KERYX BIOPHARMACEUTICALS INC
Form 10-Q
July 27, 2017

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

FORM 10-Q

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

For the quarterly period ended June 30, 2017

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 000-30929

KERYX BIOPHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	13-4087132
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

One Marina Park Drive, 12th Floor
Boston, Massachusetts 02210
(Address including zip code of principal executive offices)
(617) 466-3500
(Registrant's telephone number, including area code)

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 during the preceding 12 months (or for such shorter period 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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act:

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act: ¨

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

There were 118,750,231 shares of the registrant's common stock, $0.001 par value, outstanding as of July 20, 2017.

KERYX BIOPHARMACEUTICALS, INC.
FORM 10-Q
FOR THE QUARTER ENDED JUNE 30, 2017
TABLE OF CONTENTS

SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

Certain matters discussed in this report, including matters discussed under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations," may constitute forward-looking statements for purposes of the Securities Act of 1933, as amended, or the Securities Act, and the Securities Exchange Act of 1934, as amended, or the Exchange Act, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from the future results, performance or achievements expressed or implied by such forward-looking statements. The words "anticipate," "believe," "estimate," "may," "expect," "wi "project" and similar expressions are generally intended to identify forward-looking statements. Our actual results may differ materially from the results anticipated in these forward-looking statements due to a variety of factors, including, without limitation, those discussed under the caption "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2016, as well as under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this report, as well as other factors which may be identified from time to time in our other filings with the Securities and Exchange Commission, or the SEC, or in the documents where such forward-looking statements appear. All forward-looking statements attributable to us are expressly qualified in their entirety by these cautionary statements. Such forward-looking statements include, but are not limited to, statements about our:

- estimates regarding market size and projected growth, as well as our expectation of market acceptance of Auryxia® (ferric citrate), market share and product sales guidance;
- expectations regarding the commercialization of Auryxia;
- expectations regarding our ability to successfully develop and obtain U.S. Food and Drug Administration approval of Auryxia for the treatment of iron deficiency anemia in non-dialysis dependent chronic kidney disease patients;
- expectations regarding our ability to identify a commercial partner(s) to launch Fexeric® (ferric citrate coordination complex) in the European market;
- expectations for generating revenue, positive cash flow or becoming profitable on a sustained basis;
- estimates of the sufficiency of our existing cash and cash equivalents to finance our operating requirements;
- expected losses;
- expectations for future capital requirements;
- expectations for increases or decreases in expenses;
- expectations for pre-clinical and clinical development and regulatory progress, including manufacturing, commercialization and reimbursement (including market acceptance) of ferric citrate or any other products that we may acquire or in-license;
- expectations for incurring capital expenditures to expand our development and manufacturing capabilities;
- expectations regarding our ability to successfully market Riona® through our Japanese partner, Japan Tobacco, Inc. and its subsidiary Torii Pharmaceutical Co., Ltd.;
- expectations of the scope of patent protection with respect to Auryxia, Fexeric and Riona;
- expectations or ability to enter into marketing and other partnership agreements; and
- expectations or ability to enter into product acquisition and in-licensing transactions.

The forward-looking statements contained in this report reflect our views and assumptions only as of the date that this report is signed. Except as required by law, we assume no responsibility for updating any forward-looking statements. In addition, with respect to all of our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

PART I. FINANCIAL INFORMATION
Item 1. Financial Statements
Keryx Biopharmaceuticals, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share amounts)
(unaudited)

	June 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$140,527	$ 111,810
Inventory	18,085	12,681
Accounts receivable, net	8,459	5,236
Other current assets	8,636	3,170
Total current assets	175,707	132,897
Property, plant and equipment, net	4,172	4,211
Goodwill	3,208	3,208
Other assets, net	1,102	1,111
Total assets	$184,189	$ 141,427
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable and accrued expenses	$30,146	$ 21,190
Deferred lease incentive, current portion	244	244
Other current liabilities	131	117
Total current liabilities	30,521	21,551
Convertible senior notes	125,000	125,000
Deferred lease incentive, net of current portion	1,140	1,262
Deferred tax liability	909	870
Other liabilities	970	1,040
Total liabilities	158,540	149,723
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value per share (5,000,000 shares authorized, no shares issued and outstanding)	—	—
Common stock, $0.001 par value per share (230,000,000 and 180,000,000 shares authorized, 118,584,256 and 105,921,052 shares issued, 118,504,308 and 105,841,104 shares outstanding at June 30, 2017 and December 31, 2016, respectively)	119	106
Additional paid-in capital	970,498	827,053
Treasury stock, at cost, 79,948 shares	(357)	(357)
Accumulated deficit	(944,611)	(835,098)
Total stockholders' equity (deficit)	25,649	(8,296)
Total liabilities and stockholders' equity (deficit)	$184,189	$ 141,427

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

Keryx Biopharmaceuticals, Inc.
Condensed Consolidated Statements of Operations
(in thousands, except share and per share amounts)
(unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2017	2016	2017	2016
Revenues:				
Net U.S. Auryxia product sales	$14,116	$8,279	$24,621	$13,895
License revenue	1,028	1,009	2,343	2,218
Total revenues	15,144	9,288	26,964	16,113
Costs and expenses:				
Cost of goods sold	4,379	5,099	8,653	6,170
License expenses	617	605	1,406	1,331
Research and development	9,012	7,029	15,776	14,645
Selling, general and administrative	24,986	20,188	48,089	40,997
Total costs and expenses	38,994	32,921	73,924	63,143
Operating loss	(23,850)	(23,633)	(46,960)	(47,030)
Other income (expense):				
Amortization of debt discount	(62,965)	(18,479)	(62,965)	(34,226)
Other income (expense), net	338	(2,519)	452	(4,319)
Total other income (expense)	(62,627)	(20,998)	(62,513)	(38,545)
Loss before income taxes	(86,477)	(44,631)	(109,473)	(85,575)
Income taxes	20	20	40	40
Net loss	$(86,497)	$(44,651)	$(109,513)	$(85,615)
Basic and diluted net loss per common share	$(0.77)	$(0.42)	$(1.00)	$(0.81)
Weighted average shares used in computing basic and diluted net loss per common share	112,590,188	105,842,030	109,846,152	105,745,800

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

Keryx Biopharmaceuticals, Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands)
(unaudited)

	Six months ended June 30,	
	2017	2016
Cash flows from operating activities		
Net loss	$(109,513)	$(85,615)
Adjustments to reconcile loss to cash flows used in operating activities:		
Stock-based compensation expense	7,336	6,846
Amortization of debt discount	62,965	34,226
Change in fair value of derivative liability	(225)	4,718
Depreciation and amortization	459	520
Amortization of deferred lease incentive	(122)	(122)
Write-down of inventory to net realizable value	335	2,736
Cash received from landlord	—	637
Deferred income taxes	39	40
Changes in operating assets and liabilities:		
Other current assets	(5,466)	754
Accounts receivable, net	(3,223)	(1,445)
Inventory	(4,683)	(3,808)
Other assets	9	—
Other current liabilities	14	(340)
Accounts payable and accrued expenses	7,988	(1,735)
Deferred revenue	—	(168)
Other liabilities	(70)	158
Net cash used in operating activities	(44,157)	(42,598)
Cash flows from investing activities		
Purchases of property, plant and equipment	(420)	(2,040)
Net cash used in investing activities	(420)	(2,040)
Cash flows from financing activities		
Proceeds from issuance of common stock, net of commission	73,125	—
Payments for common stock issuance costs	(88)	—
Proceeds from exercise of stock options	257	144
Net cash provided by financing activities	73,294	144
Net increase (decrease) in cash and cash equivalents	28,717	(44,494)
Cash and cash equivalents at beginning of the period	111,810	200,290
Cash and cash equivalents at end of the period	$140,527	$155,796
Non-cash financing activities:		
Reclassification of derivative liability to equity	$62,735	$51,404

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

Keryx Biopharmaceuticals, Inc.
Notes to Condensed Consolidated Financial Statements
(unaudited)

Unless the context requires otherwise, references in this report to “Keryx,” “Company,” “we,” “us” and “our” refer to Keryx Biopharmaceuticals, Inc. and our subsidiaries.

