

Kindred Biosciences, Inc.
Form 10-Q
November 13, 2014
Table of Contents

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

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2014

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 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 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

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

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As of November 7, 2014, Kindred Biosciences, Inc. had outstanding 19,714,482 shares of common stock, \$0.0001 par value.

Table of Contents

Kindred Biosciences, Inc.

TABLE OF CONTENTS

Part No.	Item No.	Description	Page No.
I		FINANCIAL INFORMATION	
	1	<u>Financial Statements</u>	<u>3</u>
		<u>Condensed Balance Sheets as of September 30, 2014 (unaudited) and December 31, 2013</u>	<u>3</u>
		<u>Unaudited Condensed Statements of Operations and Comprehensive Loss for the Three and Nine Months Ended September 30, 2014 and 2013</u>	<u>4</u>
		<u>Unaudited Condensed Statements of Cash Flows for the Nine Months Ended September 30, 2014 and 2013</u>	<u>5</u>
		<u>Notes to Unaudited Condensed Financial Statements</u>	<u>6</u>
	2	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>12</u>
	3	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>20</u>
	4	<u>Controls and Procedures</u>	<u>20</u>
II		OTHER INFORMATION	
	1	<u>Legal Proceedings</u>	<u>21</u>
	1A	<u>Risk Factors</u>	<u>21</u>
	2	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>21</u>
	3	<u>Defaults Upon Senior Securities</u>	<u>21</u>
	4	<u>Mine Safety Disclosures</u>	<u>21</u>
	5	<u>Other Information</u>	<u>21</u>
	6	<u>Exhibits</u>	<u>22</u>
		<u>Index to Exhibits</u>	<u>22</u>
		<u>Signatures</u>	<u>23</u>

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, 2014 (Unaudited)	December 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	\$8,324	\$65,329
Short-term investments	98,103	—
Prepaid expenses and other	688	148
Total current assets	107,115	65,477
Property and equipment, net	194	12
Other assets	22	—
Total assets	\$107,331	\$65,489
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$744	\$689
Accrued liabilities	1,635	1,521
Total current liabilities	2,379	2,210
Long term liability	44	—
Total liabilities	2,423	2,210
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Common stock, \$0.0001 par value; 100,000,000 shares authorized; 19,714,482 and 16,214,620 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively		2
Additional paid-in capital	129,579	67,610
Accumulated other comprehensive income	10	—
Accumulated deficit	(24,683) (4,333
Total stockholders' equity	104,908	63,279
Total liabilities and stockholders' equity	\$107,331	\$65,489

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		Nine months ended September	
	30,		30,	
	2014	2013	2014	2013
Operating expenses:				
Research and development	\$3,755	\$953	\$13,892	\$1,394
General and administrative	2,342	259	6,525	438
Total operating expenses	6,097	1,212	20,417	1,832
Loss from operations	(6,097) (1,212) (20,417) (1,832
Interest income	25	2	67	2
Net loss	(6,072) (1,210) (20,350) (1,830
Change in unrealized gains or losses on available-for-sale securities	24	—	10	—
Comprehensive loss	\$(6,048) \$(1,210) \$(20,340) \$(1,830
Net loss per share, basic and diluted	\$(0.31) \$(0.40) \$(1.10) \$(0.61
Weighted-average number of common shares outstanding, basic and diluted	19,713	3,005	18,467	3,001

