, including materials	1,419	1,068	33 %	4,501	7,134	(37)%
Stock-based compensation	439	376	17 %	1,371	1,065	29 %
Other	592	470	26 %	1,793	1,187	51 %
	$5,033	$3,755	34 %	$14,833	$13,892	7 %

Table of Contents

During the three and nine months ended September 30, 2015, research and development expense related primarily to advancing the development of our lead product candidate, SentiKind, as well as KIND-012 for fever in horses and KIND-010 for management of weight loss in cats. During this period we completed a Target Animal Safety Study and sourced the manufacture of material necessary for regulatory approval. We also initiated additional manufacturing work in preparation for commercialization of our first product candidates. We continue to advance additional product candidates in our small molecule programs as well as continue to advance our biologics program by building an in-house team to focus on setting-up a manufacturing process for our potential biologic candidates.

Research and development expenses for the three months ended September 30, 2015, increased by 34% to $5,033,000 compared with $3,755,000 for the same period in 2014. The increase in expenses were due to $901,000 in payroll and related expenses as we continue to staff up our research and development activities. In addition, our field trial costs increased by $351,000 due to costs associated with our KIND-010 and KIND-012 pivotal studies of approximately $1,267,000 offset in part by the decrease in field trial costs of approximately $1,091,000 due to the discontinued development of CereKin and AtoKin and lower SentiKind expenses. In addition, our biologics programs and other research expenses as well as stock-based compensation expense increased by approximately $122,000 and $63,000, respectively. Outsourced research and development expenses related to our SentiKind, KIND-010, KIND-012 and other product development programs for the three months ended September 30, 2015 were $185,000, $520,000, $747,000 and $184,000, respectively. Outsourced research and development expense consists primarily of costs related to manufacturing supplies, field trials, studies and consulting.

Research and development expenses for the nine months ended September 30, 2015, increased by 7% to $14,833,000 compared with $13,892,000 for the same period in 2014. Payroll and related expenses increased by $3,040,000 due to increased headcount as we continue to bring in-house our development activities resulting in lower consulting expense of $378,000. In addition, our biologics programs and other research expenses as well as stock-based compensation expense increased by approximately $606,000 and $306,000, respectively. The increased expenses were offset in part by the decrease in field trial costs of approximately $2,633,000 as we discontinued the development of CereKin and AtoKin and our SentiKind program completed enrollment in the second quarter of 2015. Outsourced research and development expense related to our product development programs for SentiKind, KIND-010, KIND-012 and other product development programs for the nine months ended September 30, 2015 were $1,794,000, $1,233,000, $1,433,000 and $1,016,000, respectively.

We expect research and development expense to increase for the foreseeable future as we continue to increase our headcount, commence pivotal studies and further develop our small molecule compounds and biologics development programs. Due to the inherently unpredictable nature of our development, we cannot reasonably estimate or predict the nature, specific timing or estimated costs of the efforts that will be necessary to complete the development of our product candidates.

General and Administrative Expense

General and administrative expense was as follows for the periods indicated (in thousands, except for percentages):

	Three months ended September 30,			Nine months ended September 30,		
	2015	2014	% Change	2015	2014	% Change
	(In thousands)					
Payroll and related	$535	$390	37 %	1,439	1,095	31 %
Consulting, legal fees and professional services	361	407	(11)%	1,153	1,283	(10)%
Stock-based compensation	567	889	(36)%	1,732	2,453	(29)%
Corporate and marketing expenses	220	496	(56)%	799	1,175	(32)%
Other	412	160	158 %	846	519	63 %
	$2,095	$2,342	(11)%	5,969	6,525	(9)%

Table of Contents

General and administrative expenses for the three months ended September 30, 2015 decreased by 11% to $2,095,000 compared with $2,342,000 for the same period in 2014. The decrease in general and administrative expense was related to lower stock-based compensation expense as well as marketing and corporate expenses. The decrease was offset in part by higher payroll and related expenses due to increased headcount and other general business expenses. General and administrative expenses for the nine months ended September 30, 2015 decreased by 9% to $5,969,000 compared with $6,525,000 for the same period in 2014. The decrease in general and administrative expense was related to lower stock-based compensation expense, consulting fees and marketing and corporate expenses. The decrease was offset in part by higher payroll and related expenses due to increased headcount and other general business expenses. We expect general and administrative expense to increase as we continue to increase our headcount and build our corporate infrastructure.