NOTE 1 – DESCRIPTION OF BUSINESS

We are a commercial stage biopharmaceutical company focused on bringing innovative medicines to people with renal disease. Our long-term vision is to build a leading renal company. Our marketed product, Auryxia® (ferric citrate), which is an orally available, absorbable, iron-based medicine is approved in the United States for the control of serum phosphorus levels in patients with chronic kidney disease, or CKD, on dialysis. Ferric citrate is also approved in Japan under the trade name Riona® and marketed by our Japanese partner, Japan Tobacco, Inc., or JT, and its subsidiary, Torii Pharmaceutical Co., Ltd., or Torii, and approved in Europe as Fexeric®. We are also investigating the use of ferric citrate for the treatment of iron deficiency anemia, or IDA, in adults with non-dialysis dependent CKD, or NDD-CKD, and, pending potential approval for this indication, plan to leverage our U.S. clinical and commercial infrastructure and treat many more people with CKD. Our vision of building a leading renal company includes expansion of our product portfolio with other medicines that can help patients with kidney disease. We use the brand name Auryxia only when we refer to ferric citrate for use in the approved indication in the United States. We refer to the product as ferric citrate when referring to its investigational use.

NOTE 2 – BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements were prepared in accordance with U.S. generally accepted accounting principles, or GAAP, for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they may not include all of the information and footnotes required by GAAP for complete financial statements. All adjustments that are, in the opinion of management, of a normal recurring nature and are necessary for a fair presentation of these interim financial statements have been included. These interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements contained in our Annual Report on Form 10-K for the year ended December 31, 2016. The year-end condensed consolidated balance sheet data was derived from audited financial statements, but does not include all disclosures required by GAAP. The results of operations for the three and six months ended June 30, 2017 are not necessarily indicative of the results that may be expected for the entire fiscal year or any other interim period.

Principles of Consolidation

The condensed consolidated financial statements include our financial statements and those of our wholly-owned subsidiaries. Intercompany transactions and balances have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of these condensed consolidated financial statements and the reported amounts of revenues and expenses during the applicable reporting period. Actual results could differ from those estimates. Such differences could be material to these condensed consolidated financial statements.

Revenue Recognition

Our primary source of revenue during the reporting periods was product sales. We sell product to a limited number of major wholesalers, our Distributors, as well as certain pharmacies, or collectively, our Customers. Our Distributors resell the product to retail pharmacies for purposes of their reselling the product to fill patient prescriptions. In accordance with GAAP, our revenue recognition policy requires that: (i) there is persuasive evidence that an arrangement exists between us and the Customer, (ii) delivery has occurred, (iii) collectability is reasonably assured, and (iv) the price is fixed or determinable. In the fourth quarter of 2016, we began to recognize revenue under the pull-through (ex-factory) method based on sales to our Customers as a result of our ability to reasonably estimate

product returns based on our prior sales and return history.

Prior to the fourth quarter of 2016, we recognized revenue based on the resale of Auryxia for the purposes of filling patient prescriptions, and not based on initial sales from us to our Customers as we did not have sufficient history such that we could reliably estimate returns based on sales to our Customers. As a result, prior to the fourth quarter of 2016, we deferred Auryxia revenue recognition until the earlier of the product being resold for purposes of filling patient prescriptions and the expiration of the right of return (twelve months after the expiration date of the product). The deferred revenue was recorded net of discounts, rebates, and chargebacks. We also deferred the related cost of product sales and recorded such amounts as finished goods inventory held by others, which was included in inventory on our condensed consolidated balance sheet, until revenue related to such product sales was recognized.

Our U.S. Auryxia product sales for the three and six months ended June 30, 2017 and 2016 were offset by provisions for allowances and accruals as set forth in the tables below.

(in thousands)	Three months ended June 30, 2017	Percent of gross Auryxia product sales		Three months ended June 30, 2016	Percent of gross Auryxia product sales	
Gross Auryxia product sales	$26,029			$12,561		
Less provision for product sales allowances and accruals:						
Trade allowances	2,463	9	%	1,555	12	%
Rebates, chargebacks and discounts	8,784	34	%	2,543	20	%
Product returns	346	2	%	—	—	
Other incentives[1]	320	1	%	184	2	%
Total	11,913	46	%	4,282	34	%
Net U.S. Auryxia product sales	$14,116			$8,279		

(1) Includes co-pay assistance and voucher rebates.

(in thousands)	Six months ended June 30, 2017	Percent of gross Auryxia product sales		Six months ended June 30, 2016	Percent of gross Auryxia product sales	
Gross Auryxia product sales	$43,983			$21,185		
Less provision for product sales allowances and accruals						
Trade allowances	4,228	9	%	2,701	13	%
Rebates, chargebacks and discounts	14,114	32	%	4,221	20	%
Product returns	278	1	%	—	—	
Other incentives[1]	742	2	%	368	1	%
Total	19,362	44	%	7,290	34	%
Net U.S. Auryxia product sales	$24,621			$13,895		

(1) Includes co-pay assistance and voucher rebates.

Reclassifications

Certain amounts in the table above for the six months ended June 30, 2017, which also appears in Management's Discussion and Analysis of Financial Condition and Results of Operations, have been reclassified for consistency. Specifically, fees paid to a Customer for the three months ended March 31, 2017 totaling $0.5 million that were included in the caption "Rebates, chargebacks and discounts" were reclassified to the caption "Trade allowances" for the six months ended June 30, 2017. Total product sales allowances for the six months ended June 30, 2017 were not affected.

Basic and Diluted Net Loss Per Common Share

Basic net loss per share is computed by dividing the losses allocable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Diluted net loss per share does not reflect the effect of shares of common stock to be issued upon the exercise of stock options, as their inclusion would be anti-dilutive. The

options outstanding as of June 30, 2017 and 2016, which are not included in the computation of net loss per share amounts, were 12,468,869 and 8,869,094, respectively.

The following table presents amounts that were excluded from the calculation of diluted net loss per share, due to their anti-dilutive effect:

(in thousands)	June 30, 2017	June 30, 2016
Options to purchase common stock	12,469	8,869
Shares issuable upon conversion of convertible senior notes	33,422	33,422
	45,891	42,291

Concentrations of Credit Risk

We do not have significant off-balance-sheet risk or credit risk concentrations. We primarily maintain our cash and cash equivalents in deposit accounts and institutional money market funds. As of June 30, 2017, approximately $34.4 million of our total $140.5 million cash and cash equivalents balance was invested in institutional money market funds. See Note 3 – Fair Value Measurements.

Our accounts receivable, net at June 30, 2017 and December 31, 2016 represent amounts due to us from customers. We perform ongoing credit evaluations of our customers and generally do not require collateral. The following table sets forth customers who represented 10% or more of our total accounts receivable, net as of June 30, 2017 and December 31, 2016.

	June 30, 2017		December 31, 2016	
Fresenius Medical Care Rx	23	%	22	%
AmerisourceBergen Drug Corporation	22	%	23	%
Cardinal Health, Inc.	20	%	11	%
DaVita Rx	16	%	10	%
McKesson Corporation	14	%	31	%

We currently have two suppliers with three approved sites for the supply of Auryxia drug product. We are currently utilizing one of these suppliers at its two approved sites to manufacture Auryxia drug product and are conducting additional development work at the other supplier. If any of our suppliers were to limit or terminate production, or otherwise fail to meet the quality or delivery requirements needed to supply Auryxia at adequate levels, we could experience losses of revenue, which could materially and adversely impact our results of operations.

New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, or the FASB, or other standard setting bodies that we adopt as of the specified effective date.

In May 2014, the FASB issued Accounting Standards Update, or ASU, No. 2014-09, Revenue from Contracts with Customers (Topic 606), a comprehensive new standard which amends revenue recognition principles and provides a single set of criteria for revenue recognition among all industries. The new standard provides a five-step framework whereby revenue is recognized when promised goods or services are transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard also requires enhanced disclosures pertaining to revenue recognition in both interim and annual periods. The standard is effective for interim and annual periods beginning after December 15, 2017 and allows for adoption using a full retrospective method, or a modified retrospective method. The FASB has subsequently issued amendments to ASU No. 2014-09 that have the same effective date and transition date of January 1, 2018. We expect to adopt these standards using the modified retrospective method. We have identified the customer contracts that are in the scope of these standards and we are in the process of reviewing the contracts. Prior to January 1, 2018, we plan to complete our review of the identified customer contracts as well as our license agreements to determine the impact that these standards will have on our financial position, results of operations and disclosures.