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,	
	2014	2013
Cash Flows from Operating Activities		
Net loss	\$(20,350)	\$(1,830)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	3,518	504
Depreciation expense	29	1
Amortization of premium on marketable securities	49	—
Changes in operating assets and liabilities:		
Prepaid expenses and other	(540)	(360)
Other assets	(22)	—
Accounts payable	55	119
Due to related party	—	(1)
Accrued liabilities	461	536
Net cash used in operating activities	(16,800)	(1,031)
Cash Flows from Investing Activities		
Purchase of short-term investments	(128,142)	—
Proceeds from maturities of short-term investments	30,000	—
Purchase of property and equipment	(211)	(14)
Net cash used in investing activities	(98,353)	(14)
Cash Flows from Financing Activities		
Exercise of stock options	83	2
Net proceeds from issuance of Series A-1 convertible preferred stock	—	5,865
Net proceeds from issuance of Series A-1A convertible preferred stock	—	5,232
Net proceeds from sale of common stock in public offering	58,065	—
Net cash provided by financing activities	58,148	11,099
Net increase (decrease) in cash and cash equivalents	(57,005)	10,054
Cash and cash equivalents at beginning of period	65,329	938
Cash and cash equivalents at end of period	\$8,324	\$10,992
Supplemental disclosure of non-cash financing activities:		
Issuance of Series A-1 convertible preferred stock for settlement of offering costs and other legal fees	\$—	\$32
Issuance of Series A-1A convertible preferred stock for settlement of offering costs	\$—	\$78
Issuance of common stock and stock options for accrued consulting expenses	\$303	\$341
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, 2013 included in our annual report on Form 10-K as filed with the SEC on March 14, 2014, as amended. 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 8, 2014, public offering. We believe that our cash, cash equivalents and short-term investments totaling \$106,427,000 as of September 30, 2014, 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.

Recently Issued Accounting Pronouncements

On June 10, 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-10, Development Stage Entities (Topic 915) - Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation, which eliminates the concept of a development stage entity (DSE) in its entirety from current accounting guidance. A DSE is an entity devoting substantially all of its efforts to establishing a new business and for which either planned principal operations have not yet commenced or have commenced but there has been no significant revenues generated from that business. Under current guidance, DSEs are required to present inception-to-date financial information in their annual statements. We determined we were a DSE and had therefore presented inception-to-date financial information financial statements. As permitted by ASU 2014-10, we have elected to early adopt this standard, and therefore, we have not presented any inception to date financial information and we have removed all references to development stage in these condensed financial statements.

In August 2014, the FASB issued 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.

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, 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	\$3,702	\$3,702	\$—	\$—
Short-term investments:				
U.S. treasury bills	21,998	—	21,998	—
U.S. treasury bonds and notes	76,105	—	76,105	—
	\$101,805	\$3,702	\$98,103	\$—

Fair Value Measurements as of December 31, 2013

Description	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Cash equivalents:				
Money market funds	\$65,310	\$65,310	\$—	\$—
	\$65,310	\$65,310	\$—	\$—

There were no transfers of assets between Level 1, Level 2 or Level 3 of the fair value hierarchy at September 30, 2014, or December 31, 2013.

At September 30, 2014 and December 31, 2013, 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).

The fair value of available-for-sale short-term investments by type of security at September 30, 2014 were as follows (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. treasury bills	\$21,992	\$6	\$—	\$21,998
U.S. treasury bonds and notes	76,101	4	—	76,105
	\$98,093	\$10	\$—	\$98,103

At September 30, 2014, short-term investments with maturities beyond one year consisted of U.S. treasury notes with carrying values of \$8,009,000 and \$5,010,000 that mature on October 31, 2015 and November 15, 2015, respectively. These

8

Table of Contents

investments are classified as current assets since they are viewed as available to support current operations. We held no short-term investments at December 31, 2013.

4. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	September 30, 2014	December 31, 2013
Payroll and related expenses	\$819	\$635
Consulting expenses	—	304
Research and development costs	562	159
Offering costs	—	381
Other expenses	254	42
Deferred rent	44	—
	1,679	1,521
Less current portion	(1,635)	(1,521)
Long term liabilities (deferred rent)	\$44	\$—

5. Stock-Based Awards and Common Stock

The table below shows the number of shares of common stock underlying options granted to employees and directors, 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:

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
Shares underlying options granted	117,500	285,092	1,031,500	825,092
Weighted-average exercise price	\$16.60	\$0.90	\$16.67	\$0.54
Risk- free interest rate	1.9%	1.6%-1.72%	1.4%-2.6%	0.6%-1.7%
Expected term (years)	6.1	5.0	5.3 - 6.1	5.0
Expected volatility	90%	80%	90%	90%
Expected dividend yield	—	—	—	—
Weighted-average grant date fair value per share	\$12.42	\$1.80	\$12.34	\$0.76

The table below shows the number of shares of common stock underlying options granted to 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:

