KERYX BIOPHARMACEUTICALS INC
Form 10-Q
May 10, 2018

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

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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 March 31, 2018

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

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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 120,442,444 shares of the registrant's common stock, $0.001 par value, outstanding as of April 30, 2018.

KERYX BIOPHARMACEUTICALS, INC.
FORM 10-Q
FOR THE QUARTER ENDED MARCH 31, 2018
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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 captions "Risk Factors" and "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 launch and then effectively continue to commercialize Auryxia for the treatment of iron deficiency anemia in adults with chronic kidney disease, not on dialysis in the United States;
- expectations regarding our ability to identify a commercial partner(s) to launch Fexeric® (ferric citrate coordination complex) in the European market or otherwise create value from our European rights;
- expectations for generating revenue, producing positive cash flow or becoming profitable on a sustained basis;
- expectations for our mix of business between private commercial payers and government-sponsored plans;
- estimates of the sufficiency of our existing cash and cash equivalents to finance our operating requirements;
- expectations regarding future financing needs and financing sources, including regarding asset-based credit facilities;
- expected losses;
- expectations for future capital requirements;
- expectations for increases or decreases in expenses;
- expectations for 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)

| | March 31, 2018 | December 31, 2017 |
|---|---|---|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | $60,087 | $ 93,526 |
| Inventory | 35,443 | 28,695 |
| Accounts receivable, net | 12,889 | 8,146 |
| Other current assets | 11,130 | 11,199 |
| Total current assets | 119,549 | 141,566 |
| Property, plant and equipment, net | 4,347 | 4,521 |
| Goodwill | 3,208 | 3,208 |
| Other assets, net | 13,018 | 9,577 |
| Total assets | $140,122 | $ 158,872 |
| Liabilities and stockholders' (deficit) equity | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses | $44,522 | $ 45,031 |
| Deferred lease incentive, current portion | 244 | 244 |
| Other current liabilities | 152 | 145 |
| Total current liabilities | 44,918 | 45,420 |
| Convertible senior notes | 125,000 | 125,000 |
| Deferred lease incentive, net of current portion | 956 | 1,018 |
| Deferred tax liability | — | 635 |
| Other liabilities | 856 | 894 |
| Total liabilities | 171,730 | 172,967 |
| Commitments and contingencies | | |
| Stockholders' (deficit) equity: | | |
| 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 shares authorized, 120,531,321 and 119,272,304 shares issued, 120,451,373 and 119,192,356 shares outstanding at March 31, 2018 and December 31, 2017, respectively) | 120 | 119 |
| Additional paid-in capital | 988,447 | 984,681 |
| Treasury stock, at cost, 79,948 shares | (357) | (357) |
| Accumulated deficit | (1,019,818) | (998,538) |
| Total stockholders' deficit | (31,608) | (14,095) |
| Total liabilities and stockholders' deficit | $140,122 | $ 158,872 |

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 March 31, | |
|---|---|---|
| | 2018 | 2017 |
| Revenues: | | |
| Net U.S. Auryxia product sales | $20,622 | $ 10,505 |
| License revenue | 1,129 | 1,314 |
| Total revenues | 21,751 | 11,819 |
| Costs and expenses: | | |
| Cost of goods sold | 9,601 | 4,273 |
| License expense | 677 | 789 |
| Research and development | 8,388 | 6,764 |
| Selling, general and administrative | 25,837 | 23,103 |
| Total costs and expenses | 44,503 | 34,929 |
| Operating loss | (22,752) | (23,110) |
| Other income, net | 222 | 114 |
| Loss before income taxes | (22,530) | (22,996) |
| Income tax (benefit) expense | (634) | 20 |
| Net loss | $(21,896) | $ (23,016) |
| Basic and diluted net loss per common share | $(0.18) | $ (0.21) |
| Weighted average shares used in computing basic and diluted net loss per common share | 119,844,320 | 107,071,634 |

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)

| | Three months ended March 31, | |
|---|---|---|
| | 2018 | 2017 |
| Cash flows from operating activities | | |
| Net loss | $(21,896) | $(23,016) |
| Adjustments to reconcile net loss to cash flows used in operating activities: | | |
| Stock-based compensation expense | 3,680 | 3,664 |
| Depreciation and amortization | 252 | 229 |
| Amortization of deferred lease incentive | (62) | (62) |
| Write-down of inventory to net realizable value | 4,097 | 225 |
| Deferred income taxes | (635) | 20 |
| Changes in operating assets and liabilities: | | |
| Other current assets | 1,610 | (6,483) |
| Accounts receivable, net | (4,743) | (917) |
| Inventory | (8,710) | 928 |
| Other assets | (3,441) | (88) |
| Other current liabilities | 7 | 7 |
| Accounts payable and accrued expenses | (3,551) | (437) |
| Other liabilities | (38) | (33) |
| Net cash used in operating activities | (33,430) | (25,963) |
| Cash flows from investing activities | | |
| Purchases of property, plant and equipment | (78) | — |
| Net cash used in investing activities | (78) | — |
| Cash flows from financing activities | | |
| Proceeds from issuance of common stock, net of commission | — | 5,080 |
| Payments for common stock issuance costs | — | (28) |
| Proceeds from exercise of stock options | 69 | 10 |
| Net cash provided by financing activities | 69 | 5,062 |
| Net decrease in cash and cash equivalents | (33,439) | (20,901) |
| Cash and cash equivalents at beginning of the period | 93,526 | 111,810 |
| Cash and cash equivalents at end of the period | $60,087 | $90,909 |

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 kidney disease. Our long-term vision is to build a multi-product kidney care company. Our marketed product, Auryxia (ferric citrate) tablets, is an orally available, absorbable, iron-based medicine. Auryxia is approved by the U.S. Food and Drug Administration, or FDA, for two indications. Auryxia was originally approved in September 2014 for the control of serum phosphorus levels in patients with chronic kidney disease, or CKD, on dialysis. Additionally, in November 2017, the FDA approved Auryxia for the treatment of iron deficiency anemia in adults with CKD, not on dialysis. With two FDA-approved indications, we will leverage our U.S. clinical and commercial infrastructure to make Auryxia available to millions of people with CKD and either iron deficiency anemia or elevated levels of serum phosphorus, which is referred to as hyperphosphatemia. 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 use the brand name Auryxia when we refer to ferric citrate for use in the approved indications in the United States. We refer to the product as ferric citrate when referring to its investigational use. Our vision of building a multi-product kidney care company includes expansion of our product portfolio with other medicines that can help patients with kidney disease.