In February 2016, the FASB issued ASU No. 2016-02, Leases. The new standard requires that all lessees recognize the assets and liabilities that arise from leases on the balance sheet and disclose qualitative and quantitative information about its leasing arrangements. The new standard will be effective for us on January 1, 2019. The adoption of this standard may have a material impact on our financial position as it may impact the amount of our assets and liabilities. We are currently evaluating the potential impact that this standard may have on our results of

operations.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments. The new standard addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. The new standard will be effective for us on January 1, 2018. This standard is not expected to have a material impact on our statement of cash flows upon adoption.

NOTE 3 – FAIR VALUE MEASUREMENTS

The following table provides the fair value measurements of applicable financial assets as of June 30, 2017 and December 31, 2016:

	Financial assets at fair value as of June 30, 2017			Financial assets at fair value as of December 31, 2016		
(in thousands)	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Assets:						
Cash equivalents[(1)]	$34,373	$ —	$ —	$107,084	$ —	$ —
Total assets	$34,373	$ —	$ —	$107,084	$ —	$ —

(1) Cash equivalents as of June 30, 2017 and December 31, 2016 consisted of institutional money market funds. The carrying value of our money market funds approximates fair value due to their short-term maturities.

Debt

In October 2015, we issued $125 million in Convertible Senior Notes, due 2020, or the Notes, in a private financing to funds managed by Baupost Group Securities, L.L.C., or Baupost. As of June 30, 2017 and December 31, 2016, the fair value of the Notes was $242 million and $196 million, respectively, which differs from their carrying value. The fair value of the Notes is influenced by our stock price and stock price volatility. See Note 9 – Debt for additional information on our debt obligations.

NOTE 4 – INVENTORY

Inventory consists of the following at June 30, 2017 and December 31, 2016:

(in thousands)	June 30, 2017	December 31, 2016
Raw materials	$596	$ 418
Work in process	15,499	11,430
Finished goods	1,990	833
Total inventory	$18,085	$ 12,681

NOTE 5 – STOCKHOLDERS' EQUITY (DEFICIT)

2017 Annual Meeting of Stockholders

At our 2017 Annual Meeting of Stockholders held on June 8, 2017, our stockholders approved an amendment to our certificate of incorporation to increase the number of authorized shares of our common stock to 230,000,000 shares. We filed the amendment with the Secretary of State of the State of Delaware on June 13, 2017.

Change in Stockholders' Equity (Deficit)

Total stockholders' equity (deficit) increased by $33.9 million during the six months ended June 30, 2017. This increase was primarily attributable to the proceeds from the issuance of common stock of $73.1 million, the reclassification of the derivative liability related to the Notes to equity of $62.7 million and $7.3 million related to stock-based compensation, partially offset by our net loss of approximately $110 million.

NOTE 6 – STOCK-BASED COMPENSATION EXPENSE

Equity Incentive Plans

As of June 30, 2017, a total of 2,144,634 shares were available for the issuance of stock options or other stock-based awards under our stock option and incentive plans.

Stock Options

The following table summarizes stock option activity for the six months ended June 30, 2017:

	Number of shares	Weighted average exercise price
Outstanding at December 31, 2016	8,677,998	$ 7.28
Granted	4,409,150	5.39
Exercised	(62,802)	4.09
Forfeited or Expired	(555,477)	7.07
Outstanding at June 30, 2017	12,468,869	$ 6.64
Vested and expected to vest at June 30, 2017	7,531,012	$ 7.50
Exercisable at June 30, 2017	4,079,875	$ 8.98

Upon the exercise of stock options, we issue new shares of our common stock. As of June 30, 2017, 4,361,250 options issued to employees are unvested, performance-based options.

Restricted Stock

Certain employees and directors have been awarded restricted stock under our equity incentive plans. The time-vesting restricted stock awards vest primarily over a period of three years. The following table summarizes restricted share activity for the six months ended June 30, 2017:

	Number of shares	Weighted average grant date fair value
Outstanding at December 31, 2016	1,524,884	$ 7.07
Granted	1,116,275	5.66
Vested	(394,323)	6.00
Forfeited	(90,193)	5.47
Outstanding at June 30, 2017	2,156,643	$ 6.61

As of June 30, 2017, 435,000 shares of restricted stock issued to employees are unvested, performance-based shares.

Stock-Based Compensation Expense

We incurred $3.7 million and $3.6 million of stock-based compensation expense related to equity incentive grants during the three months ended June 30, 2017 and 2016, respectively and $7.3 million and $6.8 million during the six months ended June 30, 2017 and 2016, respectively. The following table reflects stock-based compensation expense for the three and six months ended June 30, 2017 and 2016:

	Three months ended June 30,		Six months ended June 30,	
(in thousands)	2017	2016	2017	2016
Cost of goods sold	$28	$8	$88	$14
Research and development	483	880	1,061	1,585
Selling, general and administrative	3,161	2,665	6,187	5,247
Total stock-based compensation expense	$3,672	$3,553	$7,336	$6,846

Stock-based compensation costs capitalized as part of inventory were immaterial for the three and six months ended June 30, 2017 and 2016.

The fair value of stock options granted is estimated at the date of grant using the Black-Scholes pricing model. The expected term of options granted is derived from historical data, the expected vesting period and the full contractual term. Expected volatility is based on the historical volatility of our common stock. The risk-free interest rate is based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. We have assumed no expected dividend yield, as dividends have never been paid to stock or option holders and will not be paid for the foreseeable future.

The weighted average grant date fair value of stock options granted during the three months ended June 30, 2017 and 2016 was $4.65 and $5.01, respectively, and during the six months ended June 30, 2017 and 2016 was $3.86 and $3.42, respectively. We used historical information to estimate forfeitures of stock options. As of June 30, 2017, there was $12.3 million and $7.1 million of total unrecognized compensation cost related to non-vested stock options and restricted stock, respectively, each of which is expected to be recognized over weighted-average periods of 2.2 years. These amounts do not include 4,361,250 unvested options and 435,000 shares of unvested restricted stock as of June 30, 2017 which are performance-based and vest upon achievement of certain corporate milestones. Stock-based compensation for these awards will be measured and recorded if and when it is probable that the milestone will be achieved.

NOTE 7—LICENSE AGREEMENTS

In November 2005, we entered into a license agreement with Panion & BF Biotech, Inc., or Panion. Under the license agreement, we acquired the exclusive worldwide rights, excluding certain Asian-Pacific countries, for the development and marketing of ferric citrate. To date, we have paid an aggregate of $11.6 million of milestone payments to Panion. In addition, Panion is eligible to receive royalty payments based on a mid-single digit percentage of net sales of ferric citrate in the licensed territory, as well as a manufacturing fee for product manufactured for use in the licensed territory.

In September 2007, we entered into a Sublicense Agreement with JT and Torii, under which JT and Torii obtained the exclusive sublicense rights for the development and commercialization of ferric citrate in Japan. JT and Torii are responsible for the future development and commercialization costs in Japan. Effective June 8, 2009, we entered into an Amended and Restated Sublicense Agreement, or Revised Agreement, with JT and Torii, which, among other things, provided for the elimination of all significant on-going obligations under the Sublicense Agreement.

In January 2014, JT and Torii received manufacturing and marketing approval of ferric citrate from the Japanese Ministry of Health, Labour and Welfare. Ferric citrate launched in May 2014 and is marketed in Japan by Torii under the brand name Riona, is indicated as an oral treatment for the improvement of hyperphosphatemia in patients with CKD. Under the terms of the Revised Agreement, we receive royalty payments based on a tiered double-digit percentage of net sales of Riona in Japan escalating up to the mid-teens and may also receive up to an additional $55.0 million upon the achievement of certain annual net sales milestones. In accordance with our revenue recognition policy, royalty revenues are recognized in the quarter that JT and Torii provide their written report and related information to us regarding sales of Riona, which generally will be one quarter following the quarter in which the underlying sales by JT and Torii occurred. For each of the three months ended June 30, 2017 and 2016, we recorded $1.0 million in license revenue related to royalties earned on net sales of Riona in Japan. For the six months ended June 30, 2017 and 2016, we recorded $2.3 million and $2.2 million, respectively, in license revenue related to royalties earned on net sales of Riona in Japan. We record the associated mid-single digit percentage of net sales royalty expense due Panion, the licensor of ferric citrate, in the same period as the royalty revenue from JT and Torii

is recorded. For each of the three months ended June 30, 2017 and 2016, we recorded $0.6 million in license expenses related to royalties due to the licensor of ferric citrate relating to sales of Riona in Japan. For the six months ended June 30, 2017 and 2016, we recorded $1.4 million and $1.3 million, respectively, in license expenses related to royalties due to the licensor of ferric citrate relating to sales of Riona in Japan.