Income Taxes

We have historically incurred operating losses and maintain a full valuation allowance against our net deferred tax assets. Our management has evaluated the factors bearing upon the realizability of our deferred tax assets, which are comprised principally of net operating loss carryforwards and concluded that, due to the uncertainty of realizing any tax benefits as of September 30, 2015, a valuation allowance was necessary to fully offset our deferred tax assets.

Liquidity and Capital Resources

We have incurred losses and negative cash flows from operations and have not generated any revenue since our inception in September 2012 through September 30, 2015. As of September 30, 2015, we had an accumulated deficit of $52,182,000. Since inception, we raised a total of $125,023,000, net of offering costs, through public offerings of our common stock and through the sale of preferred stock (subsequently converted to common stock at the time of our initial public offering). As of September 30, 2015, we had cash, cash equivalents and short-term investments of $83,586,000. We believe that our cash, cash equivalents and short-term investments balances as of September 30, 2015, are sufficient to fund our planned operations for at least the next P24M months.

Cash Flows

The following table summarizes our cash flows for the periods set forth below:

	Nine months ended September 30,	
	2015	2014
	(In thousands)	
Net cash used in operating activities	$(17,228)	$(16,800)
Net cash provided by (used in) investing activities	$8,592	$(98,353)
Net cash provided by financing activities	$206	$58,148

Net cash used in operating activities

During the nine months ended September 30, 2015, net cash used in operating activities was $17,228,000. Net cash used in operating activities resulted primarily from our net loss of $20,710,000, offset by changes in operating assets and liabilities of $143,000 and non-cash, stock-based compensation of $3,103,000.

During the nine months ended September 30, 2014, net cash used in operating activities was $16,800,000. Net cash used in operating activities resulted primarily from our net loss of $20,350,000, partially offset by non-cash, stock-based compensation of $3,518,000.

Net cash provided by (used in) investing activities

During the nine months ended September 30, 2015, net cash provided by investing activities was $8,592,000, which resulted from proceeds from maturities of marketable securities of $87,000,000 and sales of investments of

Table of Contents

$3,000,000, partially offset by $81,086,000 related to the purchase of marketable securities and $322,000 related to purchases of property and equipment.

During the nine months ended September 30, 2014, net cash used in investing activities was $98,353,000 and related to the purchase of marketable securities of $128,142,000 and property and equipment of $211,000, partially offset by proceeds from maturities of marketable securities of $30,000,000.

Net cash provided by financing activities

During the nine months ended September 30, 2015, net cash provided by financing activities consisted of $206,000 from the exercise of stock options and purchase of ESPP shares.

During the nine months ended September 30, 2014, net cash provided by financing activities of $58,148,000 consisted of $83,000 from the exercise of stock options and $58,065,000 in net proceeds from the sale of common stock.

Future Funding Requirements

We anticipate that we will continue to incur losses for the next several years due to expenses relating to:

- pivotal trials of our product candidates;
- toxicology (target animal safety) studies for our product candidates;
- small molecule manufacturing;
- establishment of biologics manufacturing capability; and
- commercialization of one or more of our product candidates, if approved.

We believe our existing cash, cash equivalents and short-term investments will be sufficient to fund our operating plan through the anticipated approval and launch of our lead product candidate SentiKind. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations. Such financing may result in dilution to stockholders, imposition of debt covenants and repayment obligations or other restrictions that may affect our business. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Our future capital requirements depend on many factors, including, but not limited to:

- the scope, progress, results and costs of researching and developing our current or future product candidates;
- the timing of, and the costs involved in, obtaining regulatory approvals for any of our current or future product candidates;
- the number and characteristics of the product candidates we pursue;
- the cost of manufacturing our current and future product candidates and any products we successfully commercialize, including cost of building internal biologics manufacturing capacity;
- the cost of commercialization activities if any of our current or future product candidates are approved for sale, including marketing, sales and distribution costs;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements; and
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing possible patent claims, including litigation costs and the outcome of any such litigation.

Since inception, we have not engaged in the use of any off-balance sheet arrangements, such as structured finance entities, special purpose entities or variable interest entities.

Contractual Obligations

Table of Contents

In April 2014, we entered into noncancelable operating leases for laboratory space and office space and in January 2015 as well as July 2015, we amended one of the operating leases to include additional lab space. In June 2015, we entered into a noncancelable operating lease for office space in San Diego, California. Under the operating leases we are obligated to make minimum lease payments totaling $1,047,000 through July 2020 the timing of which is described in more detail in the notes to the condensed financial statements.