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, 2017. 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 months ended March 31, 2018 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 our condensed consolidated financial statements, which have been prepared in accordance with GAAP requires us to make estimates, judgments and assumptions that affect the reported amounts of assets, liabilities, equity revenue and expenses and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, judgments and assumptions. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances. These estimates are subject to an inherent degree of uncertainty, and as a result, actual results may differ from these estimates under different assumptions or conditions.

Revenue Recognition

Effective January 1, 2018, the Company adopted Accounting Standards Update, or ASU, 2014-09, Revenue from Contracts with Customers (Topic 606), using the modified retrospective transition method. Under this transition method, the Company will not revise its consolidated financial statements for the years ended December 31, 2017 and 2016, and applicable interim periods within those years. Disclosure will be provided to show the impact to the consolidated financial statements, if any, as if Topic 606 had been effective for those periods.

Our primary source of revenue during the reporting periods was product sales. We sell product to a limited number of major wholesalers, or our Distributors, as well as certain pharmacies, or collectively with our Distributors, our Customers. Our Distributors resell the product to retail pharmacies for purposes of their reselling the product to fill patient prescriptions. Under the new revenue standards, we recognize product revenues when our Customer obtains control of promised goods, in an amount that reflects the consideration which we expect to receive in exchange for those goods. We recognize revenues following the five step model prescribed under ASU No. 2014-09: (i) identify contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenues when (or as) we satisfy the performance obligation.

Product Revenue: We sell product to a limited number of our Distributors as well as certain specialty pharmacies. Our Distributors resell the product to retail pharmacies for purposes of filling patient prescriptions. In addition to agreements with Customers, we enter into arrangements with health care providers and payors that provide for government-mandated or privately-negotiated discounts and rebates with respect to the purchase of our product. Revenue from product sales are recognized when the Customer obtains control of our product, which occurs at a point in time, typically upon delivery to the Customer. We expense incremental costs of obtaining a contract as and when incurred if the expected amortization period of the asset that we would have recognized is one year or less.

Reserves for Discounts and Allowances: Revenue from product sales are recorded at the transaction price, which is equal to the sales price net of reserves for discounts and allowances that are offered within contracts with our Customers, health care providers, payors or other indirect customers. These discounts and allowances represent variable consideration under the new revenue standards. Our process for estimating these components of variable consideration do not differ materially from our historical practices.

Product revenue reserves are classified as a reduction in product revenues, are generally characterized in the following categories: trade allowances, rebates and chargebacks, product returns and other incentives. These reserves are based on estimates of the amounts earned or to be claimed on the related sale of product and are classified as either a reduction of accounts receivable or an accrued expense (current liability) on our consolidated balance sheets, depending on whether the consideration is paid to a direct customer or another third party with which we contract (e.g. provider or payor) and the method of payment. Our estimates of reserves for variable consideration typically utilize the most likely method and reflect our historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. Our product revenue reserves reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the individual contracts. The transaction price, which includes variable consideration reflecting the impact of discounts and allowances, may be subject to constraint and is included in the net sales price only to the extent that it is probable that a significant reversal of the amount of the cumulative revenues recognized will not occur in a future period. Actual amounts may ultimately differ from our estimates. If actual results vary, we adjust these estimates, which could have an effect on earnings in the period of adjustment.

License Revenue: Our license revenue consists of license fees, royalties and milestone payments arising from our agreement with JT and Torii. We receive royalty revenues on sales by JT and Torii of Riona in Japan. We do not have future performance obligations under this license arrangements. We record these royalty revenues based on estimates of the net sales that occurred during the relevant period as license revenue. The relevant period estimate of sales is based on analysis of historical royalties that have been paid to us, adjusted for any changes in facts and circumstances, as appropriate. Differences between actual and estimated royalty revenues are adjusted in the period in which they become known, typically the following quarter.

Disaggregation of Revenue

Currently, our only product is Auryxia, which we commercialize only in the United States. We have no foreign operations; however, we currently generate license revenue based on net sales of Riona by our partner in Japan, as discussed above. License revenue for all periods presented represents royalty revenue generated from our sublicense agreement with JT and Torii.

Significant Judgments

Our revenue reserves, consisting of various discounts and allowances, which are components of variable consideration as discussed above, are considered an area of significant judgment. Additionally, our license revenue in each period, as discussed above, is based on estimates of the net sales of our Japanese partner that occurred during the relevant period. The relevant period estimate of sales is based on analysis of historical royalties that have been paid to us, adjusted for any changes in facts and circumstances, as appropriate, and is considered an area of significant judgment. For these areas of significant judgment, actual amounts may ultimately differ from our estimates and are adjusted in the period in which they become known.

Practical Expedients

Significant financing component: Our accounts receivable arise from product sales and primarily represent amounts due from our wholesale and other third-party distributors. We do not adjust our receivables for the effects of a significant financing component at contract inception if we expect to collect the receivables in one year or less from the time of sale.

Cost to obtain a contract: We recognize the incremental costs of obtaining a contract as an expense when incurred if the amortization period of the asset that the Company otherwise would have recognized is one year or less or the amount is immaterial.

Sales taxes: Taxes collected from Customers relating to product sales and remitted to governmental authorities, if any, are excluded from revenues.