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
Shares underlying options granted	—	156,488	32,963	347,806
Weighted-average exercise price	—	\$0.99	\$15.41	\$0.60
Risk- free interest rate	—	1.6%-2.8%	2.6%-2.7%	0.6%-2.8%
Expected term (years)	—	10.0	10.0	10.0
Expected volatility	—	80%	90%	90%
Expected dividend yield	—	—	—	—
Weighted-average grant date fair value per share	—	\$1.98	\$13.32	\$0.99

Table of Contents

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

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2014	2013	2014	2013
Research and development	\$376	\$354	\$1,065	\$435
General and administrative	889	52	2,453	69
	\$1,265	\$406	\$3,518	\$504

We had an aggregate of approximately \$10,872,000 of unrecognized stock-based compensation expense for options outstanding as of September 30, 2014 which is expected to be recognized over a weighted-average period of 3.2 years. During the nine months ended September 30, 2014, we issued 46,112 shares of common stock with an intrinsic value of \$715,000 upon exercise of stock options, for proceeds of \$83,000. During the nine months ended September 30, 2014, we issued 3,750 shares upon release of restricted stock awards.

On April 8, 2014, we completed a public offering of 3,450,000 shares of common stock at a price of \$18.00 per share, for net proceeds of \$58,065,000, after deducting underwriting discounts, commissions and offering expenses.

6. Commitments and Contingencies

In March 2014, we entered into a license agreement under which we made an up-front payment and are 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 April 2014, we entered into new noncancelable operating leases for laboratory space and office space through November 2017. As of September 30, 2014 we are obligated to make minimum lease payments under noncancelable operating leases as follows (in thousands):

Year ending December 31,	Lease Payments
2014 (remainder of year)	\$45
2015	247
2016	255
2017	209
Total	\$756

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		Nine months ended September	
	30,		30,	
	2014	2013	2014	2013
Basic and diluted net loss per share:				
Numerator:				
Net loss	\$(6,072)	\$(1,210)	\$(20,350)	\$(1,830)
Denominator:				
Weighted-average number of common shares outstanding, basic and diluted	19,713	3,005	18,467	3,001
Net loss per common share, basic and diluted	\$(0.31)	\$(0.40)	\$(1.10)	\$(0.61)

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

Table of Contents

Stock options and unvested restricted stock awards to purchase 2,390,090 shares of common stock as of September 30, 2014, 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.

Stock options to purchase 1,165,423 shares of common stock and 4,535,206 shares of common stock issuable upon the conversion of preferred stock as of September 30, 2013, were excluded from the computation of diluted net loss per share for the three and nine months ended September 30, 2013, 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," "should," "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 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 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, as amended, for the year ended December 31, 2013, which was filed with the SEC on March 14, 2014, 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 two product candidates that are in pivotal field efficacy trials, or pivotal trials, and expect approval of one or more of these product candidates as early as 2016. 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.

Our lead product candidates are AtoKin™ (fexofenadine) for the treatment of atopic dermatitis in dogs and SentiKin™ (flupirtine) for the treatment of post-operative pain in dogs, post-operative pain in cats, and osteoarthritis in dogs. In addition, we have advanced several other products. We have completed a PK study of extended-release SentiKin for postoperative pain in cats. We completed a PK study of a drug for fever in horses and a PK study of a drug for the stimulation of appetite in cats this quarter. We have replaced KIND-006 with a more potent molecule of the same class. Significant progress has been made in the biologics program, including erythropoietin for cats with anemia. We have also initiated checkpoint inhibitor programs for dogs. All of these product candidates, if approved, would be first-in-class drugs in the pet therapeutic market.

We initiated the pivotal trials for CereKin, AtoKin and SentiKin in August 2013, February 2014 and March 2014, respectively. In August 2014, we announced that our pivotal field study of CereKin in dogs did not meet its primary endpoint. We do not plan to further pursue CereKin for osteoarthritis in dogs.

The AtoKin pivotal study in dogs with atopic dermatitis and the SentiKin pivotal study in dogs for postoperative pain are actively enrolling patients and we expect topline results in mid-2015. Assuming positive results from these trials, we intend to submit the technical sections of New Animal Drug Applications, or NADAs, for marketing approval of AtoKin and SentiKin in the United States on a rolling basis in 2014 - 2015, and anticipate potential marketing approvals and product launches as early as 2016. If approved in the United States, we plan to make similar regulatory filings for these products with the European Medicines Agency, or EMA for marketing approval in the European Union, or EU.