NOTE 8 – ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consists of the following at June 30, 2017 and December 31, 2016:

(in thousands)	June 30, 2017	December 31, 2016
Accounts payable	$7,696	$ 2,225
Accrued compensation and related liabilities	5,709	8,190
Professional, license, and other fees and expenses	6,374	6,159
Commercial rebates, fees and returns	10,367	4,616
Total accounts payable and accrued expenses	$30,146	$ 21,190

NOTE 9 – DEBT

In October 2015, we completed the sale of $125 million of Notes due 2020, in a private placement, or the Private Placement, to funds managed by Baupost pursuant to a Notes Purchase Agreement dated October 14, 2015. The Notes were issued under an Indenture, or the Indenture, dated as of October 15, 2015, with The Bank of New York Mellon Trust Company, N.A. as trustee, or the Trustee. The Indenture subjects us to certain financial and business covenants and contains restrictions on the payments of cash dividends.

The Indenture contains customary terms and events of default. If an event of default (other than certain events of bankruptcy, insolvency or reorganization involving us) occurs and is continuing, the Trustee by notice to us, or the holders of at least 25% in aggregate principal amount of the outstanding Notes by written notice to us and the Trustee, may declare 100% of the principal on all of the Notes to be due and payable. Upon such a declaration of acceleration, such principal will be due and payable immediately. Upon the occurrence of certain events of bankruptcy, insolvency or reorganization involving us, 100% of the principal on all of the Notes will become due and payable automatically.

Further, in connection with the Private Placement, we entered into a Registration Rights Agreement with the purchasers of the Notes, or the Registration Rights Agreement, pursuant to which we agreed to (i) file a registration statement, or the Resale Registration Statement with the Securities and Exchange Commission, or SEC, covering the resale of the Notes and the underlying common stock which the Notes are convertible into upon the written request of Baupost, and (ii) use commercially reasonable efforts, subject to receipt of necessary information from all the purchasers of the Notes, to cause the SEC to declare the Resale Registration Statement effective. Further, the Registration Rights Agreement permits Baupost to demand from time to time that we file a shelf Registration Statement pursuant to Rule 415 of the Securities Act from which any number of shelf takedowns may be conducted upon written request from Baupost. Finally, the Registration Rights Agreement affords Baupost certain piggyback registration rights.

The Notes are convertible at the option of Baupost at an initial conversion rate of 267.3797 shares of our common stock per $1,000 principal amount, equal to a conversion price of $3.74 per share, which represents the last reported sale price of our stock on October 14, 2015. The conversion rate is subject to adjustment from time to time upon the occurrence of certain events. Further, upon the occurrence of certain fundamental changes involving us, Baupost may require us to repurchase for cash all or part of their Notes at a repurchase price equal to 100% of the principal amount of the Notes to be repurchased.

At issuance, a portion of the Notes was contingently convertible into cash if our stockholders did not approve an increase in the number of authorized shares of our common stock by July 1, 2016. In accordance with accounting guidance for debt with a conversion option, we separated the conversion option from the debt instrument and accounted for it separately as a derivative liability, due to the Notes initially being partially convertible to cash at the option of Baupost. We allocated the proceeds between the debt component and the embedded conversion option (the derivative) by performing a valuation of the derivative as of the transaction date, which was determined based on the difference between the fair value of the Notes with the conversion option and the fair value of the Notes without the conversion option. The fair value of the derivative liability was recognized as a debt discount and the carrying amount of the convertible senior notes represents the difference between the proceeds from the issuance of the Notes and the fair value of the derivative liability on the date of issuance. The excess of the principal amount of the debt component

over its carrying amount, or debt discount, was amortized to interest expense using the effective interest method over the expected life of the debt.

Our outstanding convertible senior notes balance was $125 million as of June 30, 2017 and December 31, 2016. We determined the expected life of the debt was equal to the period through July 1, 2016, as this represented the earliest point at which a portion of the Notes was initially contingently convertible into cash. Accordingly, for the three and six months ended June 30, 2016 approximately $18.5 million and $34.2 million of interest expense was recognized related to the Notes, all of which was attributable to the amortization of the debt discount.

Following our 2016 Annual Meeting of Stockholders held on May 25, 2016, we filed a certificate of amendment to our certificate of incorporation with the Secretary of State of the State of Delaware to increase the number of authorized shares of our common stock to allow for the full conversion of the Notes into our common stock. On April 10, 2017, we entered into the First Supplemental Indenture, or the First Supplement, to the Indenture. Under the terms of the First Supplement, the Notes issued under the Indenture were not convertible by the holders thereof until on or after June 8, 2017, except in connection with a “fundamental change” as defined in the Indenture. After June 8, 2017, the Notes are convertible entirely into shares of our common stock or cash depending upon the number of shares of our common stock authorized at the time of such conversion. At our 2017 Annual Meeting of Stockholders held on June 8, 2017, our stockholders ratified the filing and effectiveness of the certificate of amendment filed in May 2016. In addition, at the meeting our stockholders also approved a separate amendment to our certificate of incorporation to increase the number of authorized shares of our common stock to 230,000,000 shares. As a result, the full amount of the Notes is convertible into shares of our common stock. The holders of the Notes may, at their option, convert the Notes until the maturity date thereof.

In accordance with accounting guidance for debt modifications and exchanges, we assessed the terms of the First Supplement and determined that it resulted in a modification. During the three months ended June 30, 2017, we separated the conversion option from the debt instrument and accounted for it separately as a derivative liability, due to the Notes being contingently convertible to cash at the option of Baupost per the terms of the First Supplement. We allocated the proceeds between the debt component and the embedded conversion option (the derivative) by performing a valuation of the derivative as of the date of the First Supplement, which was determined based on the difference between the fair value of the Notes with the conversion option and the fair value of the Notes without the conversion option. The fair value of the derivative liability was recognized as a debt discount and the carrying amount of the convertible senior notes represented the difference between the principal amount of the Notes and the fair value of the derivative liability on the date of the First Supplement. The excess of the principal amount of the debt component over its carrying amount, or debt discount, was amortized to interest expense using the effective interest method over the expected life of the debt. We determined the expected life of the debt was equal to the period through June 8, 2017, as this represented the point at which the Notes was contingently convertible into cash.

In the three and six months ended June 30, 2017, $63.0 million of interest expense was recognized related to the Notes. As of June 30, 2017 and December 31, 2016, the carrying value of the Notes was $125 million, and the fair value of the Notes was $242 million and $196 million, respectively.

NOTE 10 – OTHER INCOME (EXPENSE), NET

The components of other income (expense), net are as follows:

	Three months ended June 30,		Six months ended June 30,	
(in thousands)	2017	2016	2017	2016
Interest income	$118	$185	$235	$387
Other income (expense)	(5)	7	(8)	12
Fair value adjustment to derivative liability	225	(2,711)	225	(4,718)
	$338	$(2,519)	$452	$(4,319)

The fair value adjustment to the derivative liability was recorded in connection with the Notes and related First Supplement. See Note 9 - Debt for additional information.

NOTE 11 – COMMITMENTS AND CONTINGENCIES

Commitments

As of June 30, 2017, our contractual obligations and commitments primarily consist of our obligations under non-cancelable leases, the Notes, and various agreements with third parties, including selling, general and administrative, research and development and manufacturing agreements.