Our U.S. Auryxia product sales for the three months ended March 31, 2018 and 2017 were offset by provisions for allowances and accruals as set forth in the tables below.

| (in thousands) | Three months ended March 31, 2018 | Percent of gross Auryxia product sales | Three months ended March 31, 2017 | Percent of gross Auryxia product sales |
|---|---|---|---|---|
| Gross Auryxia product sales | $41,139 | | $17,954 | |
| Less provision for product sales allowances and accruals: | | | | |
| Trade allowances | 4,182 | 10 % | 1,278 | 7 % |
| Rebates, chargebacks and discounts | 14,793 | 36 % | 5,818 | 33 % |
| Product returns | 164 | 1 % | (69) | — |
| Other incentives[1] | 1,378 | 3 % | 422 | 2 % |
| Total | 20,517 | 50 % | 7,449 | 42 % |
| Net U.S. Auryxia product sales | $20,622 | | $10,505 | |

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

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

| (in thousands) | March 31, 2018 | March 31, 2017 |
|---|---|---|
| Options to purchase common stock | 12,122 | 12,737 |
| Shares issuable upon conversion of convertible senior notes | 33,422 | 33,422 |
| | 45,544 | 46,160 |

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Concentrations of Credit Risk

We do not have significant off-balance-sheet risk or credit risk concentrations. We maintain our cash and cash equivalents with multiple financial institutions. As of March 31, 2018, approximately $2.9 million of our total $60 million cash and cash equivalents balance was invested in institutional money market funds. See Note 3 – Fair Value Measurements.

Our accounts receivable, net at March 31, 2018 and December 31, 2017 represent amounts due to us from our 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 March 31, 2018 and December 31, 2017.

| | March 31, 2018 | | December 31, 2017 | |
|---|---|---|---|---|
| Fresenius Medical Care Rx | 24 | % | 43 | % |
| AmerisourceBergen Drug Corporation | 20 | % | 26 | % |
| Cardinal Health, Inc. | 20 | % | 32 | % |
| McKesson Corporation | 19 | % | 21 | % |
| DaVita Rx | 13 | % | — | % |

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 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. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments.

The FASB has subsequently issued amendments to ASU No. 2014-09 that have the same effective date and transition date: ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations; ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing; ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients; and ASU No. 2016-20, Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers. We adopted these amendments with ASU 2014-09, or collectively, the new revenue standards.

The new revenue standards became effective for us on January 1, 2018 and were adopted using the modified retrospective method. The adoption of the new revenue standards did not have a material impact on our revenue recognition as the majority of our revenues continue to be recognized when the Customer takes control of our product. However, the adoption of the new revenue standards did result in an adjustment to retained earnings (accumulated deficit) as of the adoption date of $0.6 million related to our license revenue and related license expense. See Note 8 – License Agreements for further discussion.

Under the new revenue standards, we recognize revenues when our Customer obtains control of promised goods, in an amount that reflects the consideration which we expect to receive in exchange for those goods. We recognize revenues following the five step model prescribed under ASU No. 2014-09: (i) identify contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenues when (or as) we satisfy the performance obligation.

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 and is required to be applied using a modified retrospective transition approach with application of the new guidance for all periods presented. Although our assessment is not complete, we currently expect the adoption of this guidance to result in the addition of material balances of leased assets and corresponding lease liabilities to our consolidated balance sheets, primarily relating to our lease of office space. We do not currently expect a material impact to our consolidated statements of operations as a result of this standard.

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 was effective for us on January 1, 2018. The standard did not 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 March 31, 2018 and December 31, 2017:

| | Financial assets at fair value as of March 31, 2018 | | | Financial assets at fair value as of December 31, 2017 | | |
|---|---|---|---|---|---|---|
| (in thousands) | Level 1 | Level 2 | Level 3 | Level 1 | Level 2 | Level 3 |
| Assets: | | | | | | |
| Cash equivalents[1] | $2,905 | $ — | $ — | $ 1,895 | $ — | $ — |
| Total assets | $2,905 | $ — | $ — | $ 1,895 | $ — | $ — |

(1) Cash equivalents as of March 31, 2018 and December 31, 2017 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 March 31, 2018 and December 31, 2017, the fair value of the Notes was $136.7 million and $155.4 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 10 – Debt for additional information on our debt obligations.

NOTE 4 – INVENTORY

Inventory consists of the following at March 31, 2018 and December 31, 2017:

| (in thousands) | March 31, 2018 | December 31, 2017 |
|---|---|---|
| Raw materials | $ 1,321 | $ 469 |
| Work in process | 31,453 | 25,160 |
| Finished goods | 2,669 | 3,066 |
| Total inventory | $ 35,443 | $ 28,695 |

During the three months ended March 31, 2018, we wrote off approximately $4.1 million of inventory that was determined to no longer be suitable for commercial manufacture, which was recorded to cost of goods sold.

NOTE 5 – OTHER ASSETS

Other current assets

Other current assets consisted of the following at March 31, 2018 and December 31, 2017:

| (in thousands) | March 31, 2018 | December 31, 2017 |
|---|---|---|
| Prepaid manufacturing costs | $6,790 | $ 7,646 |
| Prepaid research and development expenses | 1,475 | 2,265 |
| Prepaid selling, general and administrative expenses | 2,865 | 1,288 |
| Total other current assets | $11,130 | $ 11,199 |

Prepaid manufacturing costs as of March 31, 2018 and December 31, 2017 primarily relate to upfront payments to our contract manufacturers related to 2018 production of inventory.

Other assets, net

Other assets, net consisted of the following at March 31, 2018 and December 31, 2017:

| (in thousands) | March 31, 2018 | December 31, 2017 |
|---|---|---|
| Deferred manufacturing costs | $10,779 | $ 7,338 |
| Deposits | 1,099 | 1,099 |
| Long-term prepaid manufacturing costs | 1,000 | 1,000 |
| Deferred registration fees | 140 | 140 |
| Total other long-term assets | $13,018 | $ 9,577 |

Deferred manufacturing costs as of March 31, 2018 and December 31, 2017 consisted of amounts paid or payable under contract manufacturing agreements, including a $5.0 million milestone related to a facility construction agreement and $2.4 million and $2.3 million in product premiums payable by us to our contract manufacturer at March 31, 2018 and December 31, 2017, respectively. We capitalize certain expenses as deferred costs related to agreements with contract manufacturers in connection with the facility expansion activities. These costs will be capitalized as incurred and will begin to be expensed at such time that we begin to receive product from the newly-constructed or expanded facilities. These costs will be expensed ratably over the relevant supply periods based on anticipated product to be received from the facilities. At March 31, 2018 and December 31, 2017, $1.9 million and $7.3 million, respectively, included in deferred manufacturing costs were also recorded as a liability on our consolidated balance sheet as they had not yet been paid.