Some of our studies, such as the pivotal trial for AtoKin, are conducted under Protocol Concurrences granted by the FDA, while other studies, such as SentiKin 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, have not concurred with our proposed SentiKin protocol, we have modified the SentiKin 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.

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 starting in late 2015. 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 \$24,683,000 through September 30, 2014 and \$20,350,000 for the nine months ended September 30, 2014. 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.

Table of Contents

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 public offering in April 2014 provided us with net proceeds of \$58,065,000 after deducting underwriting discounts and commissions of \$3,726,000 and other offering expenses of approximately \$309,000. As of September 30, 2014, we had cash, cash equivalents and short-term investments of \$106,427,000.

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 Center for Veterinary Medicine branch of the U.S. Food and Drug Administration, or 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, 2013, which was filed with SEC on March 14, 2014, as amended.

Results of Operations

The following table summarizes the results of our operations for the periods indicated:

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
	(In thousands)			
Operating expenses:				
Research and development	\$3,755	\$953	\$13,892	\$1,394
General and administrative	2,342	259	6,525	438
Total operating expenses	6,097	1,212	20,417	1,832
Loss from operations	(6,097) (1,212) (20,417) (1,832
Interest income	25	2	67	2
Net loss	\$(6,072) \$(1,210) \$(20,350) \$(1,830

Table of Contents

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:

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
	(In thousands)			
Payroll and related	\$1,422	\$235	\$3,236	\$408
Consulting	419	49	1,398	108
Field trial costs, including materials	1,251	256	7,317	377
Stock-based compensation	376	353	1,065	434
Other	287	60	876	67
	\$3,755	\$953	\$13,892	\$1,394

Table of Contents

During the three and nine months ended September 30, 2014, research and development expense related primarily to advancing the development of our lead product candidates. During these periods we completed a Target Animal Safety Study as well as the CereKin field trial and in August 2014 announced that the CereKin trial did not meet its primary endpoint. We initiated our field trials for Atokin and SentiKin 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, 2014, increased 294% to \$3,755,000 compared with \$953,000 for the same period in 2013. The higher expenses were primarily driven by the increase in outsourced research and development expense for SentiKin, CereKin and AtoKin of \$355,000, \$293,000 and \$39,000, respectively, and \$791,000 for our other product development programs. Outsourced research and development expense consists primarily of costs related to manufacturing supplies, field trials, studies and consulting. In addition, payroll and related expenses increased by \$1,187,000 as we continue to staff up the organization to advance our development programs including manufacturing activities.

Research and development expenses for the nine months ended September 30, 2014, increased by 896% to \$13,892,000 compared with \$1,394,000 for the same period in 2013. The higher expenses were primarily driven by the increase in outsourced research and development expense for SentiKin, CereKin and AtoKin of \$2,999,000, \$2,564,000 and \$1,583,000, respectively, and \$1,649,000 for our other product development programs. In addition, research and development expenses also increased by \$2,828,000 due to payroll and related expenses and by \$631,000 related to stock-based compensation expense. Research and development expense in 2013 primarily related to advancing the development of our lead product candidates. During this period we developed the protocols for CereKin and AtoKin, received Protocol Concurrences from the FDA for both compounds and increased our staffing to support the planning for initiation of the pivotal trials of CereKin and AtoKin.

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:

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
	(In thousands)			
Payroll and related	\$392	\$90	\$1,213	\$218
Consulting and legal fees	536	89	1,710	110
Stock-based compensation	890	52	2,454	69
Other	524	28	1,148	41
	\$2,342	\$259	\$6,525	\$438

During the three and nine months ended September 30, 2014, general and administrative expense related primarily to salaries, professional and consulting fees for legal, accounting and tax services, stock-based compensation, costs of being a public company, rent and other facilities costs, and other general business services. We expect general and administrative expense to increase significantly as we continue to increase our headcount and build our corporate infrastructure.

During the three and nine months ended September 30, 2013, general and administrative expense related primarily to salaries and related expenses, consulting fees for legal and accounting services and stock-based compensation.