Contingencies

We accrue a liability for legal contingencies when we believe that it is both probable that a liability has been incurred and that we can reasonably estimate the amount of the loss. We review these accruals and adjust them to reflect the best information available at the time. To the extent new information is obtained and our views on the probable outcomes of claims, suits, assessments, investigations or legal proceedings change, changes in our accrued liabilities would be recorded in the period in which such determination is made. For the matters referenced below, a liability is not probable or the amount cannot be reasonably estimated and, therefore, an accrual has not been made. In addition, in accordance with the relevant authoritative guidance, for any matters in which the likelihood of material loss is at least reasonably possible, we will provide disclosure of the possible loss or range of loss. If a reasonable estimate cannot be made, however, we will provide disclosure to that effect. We expense legal costs as they are incurred.

Four purported class action lawsuits have been filed against us and certain of our current and former officers (Gregory P. Madison, Scott A. Holmes, Ron Bentsur, and James Oliviero). Three of these actions were filed in the U.S. District Court for the Southern District of New York, captioned respectively Terrell Jackson v. Keryx Biopharmaceuticals, Inc., et al., No. 1:16-cv-06131, filed on August 2, 2016, Richard J. Erickson v. Keryx Biopharmaceuticals, Inc., et al. No. 1:16-cv-06218, filed on August 4, 2016, and Richard King v. Keryx Biopharmaceuticals, Inc., et al., No. 1:16-cv-06233, filed on August 5, 2016. The Jackson complaint purports to be brought on behalf of stockholders who purchased our common stock between February 25, 2016 and August 1, 2016, the Erickson complaint purports to be brought on behalf of stockholders who purchased our common stock between March 2, 2016 and July 29, 2016, and the King complaint purports to be brought on behalf of stockholders who purchased our common stock between February 25, 2016 and July 29, 2016. On August 26, 2016, the fourth complaint, captioned Tim Karth v. Keryx Biopharmaceuticals, Inc., et al., No. 1:16-cv-11745, was filed in the U.S. District Court for the District of Massachusetts, which complaint was subsequently amended. The Karth complaint purports to be brought on behalf of stockholders who purchased our common stock between May 8, 2013 and August 1, 2016. The Jackson, Erickson and King matters were transferred to the U.S. District Court for the District of Massachusetts on April 5, 2017. The Karth plaintiffs have filed a motion to consolidate the actions and the defendants have joined in that motion. The Jackson, Erickson and King plaintiffs are currently challenging the appointment of the Karth plaintiffs as lead plaintiff. Each complaint generally alleges that we and certain of our current and former officers violated Sections 10(b) and/or 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder by making allegedly false and/or misleading statements concerning us and our business operations and future prospects in light of the August 1, 2016 announcement of an interruption in our supply of Auryxia. Two stockholder derivative complaints were also filed on December 16, 2016 against us and certain of our current and former officers (Gregory P. Madison, Scott A. Holmes, Ron Bentsur and

James Oliviero), certain of our current directors (Kevin J. Cameron, Daniel P. Regan, Steven C. Gilman, Michael Rogers and John P. Butler) and our former directors (Michael P. Tarnok, Joseph Feczko, Jack Kaye and Wyche Fowler, Jr.), in the Superior Court of Massachusetts, one captioned Venkat Vara Prasad Malledi v. Keryx Biopharmaceuticals, Inc., et al., No. 16-3865 and one captioned James Anderson v. Keryx Biopharmaceuticals, Inc., et al., No. 16-3866. Each of these two complaints generally allege that the individual defendants breached their fiduciary duties owed to us, unjustly enriched themselves by their actions, abused their control positions with us, mismanaged us and wasted corporate assets since July 31, 2013 in light of our August 1, 2016 announcement by us of an interruption in the supply of the our product Auryxia. On June 27, 2017, the Superior Court granted the parties' motion to consolidate and stay the derivative litigations. All of the complaints seek unspecified damages, interest, attorneys' fees, and other costs. We deny any allegations of wrongdoing and intend to vigorously defend against these lawsuits. There is no assurance, however, that we or the other defendants will be successful in our defense of either of these lawsuits or that insurance will be available or adequate to fund any settlement or judgment or the litigation costs of these actions. Moreover, we are unable to predict the outcome or reasonably estimate a range of possible losses at this time. A resolution of these lawsuits adverse to us or the other defendants, however, could have a material effect on our financial position and results of operations in the period in which the particular lawsuit is resolved.

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

Unless the context requires otherwise, references in this report to "Keryx," the "Company," "we," "us" and "our" refer to Kery Biopharmaceuticals, Inc. and our subsidiaries.

The following discussion and analysis contains forward-looking statements about our plans and expectations of what may happen in the future. Forward-looking statements are based on a number of assumptions and estimates that are inherently subject to significant risks and uncertainties, and our results could differ materially from the results anticipated by our forward-looking statements as a result of many known or unknown factors, including, but not limited to, those factors discussed under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2016. See also the "Special Cautionary Notice Regarding Forward-Looking Statements" set forth at the beginning of this report.

You should read the following discussion and analysis in conjunction with the unaudited condensed consolidated financial statements, and the related footnotes thereto, appearing elsewhere in this report, and in conjunction with management's discussion and analysis and the audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2016.

OVERVIEW

We are a commercial stage biopharmaceutical company focused on bringing innovative medicines to people with renal disease. Our long-term vision is to build a leading renal company. Our marketed product, Auryxia (ferric citrate), which is an orally available, absorbable, iron-based medicine is approved in the United States for the control of serum phosphorus levels in patients with chronic kidney disease, or CKD, on dialysis. Ferric citrate is also approved in Japan under the trade name Riona and marketed by our Japanese partner, Japan Tobacco, Inc., or JT, and its subsidiary, Torii Pharmaceutical Co., Ltd., or Torii, and approved in Europe as Fexeric. We are also investigating the use of ferric citrate for the treatment of iron deficiency anemia, or IDA, in adults with stage 3-5 non-dialysis dependent CKD, or NDD-CKD, and, pending potential approval for this indication, plan to leverage our U.S. clinical and commercial infrastructure and treat many more people with CKD. Our vision of building a leading renal company includes expansion of our product portfolio with other medicines that can help patients with kidney disease. We use the brand name Auryxia only when we refer to ferric citrate for use in the approved indication in the United States. We refer to the product as ferric citrate when referring to its investigational use.

OUR STRATEGY

Our business is focused on creating long-term stockholder value by bringing differentiated medicines for the treatment of people with kidney disease to the market that provide meaningful benefits to patients and their healthcare providers. The three pathways to our strategy are:

Maximize Auryxia's Potential

We developed and subsequently launched Auryxia in the United States in late December 2014. Auryxia is a non-calcium, non-chewable orally-administered phosphate binder for patients with CKD on dialysis. Auryxia is being marketed in the United States to renal care teams through our specialty salesforce and commercial infrastructure. In the United States, there are approximately 450,000 adult patients with CKD requiring dialysis (referred to as End Stage Renal Disease, or ESRD), including approximately 350,000 adults currently taking a phosphate binder. Our field-based organization is aligned to 95 territories calling on target nephrologists and their associated dialysis centers. We believe strong fundamentals are in place to continue to drive commercial adoption of Auryxia in the dialysis setting.

We also believe that we can maximize the potential of ferric citrate through potential approval of a second indication - the treatment of IDA, NDD-CKD patients. We completed a pivotal Phase 3 clinical trial evaluating ferric citrate for this indication and presented results from this trial to the medical community at the American Society of Nephrology’s Kidney Week 2016 Annual Meeting. The results from this trial were also published online in the Journal of the American Society of Nephrology in January 2017. We submitted a supplemental new drug application, or sNDA, to the U.S. Food and Drug Administration, or FDA, in January 2017 seeking to expand the label for Auryxia to include the treatment of IDA in NDD-CKD patients, which was accepted by the FDA for review in March 2017. A Prescription Drug User Fee Act, or PDUFA, target action date for the FDA's review of this sNDA was set for November 6, 2017, and, if approved, we could potentially make the medicine available to these patients immediately thereafter. We estimate that in the United States, approximately 1.7 million adults under the care of a nephrologist have IDA, NDD-CKD, including approximately 650,000 adults currently being treated by nephrologists for IDA. IDA is common in the NDD-CKD population and the prevalence and severity increases as CKD advances. IDA is symptomatic and can significantly impact quality of life. There is significant literature that correlates anemia with increased risk of heart disease and death. No oral iron medications are currently FDA-approved to treat IDA, NDD-CKD.