NOTE 6 – STOCKHOLDERS' DEFICIT

Change in Stockholders' Deficit

Total stockholders' deficit was $31.6 million at March 31, 2018, which is an increase of $17.5 million as compared to stockholders' deficit at December 31, 2017 of $14.1 million. This increase was primarily attributable to our net loss of approximately $21.9 million, partially offset by $3.7 million related to stock-based compensation expense and $0.6 million related to an adjustment to accumulated deficit as of January 1, 2018 upon the adoption of ASU 2014-09. See Note 8 - License Agreements for further discussion related to the adjustment recorded.

NOTE 7 – STOCK-BASED COMPENSATION EXPENSE

Equity Incentive Plans

As of March 31, 2018, a total of 672,606 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 three months ended March 31, 2018:

| | Number of shares | Weighted average exercise price |
|---|---|---|
| Outstanding at December 31, 2017 | 11,967,815 | $ 6.73 |
| Granted | 759,000 | 4.20 |
| Exercised | (19,913) | 3.44 |
| Forfeited or Expired | (585,216) | 5.13 |
| Outstanding at March 31, 2018 | 12,121,686 | $ 6.65 |
| Vested and expected to vest at March 31, 2018 | 8,964,551 | $ 7.08 |
| Exercisable at March 31, 2018 | 5,663,537 | $ 8.22 |

Upon the exercise of stock options, we issue new shares of our common stock. As of March 31, 2018, 3,215,000 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 three months ended March 31, 2018:

| | Number of shares | Weighted average grant date fair value |
|---|---|---|
| Outstanding at December 31, 2017 | 1,884,297 | $ 6.39 |
| Granted | 1,348,150 | 4.43 |
| Vested | (412,401) | 5.66 |
| Forfeited | (109,046) | 4.96 |
| Outstanding at March 31, 2018 | 2,711,000 | $ 5.58 |

As of March 31, 2018, 310,000 shares of restricted stock issued to employees are unvested, performance-based shares.

Stock-Based Compensation Expense

We incurred $3.7 million of stock-based compensation expense related to equity incentive grants during each of the three months ended March 31, 2018 and 2017. The following table reflects stock-based compensation expense for the three months ended March 31, 2018 and 2017:

| | Three months ended March 31, | |
|---|---|---|
| (in thousands) | 2018 | 2017 |
| Cost of goods sold | $18 | $6 |
| Research and development | 741 | 632 |
| Selling, general and administrative | 2,921 | 3,026 |
| Total stock-based compensation expense | $3,680 | $3,664 |

Stock-based compensation costs capitalized as part of inventory were immaterial for the three months ended March 31, 2018 and 2017.

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 March 31, 2018 and 2017 was $3.00 and $3.81 per share, respectively. We use historical information to estimate forfeitures of stock-based awards. As of March 31, 2018, there was $10.5 million and $9.3 million of total unrecognized compensation cost related to non-vested stock options and restricted stock, respectively, which is expected to be recognized over weighted-average periods of 2.2 years and 2.1 years, respectively. These amounts do not include 3,215,000 unvested options and 310,000 shares of unvested restricted stock as of March 31, 2018 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 8 – 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 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, which is being marketing in the United States under the trade name Auryxia. JT and Torii are responsible for the future development and commercialization costs in Japan. Effective as of June 8, 2009, we entered into an Amended and Restated Sublicense 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 2013, JT and Torii filed its new drug application with the Japanese Ministry of Health, Labour and Welfare for marketing approval of ferric citrate in Japan for the treatment of hyperphosphatemia in patients with CKD.

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 being marketed in Japan by JT's subsidiary, Torii, under the brand name Riona, and is indicated as an oral treatment for the improvement of hyperphosphatemia in patients with CKD. We receive royalty payments based on a tiered double-digit percentage of net sales of Riona in Japan escalating up to the mid-teens, as well as up to an additional $55.0 million upon the achievement of certain annual net sales milestones.

We assessed the sublicense agreement in accordance with ASU 2014-09 and concluded that the contract counterparties, JT and Torii, are a customer. As of the adoption date of January 1, 2018, the sublicense represents our only open contract with a customer. The primary performance obligation identified in the contract is the sublicense to JT and Torii for the right to develop and commercialize ferric citrate in the licensed territory, Japan. Other potential performance obligations identified were either completed before the adoption date or did not meet the definition of a

performance obligation, for instance because they were not capable of being distinct within the context of the contract, and therefore were not required to be accounted for separately.

In determining the transaction price associated with the sublicense, we considered the initial license fee as well as any development-based milestones, manufacturing fee revenue, and sales-based royalties and milestones that were included in the arrangement. The performance obligations related to the initial license fee, development-based milestones and manufacturing fee revenue were all completed and the relevant consideration was received prior to the adoption of the new standards. As a result, we determined that the remaining consideration that may be payable to us under the terms of the sublicense agreement are either quarterly royalties on net sales or payments due upon the achievement of sales-based milestones. In accordance with the standards, elements of consideration subject to a sales or usage-based royalty exception do not need to be estimated at the time of adoption and should be recognized when the subsequent sale or usage occurs. As a result, as of January 1, 2018, we began recognizing license revenue based on our estimate of net sales of Riona in Japan in the quarter in which the underlying net sales occur. This differs from our historical practice of recognizing license revenue one quarter in arrears once a net sales report was received from JT and Torii. As a result of this change in timing of revenue recognition for license revenue, we recorded an adjustment of $0.6 million to retained earnings (accumulated deficit) as of the adoption date, representing the net impact to our statement of operations of the license revenue and related license expense based on net sales of Riona in Japan during the fourth quarter of 2017.