Table of Contents

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, 2014, 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, 2014. As of September 30, 2014, we had an accumulated deficit of \$24,683,000. During the year ended December 31, 2013, we raised a total of \$65,959,000, net of offering costs, primarily in connection with our initial public offering and through the sale of preferred stock (subsequently converted to common stock at the time of our initial public offering). On April 8, 2014, we completed a public offering of common stock, resulting in net proceeds of \$58,065,000. As of September 30, 2014, we had cash, cash equivalents and short-term investments of \$106,427,000. We believe that our cash, cash equivalents and short-term investments balances as of September 30, 2014, are sufficient to fund our planned operations for at least the next 24 months.

Cash Flows

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

	Nine months ended September 30,	
	2014	2013
	(In thousands)	
Net cash used in operating activities	\$(16,800) \$(1,031
Net cash used in investing activities	\$(98,353) \$(14
Net cash provided by financing activities	\$58,148	\$11,099
Net cash used in operating activities		

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 and changes in operating assets and liabilities of \$46,000.

During the nine months ended September 30, 2013, net cash used in operating activities was \$1,031,000. Net cash used in operating activities resulted primarily from our net loss of \$1,830,000, partially offset by non-cash, stock-based compensation of \$504,000 and changes in operating assets and liabilities of \$294,000.

Net cash used investing activities

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

During the nine months ended September 30, 2013, net cash used in investing activities of \$14,000 related to the purchase of property and equipment.

Net cash provided by financing activities

During the nine months ended September 30, 2014, net cash provided by financing activities consisted of \$58,065,000 of net proceeds from a public offering and \$83,000 from the exercise of stock options.

Table of Contents

During the nine months ended September 30, 2013, net cash provided by financing activities of \$11,099,000 resulted primarily from proceeds from issuance of Series A-1 and Series A-1A convertible preferred 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 studies for our product candidates;
- 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 at least the next 24 months and the anticipated approval and launch of one or more of our lead product candidates, AtoKin and SentiKin. 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 in connection with possible strategic acquisitions 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;
- 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

In April 2014, we entered into noncancelable operating leases for laboratory space and office space under which we are obligated to make minimum lease payments totaling \$791,000 through November 2017 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 are 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.

Off-Balance Sheet Arrangements

As of September 30, 2014, we did not have any material off-balance sheet arrangements as defined in Item 303(a)(4)(ii) of SEC Regulation S-K.

Table of Contents

Recently Issued Accounting Pronouncements

On June 10, 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-10, Development Stage Entities (Topic 915) - Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation, which eliminates the concept of a development stage entity (DSE) in its entirety from current accounting guidance. A DSE is an entity devoting substantially all of its efforts to establishing a new business and for which either planned principal operations have not yet commenced or have commenced but there has been no significant revenues generated from that business. Under current guidance, DSEs are required to present inception-to-date financial information in their annual statements. We determined we were a DSE and had therefore presented inception-to-date financial information financial statements. As permitted by ASU 2014-10, we have elected to early adopt this standard, and therefore, we have not presented any inception to date financial information and we have removed all references to development stage in these condensed financial statements.

In August 2014, the FASB issued 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, 2014, our cash equivalents and short-term investments are invested in money market funds, U.S. treasury bills and U.S treasury bonds. 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 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, 2014 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, 2013 filed with the SEC on March 14, 2014, as amended. 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

For purposes of filing this Quarterly Report on Form 10-Q, effective November 12, 2014, Richard Chin began serving as our interim Chief Financial Officer.

Table of Contents

ITEM 6. EXHIBITS

EXHIBIT INDEX

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of Kindred Biosciences, Inc.(1)
3.2	Amended and Restated Bylaws of Kindred Biosciences, Inc.(1)
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

(1) Previously filed on December 17, 2013 as an exhibit to Registrant’s Report on Form 8-K and incorporated herein by reference.

Pursuant to applicable securities laws and regulations, the Registrant is deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and is not subject to liability under any anti-fraud provisions of the federal securities laws as long as the Registrant has made a good faith attempt to comply with the submission requirements and promptly amends the interactive data files after becoming aware that the interactive data files fails to comply with the submission requirements. These interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under these sections.

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 13, 2014

Kindred Biosciences, Inc.

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