Expand Our Portfolio

We will evaluate opportunities to expand our product portfolio with other medicines that can help patients with kidney disease. Our business development activities include evaluating several clinical-drug candidates and commercial medicines to in-license or acquire to add to our portfolio and provide us with new commercial opportunities. We will seek to add assets that leverage the infrastructure we have built to support our foundational medicine, Auryxia, including our clinical development and commercial teams. We believe these efforts have the potential to provide additional revenues to us in the future.

Manage Growth and Talent

We are committed to creating a culture of success and continue to engage a work force of high-quality and talented people to support our potential growth.

Financial Performance Overview

Net U.S. Auryxia product sales represents the gross product sales of Auryxia in the United States less provisions for product sales allowances and accruals. These provisions include trade allowances, rebates, chargebacks and discounts, product returns and other incentives.

Our license revenues consist of license fees, royalties, and milestone payments arising from our agreement with JT and Torii. Royalty revenue consists of royalties received from JT and Torii on net sales of Riona in Japan. Based on our agreement with JT and Torii, and in accordance with our revenue recognition policy described below, royalty revenues are recognized in the quarter that JT and Torii provide their written report and related information to us regarding sales of Riona, which generally will be one quarter following the quarter in which the underlying sales by JT and Torii occurred.

Cost of goods sold includes the cost of active pharmaceutical ingredient, or API, for Auryxia on which product sales were recognized during the period, the associated costs for tableting, packaging, shipment, insurance and quality assurance, as well as any idle capacity charges we may incur at our contract manufacturers and write-offs of inventory that fails to meet specifications or is otherwise no longer suitable for commercial manufacture. Cost of goods sold also includes expenses due to the licensor of Auryxia related to the manufacturing of product and product sales recognized during the period.

Our license expenses consist of royalty and other expenses due to the licensor of Auryxia related to our license agreement with JT and Torii. With regard to license expense, such expense is directly related to the royalty revenue received from JT and Torii and is recognized in the same period as the license revenue is recorded. Other expenses are recognized in the period they are incurred.

Our research and development expenses consist primarily of salaries and related personnel costs, including stock-based compensation, fees paid to consultants and outside service providers for clinical and laboratory development, manufacturing, including pre-approval inventory build-up, regulatory, facilities-related and other expenses relating to the design, development, manufacture, testing, and enhancement of our drug candidates and technologies, as well as expenses related to in-licensing of new product candidates. We expense our research and development costs as they are incurred.

Our selling, general and administrative expenses consist primarily of salaries and related expenses, including stock-based compensation, for executive, finance, sales, marketing and other administrative personnel, recruitment expenses, professional fees and other corporate expenses, including investor relations, legal activities, pre-commercial/commercial activities and facilities-related expenses.

Our results of operations include stock-based compensation expense as a result of the grants of stock options and restricted stock. Stock-based compensation expense for awards of options and restricted stock granted to employees and directors represents the fair value of the award recorded over the respective vesting periods of the individual awards. The expense is classified by expense categories in the condensed consolidated statements of operations. We expect to continue to incur significant stock-based compensation expenses.

Even though our trials demonstrated that Auryxia is effective in the control of serum phosphorus levels in patients with CKD on dialysis, there is no guarantee that we will be able to record meaningful commercial sales of Auryxia in the future or become profitable. In addition, we expect losses to continue as we continue to fund the development and commercialization of Auryxia, including, but not limited to, sNDA submissions, building of inventory, commercial activities, ongoing and additional clinical trials, and the potential acquisition and development of additional drugs or drug candidates in the future. As we continue our development efforts, we may enter into additional third-party collaborative agreements and may incur additional expenses, such as licensing fees and milestone payments. As a result, our quarterly results may fluctuate and a quarter-by-quarter comparison of our operating results may not be a meaningful indication of our future performance.

GENERAL CORPORATE

We have devoted substantially all of our efforts to the identification, in-licensing, development and partnering of drug candidates, as well as pre-commercial/commercial activities related to Auryxia, and have incurred negative cash flow from operations each year since our inception. We have spent, and expect to continue to spend, substantial amounts in connection with implementing our business strategy, including our product development efforts, our clinical trials, commercial, partnership and licensing activities. Prior to the U.S. launch of Auryxia in late December 2014, we had not commercialized any drug. Our ability to achieve profitability depends on a number of factors, including our ability to complete our development efforts, obtain additional regulatory approvals for our drug, successfully complete any post-approval regulatory obligations and successfully manufacture and commercialize our drug. We may continue to

incur substantial operating losses even after we begin to generate meaningful revenues from our drug.

CRITICAL ACCOUNTING POLICIES

The discussion and analysis of our financial condition and results of operations is based upon our condensed consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amount of assets and liabilities and related disclosure of contingent assets and liabilities at the date of our condensed consolidated financial statements and the reported amounts of revenues and expenses during the applicable period. On an ongoing basis, we evaluate our estimates and judgments, including those related to net product revenue, stock-based compensation, accruals for Clinical Research Organizations and Clinical Site Costs, inventory, net accounts receivable and accounting related to goodwill. We base our estimates on historical experience, known trends and events and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

For a discussion of our critical accounting estimates, please see Part II, Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations - Critical Accounting Policies" of our Annual Report on Form 10-K for the year ended December 31, 2016. There have been no material changes to these critical accounting estimates as described in that Form 10-K.

NEW ACCOUNTING PRONOUNCEMENTS

For a discussion of new accounting standards, see Note 2—Basis of Presentation and Summary of Significant Accounting Policies to our condensed consolidated financial statements included in this report.

RESULTS OF OPERATIONS

Three months ended June 30, 2017 and June 30, 2016

Net U.S. Auryxia Product Sales. For the three months ended June 30, 2017, we recognized $14.1 million in product sales of Auryxia, net of allowances, discounts, incentives, rebates and chargebacks, as compared with $8.3 million for the three months ended June 30, 2016.

(in thousands)	Three months ended June 30, 2017	Percent of gross Auryxia product sales		Three months ended June 30, 2016	Percent of gross Auryxia product sales	
Gross Auryxia product sales	$26,029			$12,561		
Less provision for product sales allowances and accruals						
Trade allowances	2,463	9	%	1,555	12	%
Rebates, chargebacks and discounts	8,784	34	%	2,543	20	%
Product returns	346	2	%	—	—	
Other incentives[(1)]	320	1	%	184	2	%
Total	11,913	46	%	4,282	34	%
Net U.S. Auryxia product sales	$14,116			$8,279		

[(1)] Includes co-pay mitigation and voucher rebates.

Gross Auryxia product sales increased for the three months ended June 30, 2017 as compared to the same period in 2016 primarily as a result of an increase in patient prescriptions and related units sold. Provisions for product sales allowances and accruals as a percentage of gross Auryxia product sales for the three months ended June 30, 2017 as compared to the same period in 2016 increased primarily as a result of a higher percentage of sales through government and commercial contracts that receive a larger rebate.

Beginning in the fourth quarter of 2016, we began to recognize revenue under the pull-through (ex-factory) method based on sales to our customers as a result of our ability to reasonably estimate product returns. We expect net Auryxia product sales to increase for the remainder of 2017 as compared to the first half of 2017 as we continue to focus our efforts on expanding the commercialization of Auryxia and continue to gain market share as a result of our selling efforts and broader reimbursement of Auryxia.

License Revenue. For each of the three months ended June 30, 2017 and 2016, we recognized $1.0 million in license revenue on royalty payments from sales of Riona in Japan.

Cost of Goods Sold. For the three months ended June 30, 2017, we recognized $4.4 million in cost of goods sold, as compared to $5.1 million for the three months ended June 30, 2016. This decrease was primarily due to a decrease of inventory write-offs in the 2017 period as compared to the 2016 period, partially offset by additional units sold in the 2017 period as compared to the 2016 period.

License Expenses. For each of the three months ended June 30, 2017 and 2016, we recognized $0.6 million in license expenses related to royalties due to the licensor of Auryxia relating to sales of Riona in Japan.