As discussed above and in accordance with our revenue recognition policy, royalty revenues are estimated in the quarter that JT and Torii recognize net sales of Riona in Japan. Any difference between the estimated license revenue and actual revenue is recorded as an adjustment in the following reporting period. For the three months ended March 31, 2018 and 2017, we recorded $1.1 million and $1.3 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 the three months ended March 31, 2018 and 2017, we recorded $0.7 million and $0.8 million, respectively, in license expense related to royalties due to the licensor of ferric citrate relating to sales of Riona in Japan.

NOTE 9 – ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consists of the following at March 31, 2018 and December 31, 2017:

| (in thousands) | March 31, 2018 | December 31, 2017 |
|---|---|---|
| Commercial rebates and fees | $21,542 | $ 16,362 |
| Accounts payable | 11,260 | 6,474 |
| Professional, license, and other fees and expenses | 6,821 | 5,257 |
| Accrued compensation and related liabilities | 3,379 | 7,504 |
| Accrued manufacturing expenses | 1,520 | 9,434 |
| Total accounts payable and accrued expenses | $44,522 | $ 45,031 |

NOTE 10 – 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 into which the Notes are convertible 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 Notes represented 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.

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 to our certificate of incorporation 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 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.

As of March 31, 2018 and December 31, 2017, the balance of the Notes and the carrying value of the Notes was $125 million, and the fair value of the Notes was $136.7 million and $155.4 million, respectively.

See Note 14 - Subsequent Events for additional information regarding the Notes that occurred subsequent to the balance sheet date.

NOTE 11 – INCOME TAXES

In December 2017, H.R.1, known as the Tax Cuts and Jobs Act, was signed into law. The Tax Cuts and Jobs Act, among other items, reduced the corporate income tax rate from 35% to 21%, effective January 1, 2018. Our deferred tax assets, net of deferred tax liabilities, represent expected corporate tax benefits anticipated to be realized in the future. The reduction in the federal corporate tax rate reduces these benefits.

We have evaluated the impact of the Tax Cuts and Jobs Act and determined that any net operating losses generated subsequent to January 1, 2018 are able to be used indefinitely, and as a result, we generated sufficient net operating losses in the three months ended March 31, 2018 to fully offset the net deferred tax liability that was recorded on our consolidated balance sheet. This results in a reduction in our net deferred tax liability of $0.6 million in the first quarter of 2018 and a corresponding $0.6 million income tax benefit.

We account for income taxes under the asset and liability method. Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is established when necessary to reduce deferred tax assets to the amount expected to be realized. In determining the need for a valuation allowance, management reviews both positive and negative evidence, including current and historical results of operations, future income projections and the overall prospects of our business. Based upon management's assessment of all available evidence, we believe that it is more-likely-than-not that the deferred tax assets will not be realizable; and therefore, a full valuation allowance is established.

NOTE 12 – OTHER INCOME, NET

The components of other income, net are as follows:

| | Three months ended March 31, | |
|---|---|---|
| (in thousands) | 2018 | 2017 |
| Interest income | $201 | $117 |
| Other income (expense) | 21 | (3) |
| | $222 | $114 |

NOTE 13 – COMMITMENTS AND CONTINGENCIES

Commitments

As of March 31, 2018, 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 and subsequently consolidated with the Karth action. 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. We have moved to dismiss the consolidated action. 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 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.

NOTE 14 – SUBSEQUENT EVENTS

On April 27, 2018, Gregory P. Madison notified us of his resignation as our President and Chief Executive Officer and as a member of our Board. We appointed Jodie P. Morrison as Interim Chief Executive Officer while we conduct a search for our next Chief Executive Officer. As a result of this management change, Kevin Cameron replaced Ms. Morrison as a member on the Audit Committee of our Board. On May 10, 2018, we entered into an employment agreement with Ms. Morrison in connection with her role as Interim Chief Executive Officer.

On May 8, 2018, we entered into a Notes Exchange Agreement, or the Notes Exchange Agreement, with funds managed by Baupost pursuant to which, on May 9, 2018, we issued $164.746 million of Convertible Senior Notes due 2021, or the New Notes, to Baupost in exchange for (a) our outstanding $125 million Convertible Senior Notes due 2020, or the Existing Notes, and (b) an additional investment of $10 million in cash.

The New Notes were issued under an Indenture dated as of May 9, 2018, with The Bank of New York Mellon Trust Company, N.A. as trustee, or the New Indenture. Under the terms of the New Indenture, the New Notes may be converted into shares of our common stock, or the Shares, at the discretion of Baupost, at an initial conversion rate of 215.983 Shares per $1,000 principal amount of New Notes, which represents an initial conversion price of $4.63 based on the per Share closing price the day before entering into the Notes Exchange Agreement. The principal amount of the New Notes initially converts into a total amount of Shares approximately equal to the 33.4 million Shares into which the Existing Notes were convertible plus an additional approximately 2.2 million Shares in consideration of the additional cash investment. The conversion price of the New Notes is subject to adjustment based on the occurrence of certain events as set forth in the New Indenture. Further, the New Indenture subjects us to certain financial and business covenants. The New Indenture also allows us to secure up to a $40 million asset-based credit facility.

In connection with the issuance of the New Notes, on May 9, 2018, we entered into a Registration Rights Agreement with Baupost, or the New Registration Rights Agreement, on substantially similar terms as the Registration Rights Agreement entered into in connection with the Existing Notes, pursuant to which we agreed to (i) file a registration statement (the “Resale Registration Statement”) with the SEC covering the resale of the New Notes and the underlying Shares upon the written request of Baupost and (ii) use commercially reasonable efforts, subject to the receipt of necessary information from all the purchasers of the New Notes, to cause the SEC to declare the Resale Registration Statement effective. Further, the New 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 New Registration Rights Agreement affords Baupost certain piggyback registration rights. Under the Registration Rights Agreement, Baupost also retains its existing right to appoint one individual to our Board of Directors for so long as Baupost beneficially owns twenty percent (20%) or more of our outstanding common stock and to a board observer for so long as Baupost beneficially owns ten percent (10%) or more of our outstanding common stock.