In March 2014, we entered into a license agreement under which we made an up-front payment and were obligated to make annual payments and, subject to certain terms and conditions, milestone payments upon achievement of development milestones and a royalty based on sales of products developed under the agreement. In January 2015, we terminated this agreement since our internal technologies made the licensed technology redundant.

Off-Balance Sheet Arrangements

As of September 30, 2015, we did not have any material off-balance sheet arrangements as defined in Item 303(a)(4)(ii) of SEC Regulation S-K.

Recently Issued Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-15, Presentation of Financial Statements - Going Concern (Subtopic 205-40) - Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern, which provides guidance regarding management’s responsibility to assess whether substantial doubt exists regarding the ability to continue as a going concern and to provide related footnote disclosures. In connection with preparing financial statements for each annual and interim reporting period, an entity’s management should evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity’s ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable). This ASU is effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. We are currently evaluating the new guidance and have not determined the impact this standard may have on our condensed financial statements.

We do not believe there are any other recently issued standards not yet effective that will have a material impact on our financial statements when the standards become effective.

Table of Contents

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The primary objective of our investment activities is to preserve capital. We do not utilize hedging contracts or similar instruments.

We are exposed to certain market risks relating primarily to (1) interest rate risk on our cash and cash equivalents, (2) market price risk on our short-term investments, and (3) risks relating to the financial viability of the institutions which hold our capital and through which we have invested our funds. We manage such risks by investing in short-term, liquid, highly-rated instruments. As of September 30, 2015, our cash equivalents and short-term investments are invested in money market funds, U.S. treasury bills, U.S. federal agency notes and U.S treasury bonds and notes. We do not believe we have any material exposure to interest rate risk due to the extremely low interest rate environment, the short duration of the securities we hold and our ability to hold our investments to maturity if necessary. Declines in interest rates would reduce investment income, but would not have a material effect on our financial condition or results of operations.

We do not currently have exposure to foreign currency risk.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

As of the end of the period covered by this quarterly report on Form 10-Q, our management, with the participation of our Chief Executive Officer and Interim Chief Financial Officer (the "Certifying Officer"), evaluated the effectiveness of our disclosure controls and procedures. Disclosure controls and procedures are controls and procedures designed to reasonably assure that information required to be disclosed in our reports filed under the Securities Exchange Act of 1934 (the "Exchange Act"), such as this report, is recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms. Disclosure controls and procedures are also designed to reasonably assure that such information is accumulated and communicated to our management, including the Certifying Officer, as appropriate to allow timely decisions regarding required disclosure. Based on these evaluations, the Certifying Officer has concluded, that, as of the end of the period covered by this report:

(a) our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act was recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms; and

(b) our disclosure controls and procedures were effective to provide reasonable assurance that material information required to be disclosed by us in the reports we file or submit under the Exchange Act was accumulated and communicated to our management, including the Certifying Officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There has not been any change in our internal control over financial reporting that occurred during the period ended September 30, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

PART II — OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 1A. RISK FACTORS

You should consider the "Risk Factors" included under Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2014 filed with the SEC on March 13, 2015. There have been no material changes to those Risk Factors.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Unregistered Sales of Equity Securities and Issuer Purchases of Equity Securities

None.

Use of Proceeds from the Sale of Registered Securities

On December 11, 2013, our registration statement on Form S-1 (File No. 333-192242) was declared effective by the Securities and Exchange Commission (SEC) for our initial public offering pursuant to which we sold an aggregate of 8,625,000 shares of our common stock at a price to the public of $7.00 per share. There has been no material change in our use of proceeds from our initial public offering as described in our final prospectus filed with the SEC on December 12, 2013 pursuant to Rule 424(b).

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

Table of Contents

ITEM 6. EXHIBITS

EXHIBIT INDEX

Exhibit Number	Description
31.1	Sarbanes-Oxley Act Section 302 Certification of Chief Executive Officer and Interim Chief Financial Officer.
32.1	Sarbanes-Oxley Act Section 906 Certification of Chief Executive Officer and Interim Chief Financial Officer.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

Table of Contents

SIGNATURES

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 thereunto duly authorized.

Date: November 9, 2015

Kindred Biosciences, Inc.

By: /s/ Richard Chin
Richard Chin, M.D.
President and Chief Executive Officer and Interim Chief Financial Officer