Research and Development Expenses. Research and development expenses increased by $2.0 million to $9.0 million for the three months ended June 30, 2017, as compared to $7.0 million for the three months ended June 30, 2016. The increase in research and development expenses was primarily due to an increase in process development-related manufacturing costs as we seek to increase our manufacturing capabilities. We expect our research and development expenses will increase for the remainder of 2017 as compared to the six months ended June 30, 2017, due to continued process development-related manufacturing costs, as well as our investments in investigator sponsored research, pediatric study requirements and other clinical trials which we expect will begin in 2017.

16

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased by $4.8 million to $25.0 million for the three months ended June 30, 2017, as compared to $20.2 million for the three months ended June 30, 2016. The increase was primarily due to an increase in personnel costs attributable to the continued commercialization of Auryxia. We expect our selling, general and administrative costs to increase slightly for the remainder of 2017 as compared to the six months ended June 30, 2017, due to costs associated with preparing for the potential approval and launch of ferric citrate for the treatment of IDA in patients with stage 3-5 NDD-CKD.

Other income (expense). Other income (expense) for the three months ended June 30, 2017 was $62.6 million in expenses as compared to $21.0 million in expenses for the three months ended June 30, 2016. The increase was primarily due to an increase in the amortization of the debt discount of $44.5 million offset by a change in the fair value adjustment to the derivative liability related to our convertible senior notes of $3.0 million.

Income Taxes. For each of the three months ended June 30, 2017 and 2016, we recognized $20,000 in income tax expense related to the recording of a deferred tax liability associated with capitalized goodwill, an indefinite-lived intangible asset that is being amortized for tax purposes.

Six months ended June 30, 2017 and June 30, 2016

Net U.S. Auryxia Product Sales. For the six months ended June 30, 2017, we recognized $24.6 million in product sales of Auryxia, net of allowances, discounts, incentives, rebates and chargebacks, as compared with $13.9 million for the six months ended June 30, 2016.

(in thousands)	Six months ended June 30, 2017	Percent of gross Auryxia product sales		Six months ended June 30, 2016	Percent of gross Auryxia product sales	
Gross Auryxia product sales	$43,983			$21,185		
Less provision for product sales allowances and accruals						
Trade allowances	4,228	9	%	2,701	13	%
Rebates, chargebacks and discounts	14,114	32	%	4,221	20	%
Product returns	278	1	%	—	—	
Other incentives[1]	742	2	%	368	1	%
Total	19,362	44	%	7,290	34	%
Net U.S. Auryxia product sales	$24,621			$13,895		

[1] Includes co-pay mitigation and voucher rebates.

Gross Auryxia product sales increased for the six months ended June 30, 2017 as compared to the same period in 2016 primarily as a result of an increase in patient prescriptions and related units sold. Provisions for product sales allowances and accruals as a percentage of gross Auryxia product sales for the six months ended June 30, 2017 as compared to the same period in 2016 increased primarily as a result of a higher percentage of sales through government and commercial contracts that receive a larger rebate.

As noted above, beginning in the fourth quarter of 2016, we began to recognize revenue under the pull-through (ex-factory) method based on sales to our customers as a result of our ability to reasonably estimate product returns.

License Revenue. For the six months ended June 30, 2017, we recognized $2.3 million in license revenue on royalty payments from sales of Riona in Japan as compared to $2.2 million for the six months ended June 30, 2016. This increase was due to increased sales by JT and Torii of Riona in Japan.

Cost of Goods Sold. For the six months ended June 30, 2017, we recognized $8.7 million in cost of goods sold, as compared to $6.2 million for the six months ended June 30, 2016. This increase was primarily due to additional units sold during the 2017 period as compared to the 2016 period, partially offset by a decrease of inventory write-offs in the 2017 period as compared to the 2016 period.

License Expenses. For the six months ended June 30, 2017, we recognized $1.4 million in license expenses related to royalties due to the licensor of Auryxia relating to sales of Riona in Japan as compared to $1.3 million for the six months ended June 30, 2016. This increase was due to an increase in sales of Riona in Japan during the 2017 period.

17

Research and Development Expenses. Research and development expenses increased by $1.2 million to $15.8 million for the six months ended June 30, 2017, as compared to $14.6 million for the six months ended June 30, 2016. The increase in research and development expenses was primarily due to an increase in process development-related manufacturing costs as we seek to increase our manufacturing capabilities, as well as an increase in filing fees related to our submission of the sNDA for ferric citrate in the NDD-CKD setting, which occurred in the first quarter of 2017.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased by $7.1 million to $48.1 million for the six months ended June 30, 2017, as compared to $41.0 million for the six months ended June 30, 2016. The increase was primarily due to an increase in personnel costs attributable to the continued commercialization of Auryxia and costs associated with preparing for the potential approval and launch of ferric citrate for the treatment of IDA in patients with stage 3-5 NDD-CKD.

Other income (expense). Other income (expense) for the six months ended June 30, 2017 was $62.5 million in expenses as compared to $38.5 million in expenses for the six months ended June 30, 2016. The increase was primarily due to an increase in the amortization of the debt discount of $29.0 million offset by a change in the fair value adjustment to the derivative liability related to our convertible senior notes of $5.0 million.

Income Taxes. For each of the six months ended June 30, 2017 and 2016, we recognized $40,000 in income tax expense related to the recording of a deferred tax liability associated with capitalized goodwill, an indefinite-lived intangible asset that is being amortized for tax purposes.

LIQUIDITY AND CAPITAL RESOURCES

Our major sources of cash have been proceeds from various public and private offerings of our common stock, the issuance of convertible senior notes, from the upfront and milestone payments from our agreement with JT and Torii, sales of Auryxia, option and warrant exercises, interest income, and miscellaneous payments from our other prior licensing activities. The commercial launch of our product, Auryxia, occurred in late December 2014 and we began to recognize revenue from the sales of Auryxia in 2015. Even if we successfully commercialize Auryxia, we may not become profitable. Our ability to achieve profitability depends on a number of factors, including our ability to complete our development efforts, obtain additional regulatory approvals for our drug, successfully complete any post-approval regulatory obligations and successfully manufacture and commercialize our drug alone or in partnership. We may continue to incur substantial operating losses even after we begin to generate meaningful revenues from Auryxia.

In November 2016, we filed a registration statement on Form S-3 (No. 333-214513), which the SEC declared effective on December 6, 2016, which registered the issuance from time to time of up to $250 million of our securities. At that time, we also entered into a Controlled Equity Offering^{SM} Sales Agreement, or the Sales Agreement, with Cantor Fitzgerald & Co., as sales agent, or Cantor Fitzgerald, pursuant to which we were initially able to offer and sell, from time to time, through Cantor Fitzgerald, shares of our common stock having an aggregate offering price of up to $75.0 million. During the three and six months ended June 30, 2017, we sold 10,753,754 and 11,574,320 shares, respectively, under the Sales Agreement for aggregate net proceeds of $68.0 million and $73.1 million, respectively. The sales during the six months ended June 30, 2017 amounted to the initial $75.0 million issuable pursuant to the Sales Agreement. Shortly after the filing of this report, we intend to file a new prospectus supplement with the SEC relating to the Sales Agreement under which we may offer and sell, from time to time, through Cantor Fitzgerald, shares of our common stock having an additional aggregate offering price of up to $75.0 million. The initial $75.0 million of common stock issued pursuant to the Sales Agreement and the additional $75.0 million of common stock we expect to be issuable pursuant to the Sales Agreement is included as part of the $250 million registered on the registration statement referred to above.

In October 2015, we completed the sale of $125 million of Convertible Senior Notes due 2020, or the Notes, to funds managed by The Baupost Group, L.L.C, or Baupost. See Note 9 – Debt for a description of the Notes. We also entered into a Registration Rights Agreement with the purchasers of the Notes, or the Registration Rights Agreement, pursuant to which we agreed to (i) file a registration statement with the SEC covering the resale of the Notes and the underlying common stock which the Notes are convertible into upon the written request of Baupost, and (ii) use commercially reasonable efforts, subject to receipt of necessary information from all the purchasers of the Notes, to cause the SEC to declare such resale registration statement effective. Further, the Registration Rights Agreement

permits Baupost to demand from time to time that we file a shelf Registration Statement pursuant to Rule 415 of the Securities Act from which any number of shelf takedowns may be conducted upon written request from Baupost. In addition, the Registration Rights Agreement provides Baupost certain piggyback registration rights.