In connection with the issuance of the New Notes, (i) the Notes Purchase Agreement dated as of October 14, 2015 and the Registration Rights Agreement dated as of October 15, 2015, each between us and Baupost were each terminated pursuant to the Notes Exchange Agreement and (ii) the Indenture dated as of October 15, 2015, between us and The Bank of New York Mellon Trust Company, N.A., was discharged in connection with the cancellation of the Existing Notes. See Note 10 – Debt for additional information regarding the Existing Notes, the Notes Purchase Agreement, the 2015 Indenture and the 2015 Registration Rights Agreement.

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 this report. 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, 2017.

OVERVIEW

We are a commercial stage biopharmaceutical company focused on bringing innovative medicines to people with kidney disease. Our long-term vision is to build a multi-product kidney care company. Our marketed product, Auryxia (ferric citrate) tablets, is an orally available, absorbable, iron-based medicine. Auryxia is approved by the U.S. Food and Drug Administration, or FDA, for two indications. Auryxia was originally approved in September 2014 for the control of serum phosphorus levels in patients with chronic kidney disease, or CKD, on dialysis. Additionally, in November 2017, the FDA approved Auryxia for the treatment of iron deficiency anemia in adults with CKD, not on dialysis. With two FDA-approved indications, we will leverage our U.S. clinical and commercial infrastructure to make Auryxia available to millions of people with CKD and either iron deficiency anemia or elevated levels of serum phosphorus, which is referred to as hyperphosphatemia. 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 use the brand name Auryxia when we refer to ferric citrate for use in the approved indications in the United States. We refer to the product as ferric citrate when referring to its investigational use. Our vision of building a multi-product kidney care company includes expansion of our product portfolio with other medicines that can help patients with kidney disease.

OUR STRATEGY

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

Maximize Auryxia's Potential

Auryxia is approved for two indications in the United States. We developed and subsequently launched Auryxia in the United States in late December 2014 following the FDA's approval of Auryxia for the control of serum phosphorus levels in adult patients with CKD on dialysis. In November 2017, the FDA approved Auryxia for the treatment of iron deficiency anemia in adult patients with CKD, not on dialysis. Auryxia is a non-calcium, non-chewable, orally-administered phosphate binder. Auryxia is the first FDA-approved oral iron medication that was specifically developed to treat iron deficiency anemia in CKD patients, not on dialysis. In the United States, there are approximately 450,000 adult patients with CKD requiring dialysis (referred to as End Stage Renal Disease), including approximately 350,000 adults currently taking a phosphate binder. We estimate that in the United States, approximately 1.7 million adults under the care of a nephrologist for CKD have iron deficiency anemia, not on dialysis, including approximately 650,000 adults currently being treated by nephrologists for iron deficiency anemia. Iron deficiency anemia is common in the non-dialysis population and the prevalence and severity increases as CKD advances. Iron deficiency anemia is symptomatic and can significantly impact quality of life. Auryxia is being marketed in the United States to nephrologists and renal care teams through our specialty salesforce and commercial infrastructure. Our field-based organization is aligned to 95 territories calling on target nephrologists and their associated dialysis centers. These target nephrologists treat CKD patients on dialysis and those not on dialysis. We believe strong fundamentals are in place to drive commercial adoption of Auryxia in the dialysis setting and maximize the potential of Auryxia as a treatment of iron deficiency anemia in adults with CKD, not on dialysis.

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 clinical-stage drug candidates, as well as commercially available 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 workforce of high-quality and talented people to support our potential growth.

Recent Developments

On April 27, 2018, Gregory P. Madison notified us of his resignation as our President and Chief Executive Officer and as a member of our Board. We appointed Jodie P. Morrison as Interim Chief Executive Officer while we conduct a search for our next Chief Executive Officer. On May 10, 2018, we entered into an employment agreement with Ms. Morrison in connection with her role as Interim Chief Executive Officer.

On May 8, 2018, we entered into a Notes Exchange Agreement, or the Notes Exchange Agreement, with funds managed by Baupost pursuant to which, on May 9, 2018, we issued $164.746 million of Convertible Senior Notes due 2021, or the New Notes, to Baupost in exchange for (a) our outstanding $125 million Convertible Senior Notes due 2020, or the Existing Notes, and (b) an additional investment of $10 million in cash.

The New Notes were issued under an Indenture dated as of May 9, 2018, with The Bank of New York Mellon Trust Company, N.A. as trustee, or the New Indenture. Under the terms of the New Indenture, the New Notes may be converted into shares of our common stock, or the Shares, at the discretion of Baupost, at an initial conversion rate of 215.983 Shares per $1,000 principal amount of New Notes, which represents an initial conversion price of $4.63 based on the per Share closing price the day before entering into the Notes Exchange Agreement. The principal amount of the New Notes initially converts into a total amount of Shares approximately equal to the 33.4 million Shares into which the Existing Notes were convertible plus an additional approximately 2.2 million Shares in consideration of the additional cash investment. The conversion price of the New Notes is subject to adjustment based on the occurrence of certain events as set forth in the New Indenture. Further, the New Indenture subjects us to certain financial and business covenants. The New Indenture also allows us to secure up to a $40 million asset-based credit facility.

In connection with the issuance of the New Notes, on May 9, 2018, we entered into a Registration Rights Agreement with Baupost, or the New Registration Rights Agreement, on substantially similar terms as the Registration Rights Agreement entered into in connection with the Existing Notes, pursuant to which we agreed to (i) file a registration statement (the “Resale Registration Statement”) with the SEC covering the resale of the New Notes and the underlying Shares upon the written request of Baupost and (ii) use commercially reasonable efforts, subject to the receipt of necessary information from all the purchasers of the New Notes, to cause the SEC to declare the Resale Registration Statement effective. Further, the New 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 New Registration Rights Agreement affords Baupost certain piggyback registration rights. Under the Registration Rights Agreement, Baupost also retains its existing right to appoint one individual to our Board of Directors for so long as Baupost beneficially owns twenty percent (20%) or more of our outstanding common stock and to a board observer for so long as Baupost beneficially owns ten percent (10%) or more of our outstanding common stock.

In connection with the issuance of the New Notes, (i) the Notes Purchase Agreement dated as of October 14, 2015 and the Registration Rights Agreement dated as of October 15, 2015, each between us and Baupost were each terminated pursuant to the Notes Exchange Agreement and (ii) the Indenture dated as of October 15, 2015, between us and The Bank of New York Mellon Trust Company, N.A., was discharged in connection with the cancellation of the Existing Notes. See Note 10 – Debt for additional information regarding the Existing Notes, the Notes Purchase Agreement, the 2015 Indenture and the 2015 Registration Rights Agreement.

Financial Performance Overview

Product revenue is currently derived from sales of our sole commercial product, Auryxia, in the United States. License revenue relates to our license agreement with JT and Torii and includes license fees, milestone payments and royalties on net product sales.

Even though our trials demonstrated that Auryxia is effective in the control of serum phosphorus levels in patients with CKD on dialysis and for the treatment of iron deficiency anemia in patients with CKD, not 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, 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.

Operating Expenses

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 inventory manufactured prior to regulatory approval of a product or a new contract manufacturing site, 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, legal, sales, pharmacovigilance, 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 awards. 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.

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 any additional regulatory approvals which we may seek 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 and related reserves, 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.

Revenue Recognition

In May 2014, the FASB issued 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. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments.

The FASB has subsequently issued amendments to ASU No. 2014-09 that have the same effective date and transition date: ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations; ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing; ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients; and ASU No. 2016-20, Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers. We adopted these amendments with ASU 2014-09, or collectively, the new revenue standards.

The new revenue standards became effective for us on January 1, 2018 and were adopted using the modified retrospective method. The adoption of the new revenue standards did not have a material impact on our revenue recognition as the majority of our revenues continue to be recognized when the customer takes control of our product. However, the adoption of the new revenue standards did result in an adjustment to retained earnings (accumulated deficit) as of the adoption date of $0.6 million related to our license revenue and related license expense. See Note 8 – License Agreements for further discussion.

Under the new revenue standards, we recognize revenues when our customer obtains control of promised goods, in an amount that reflects the consideration which we expect to receive in exchange for those goods. We recognize revenues following the five step model prescribed under ASU No. 2014-09: (i) identify contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenues when (or as) we satisfy the performance obligation.

Product Revenue: We sell product to a limited number of major wholesalers, our Distributors, as well as certain specialty pharmacies, or collectively our Customers. Our Distributors resell the product to retail pharmacies for purposes of filling patient prescriptions. In addition to agreements with Customers, we enter into arrangements with health care providers and payors that provide for government-mandated or privately-negotiated discounts and rebates with respect to the purchase of our product.

Revenue from product sales are recognized when the customer obtains control of our product, which occurs at a point in time, typically upon delivery to the customer. We expense incremental costs of obtaining a contract as and when incurred if the expected amortization period of the asset that we would have recognized is one year or less.

Reserves for Discounts and Allowances: Revenue from product sales are recorded at the transaction price, which is equal to the sales price net of reserves for discounts and allowances that are offered within contracts with our Customers, health care providers, payors or other indirect customers. These discounts and allowances represent variable consideration under the new revenue standards. Our process for estimating these components of variable consideration do not differ materially from our historical practices.

Product revenue reserves are classified as a reduction in product revenues ande generally characterized in the following categories: trade allowances, rebates and chargebacks, product returns and other incentives. These reserves are based on estimates of the amounts earned or to be claimed on the related sale of product and are classified as either a reduction of accounts receivable or an accrued expense (current liability) on our consolidated balance sheets, depending on whether the consideration is paid to a direct customer or another third party with which we contract (e.g. provider or payor) and the method of payment. Our estimates of reserves for variable consideration typically utilize the most likely method and reflect our historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. Our product revenue reserves reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the individual contracts. The transaction price, which includes variable consideration reflecting the impact of discounts and allowances, may be subject to constraint and is included in the net sales price only to the extent that it is probable that a significant reversal of the amount of the cumulative revenues recognized will not occur in a future period. Actual amounts may ultimately differ from our estimates. If actual results vary, we adjust these estimates, which could have an effect on earnings in the period of adjustment.

License Revenue: Our license revenue consists of license fees, royalties and milestone payments arising from our agreement with JT and Torii. We receive royalty revenues on sales by JT and Torii of Riona in Japan. We do not have future performance obligations under this license arrangements. We record these royalty revenues based on estimates of the sales that occurred during the relevant period as license revenue. The relevant period estimate of sales is based on analysis of historical royalties that have been paid to us, adjusted for any changes in facts and circumstances, as appropriate. Differences between actual and estimated royalty revenues are adjusted for in the period in which they become known, typically the following quarter.

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, 2017. Except as discussed above, 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 March 31, 2018 and March 31, 2017

Net U.S. Auryxia Product Sales. For the three months ended March 31, 2018, we recognized $20.6 million in product sales of Auryxia, net of allowances, discounts, incentives, rebates and chargebacks, as compared with $10.5 million for the three months ended March 31, 2017.

| (in thousands) | Three months ended March 31, 2018 | Percent of gross Auryxia product sales | Three months ended March 31, 2017 | Percent of gross Auryxia product sales |
|---|---|---|---|---|
| Gross Auryxia product sales | $41,139 | | $17,954 | |
| Less provision for product sales allowances and accruals | | | | |
| Trade allowances | 4,182 | 10 % | 1,278 | 7 % |
| Rebates, chargebacks and discounts | 14,793 | 36 % | 5,818 | 33 % |
| Product returns | 164 | 1 % | (69) | — |
| Other incentives[1] | 1,378 | 3 % | 422 | 2 % |
| Total | 20,517 | 50 % | 7,449 | 42 % |
| Net U.S. Auryxia product sales | $20,622 | | $10,505 | |

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

Gross Auryxia product sales increased for the three months ended March 31, 2018 as compared to the same period in 2017 primarily as a result of an increase in patient prescriptions and related units sold, partially offset by a higher gross-to-net adjustment. Provisions for product sales allowances and accruals as a percentage of gross Auryxia product sales for the three months ended March 31, 2018 as compared to the same period in 2017 increased primarily as a result of a higher percentage of sales through government (Medicare Part D) contracts that generally receive a larger rebate. Our gross-to-net adjustments may increase depending on our mix of business between Medicare Part D and commercial payers as well as the portion of our business coming from the use of Auryxia as a treatment for hyperphosphatemia as compared to the portion of our business coming from the use of Auryxia as a treatment for iron deficiency anemia.