As of June 30, 2017, we had $141 million in cash and cash equivalents, as compared to $112 million in cash and cash equivalents at December 31, 2016, representing an increase of $29 million. The increase in cash and cash equivalents was primarily due to net proceeds from sales of our common stock under the Sales Agreement as discussed above, partially offset by cash used to fund operations.

We currently expect that our existing capital resources, future anticipated cash flows from product sales and the funds from the future issuance of common stock will be sufficient to execute our current business objectives. The actual amount of cash that we will need to operate is subject to many factors, including, but not limited to, the timing and expenditures associated with commercial activities related to Auryxia and the timing and magnitude of cash received from product sales, the timing and expenditures associated with the build-up of inventory and capacity expansion, and the timing, design and conduct of clinical trials for ferric citrate. As a result of these factors, we will need to seek additional financings to provide the cash necessary to execute our current operations, including beyond commercializing Auryxia, and to develop and commercialize any drugs or drug candidates we may in-license or acquire. For a detailed discussion regarding the risks and uncertainties related to our liquidity and capital resources, please refer to our Risk Factor, “Our existing capital resources may not be adequate to finance our operating cash requirements for the length of time that we have estimated” included in our Annual Report on Form 10-K for the year ended December 31, 2016 and the other risk factors contained therein.

Net cash used in operating activities for the six months ended June 30, 2017 was $44.2 million as compared to $42.6 million net cash used in operating activities for the same period in 2016. This increase in net cash used in operating activities was primarily related to an increase in net loss after non-cash adjustments.

Net cash used in investing activities for the six months ended June 30, 2017 was $0.4 million as compared to $2.0 million net cash used in investing activities for the same period in 2016. The net cash used in investing activities for the six months ended June 30, 2017 and 2016 relates to purchases of property, plant and equipment in connection with certain leasehold improvements.

Net cash provided by financing activities for the six months ended June 30, 2017 was $73.3 million as compared to $0.1 million for the same period in 2016. Net cash provided by financing activities for the six months ended June 30, 2017 is attributable to the net proceeds from the issuance of common stock under the Sales Agreement.

OBLIGATIONS AND COMMITMENTS

As of June 30, 2017, our contractual obligations and commitments primarily consist of our obligations under non-cancelable leases, the Notes, and various agreements with third parties, including selling, general and administrative, research and development and manufacturing agreements.

There have been no other material changes to our contractual obligations and commitments outside the ordinary course of business from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2016.

Leases

In April 2015, we signed a lease agreement for approximately 27,300 square feet in Boston, Massachusetts, for a 94-month term that commenced on May 1, 2015. In order to make the space usable for our operations, substantial improvements were made. Our landlord agreed to pay for up to approximately $1.9 million of the improvements, and we bore all additional costs that were incurred. As such, we have determined that we are the owner of the improvements and account for tenant improvements paid by our landlord as a lease incentive. On May 1, 2015, in accordance with ASC 840-20, Operating Leases, we recorded a deferred lease incentive, and an associated receivable from our landlord, for the total amount to be paid by the landlord for improvements. The deferred lease incentive is being amortized as a partial offset to rent expense over the term of the lease, and the receivable was drawn down as cash was received from our landlord. We began occupying the space in November 2015. Improvements made to our leased space have been recorded as fixed assets and will be amortized over the assets' useful lives or the remaining lease term, whichever is shorter.

Royalty and Contingent Milestone Payments

Under the license agreement with Panion & BF Biotech, Inc., or Panion, we acquired the exclusive worldwide rights, excluding certain Asian-Pacific countries, for the development and marketing of ferric citrate. As of June 30, 2017, we have paid an aggregate of $11.6 million of milestone payments to Panion, including the $2.0 million paid upon European marketing approval in 2015. In addition, Panion is eligible to receive royalty payments based on a mid-single digit percentage of net sales of Auryxia in the United States and of Riona in Japan. We record royalties on net sales of Auryxia in cost of goods sold and royalties on net sales of Riona in license expense.

OFF-BALANCE SHEET ARRANGEMENTS

We have not entered into any transactions with unconsolidated entities whereby we have financial guarantees, subordinated retained interests, derivative instruments or other contingent arrangements that expose us to material continuing risks, contingent liabilities, or any other obligations under a variable interest in an unconsolidated entity that provides us with financing, liquidity, market risk or credit risk support, or engages in leasing, hedging, or research and development services on our behalf.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

The primary objective of our investment activities is to preserve principal while maximizing our income from investments and minimizing our market risk. As of June 30, 2017, our portfolio of financial instruments consists of cash equivalents, which includes money market funds. Due to the short-term nature of these financial instruments, we believe there is no material exposure to interest rate risk, and/or credit risk, arising from our portfolio of financial instruments.

Equity Price Risk

The Notes include conversion provisions that are based on the price of our common stock at conversion or at maturity of the Notes. The fair values of the Notes are dependent on the price and volatility of our common stock and will generally increase or decrease as the market price of our common stock changes.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of June 30, 2017, management carried out, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our disclosure

controls and procedures are designed to provide reasonable assurance that information we are required to disclose in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in applicable rules and forms. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of June 30, 2017, our disclosure controls and procedures were effective.

Changes in Internal Controls over Financial Reporting

There were no changes in our internal control over financial reporting during the three months ended June 30, 2017, that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

Limitations on Effectiveness of Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal controls over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our company have been detected.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

See Note 11 – Commitments and Contingencies to our condensed consolidated financial statements included in this report, which is incorporated into this item by reference.

ITEM 1A. RISK FACTORS

Information regarding risk factors appears in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2016. There have been no material changes from the risk factors previously disclosed in that Form 10-K.

ITEM 6. EXHIBITS

The exhibits listed on the Exhibit Index immediately following the signatures to this report, which is incorporated herein by reference, are filed or furnished as part of this report.

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.

KERYX BIOPHARMACEUTICALS, INC.

Date: July 27, 2017 By: /s/ Scott A. Holmes
Scott A. Holmes
Chief Financial Officer
Principal Financial and Accounting Officer

EXHIBIT INDEX

The following exhibits are included as part of this Quarterly Report on Form 10-Q:

Exhibit Number	Exhibit Description
3.1	Amended and Restated Certificate of Incorporation of Keryx Biopharmaceuticals, Inc., dated December 17, 2003, and the Amendment thereto, dated June 18, 2004, filed as Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, filed on August 12, 2004 (File No. 000-30929), and incorporated herein by reference.
3.2	Amendment to Amended and Restated Certificate of Incorporation of Keryx Biopharmaceuticals, Inc., dated July 24, 2007, filed as Exhibit 3.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007, filed on August 9, 2007 (File No. 000-30929), and incorporated herein by reference.
3.3	Amendment to Amended and Restated Certificate of Incorporation of Keryx Biopharmaceuticals, Inc., dated June 18, 2013, filed as Exhibit 3.4 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, filed on August 2, 2013 (File No. 000-30929), and incorporated herein by reference.
3.4	Amendment to Amended and Restated Certificate of Incorporation of Keryx Biopharmaceuticals, Inc., dated May 25, 2016, filed as Exhibit 3.4 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, filed on August 5, 2016 (File No. 000-30929), and incorporated herein by reference.
3.5	Certificate of Validation of the filing and effectiveness of the Amendment to Amended and Restated Certificate of Incorporation of Keryx Biopharmaceuticals, Inc., dated June 13, 2017.
3.6	Amendment to Amended and Restated Certificate of Incorporation of Keryx Biopharmaceuticals, Inc., dated June 13, 2017.
10.1	First Supplemental Indenture, dated as of April 10, 2017, by and among Keryx Biopharmaceuticals, Inc., The Bank of New York Mellon Trust Company, N.A. and the note holder signatory thereto, to the Indenture, dated as of October 15, 2015, filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on April 10, 2017 (File No. 000-30929), and incorporated herein by reference.
31.1	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated July 27, 2017.
31.2	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated July 27, 2017.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated July 27, 2017.
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated July 27, 2017.
101	Interactive data files pursuant to Rule 405 of Regulation S-T: (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statements of Cash Flows, and (iv) the Notes to Condensed Consolidated Financial Statements.

22