We recognize revenue when the customer obtains control of our product, which occurs at a point in time, typically upon delivery to the customer.

License Revenue. For the three months ended March 31, 2018 and 2017, we recognized $1.1 million and $1.3 million, respectively, in license revenue on royalty payments from sales of Riona in Japan. In accordance with the new revenue standards, license revenue for the three months ended March 31, 2018 was recorded based on an estimate of net sales of Riona in Japan during the three months ended March 31, 2018, as compared to license revenue for the three months ended March 31, 2017 which was based on net sales of Riona in Japan one quarter in arrears.

We are not currently marketing Fexeric in the European Union and do not intend to commercialize Fexeric in the European Union on our own. Additionally, we have not been successful in finding a suitable commercialization partner for Fexeric in the European Union to date. As a result, we do not expect to receive license revenue, or any other form of revenue, from our rights to Fexeric.

Cost of Goods Sold. For the three months ended March 31, 2018, we recognized $9.6 million in cost of goods sold, as compared to $4.3 million for the three months ended March 31, 2017. This increase was primarily due to an increase of $3.9 million in inventory write-offs in the 2018 period as compared to the 2017 period, partially offset by additional units sold in the 2018 period as compared to the 2017 period.

License Expense. For the three months ended March 31, 2018, we recognized $0.7 million in license expense related to royalties due to the licensor of Auryxia relating to sales of Riona in Japan as compared to $0.8 million for the three months ended March 31, 2017. The decrease was due to a decrease in license revenue recorded in each respective period.

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Research and Development Expenses. Research and development expenses increased by $1.6 million to $8.4 million for the three months ended March 31, 2018, as compared to $6.8 million for the three months ended March 31, 2017. 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 clinical trial costs. We expect our research and development expenses will increase slightly for the remainder of 2018 as compared to the three months ended March 31, 2018, due to continued process development-related manufacturing costs, as well as our investments in investigator sponsored research and other clinical trial costs.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased by $2.7 million to $25.8 million for the three months ended March 31, 2018, as compared to $23.1 million for the three months ended March 31, 2017. The increase was primarily due to an increase in costs associated with the continued commercialization of Auryxia, as well as costs related to the launch of Auryxia for the treatment of iron deficiency anemia in adults with CKD, not on dialysis. We expect our selling, general and administrative costs to remain relatively consistent for the remainder of 2018 as compared to the three months ended March 31, 2018.

Other income, net. For the three months ended March 31, 2018 and March 31, 2017, we recognized $0.2 million and $0.1 million, respectively, in other income, net.

Income Tax (Benefit) Expense. Income tax (benefit) expense for the three months ended March 31, 2018 was $0.6 million (benefit) as compared to $20,000 expense for the three months ended March 31, 2017. The net income tax benefit recognized in 2018 relates to tax reform that was signed into law at the end of 2017, which allows for net operating losses generated after January 1, 2018 to be used indefinitely, which were used to offset the previously recorded net deferred tax liability, resulting in a corresponding income tax benefit.

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, milestone and royalty 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. On November 6, 2017, the FDA approved Auryxia for the treatment of iron deficiency anemia in adults with CKD, not on dialysis, expanding the number of patients which can benefit from Auryxia. Even if we successfully commercialize Auryxia, including in the non-dialysis setting, 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 any additional regulatory approvals which we may seek 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 Securities and Exchange Commission, or 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℠ 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. In July 2017, we filed 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. During the year ended December 31, 2017, we sold 11,937,174 shares under the Sales Agreement for aggregate net proceeds of $75.7 million, which included all of the initial $75.0 million shares issuable pursuant to the Sales Agreement. As of the date of this report, we may sell up to an additional $72.4 million under the Sales Agreement pursuant to the July 2017 prospectus supplement. The initial $75.0 million of common stock issued pursuant to the Sales Agreement and the additional $75.0 million of common stock 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 10 – Debt for a description of the Notes. On May 8,

2018, we entered into a Notes Exchange Agreement, or the Notes Exchange Agreement, with funds managed by Baupost pursuant to which, on May 9, 2018, we issued $164.746 million of Convertible Senior Notes due 2021, or the New Notes, to Baupost in exchange for (a) our outstanding $125 million Convertible Senior Notes due 2020 and (b) an additional investment of $10 million in cash. See Note 14 – Subsequent Events for a description of the New Notes. On May 9, 2018, we also entered into a Registration Rights Agreement with the purchaser of the New Notes, or the New Registration Rights Agreement, on substantially similar terms as the registration rights agreement we entered into with the same purchaser of the Notes, pursuant to which we agreed to (i) file a registration statement with the SEC covering the resale of the New Notes and the underlying common stock which the New 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 New Notes, to cause the SEC to declare such resale registration statement effective. Further, the New 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 New Registration Rights Agreement provides Baupost certain piggyback registration rights.

As of March 31, 2018, we had $60.1 million in cash and cash equivalents, as compared to $93.5 million in cash and cash equivalents at December 31, 2017, representing a decrease of 33.4 million. The decrease in cash and cash equivalents was primarily due to cash used to fund operations.

We believe that our existing cash and cash equivalents will be sufficient to fund our current and planned operations for at least the next twelve months. The actual amount of cash that we will need to execute our current business objectives is subject to many factors, including, but not limited to, the timing and magnitude of cash received from product sales, the timing and expenditures associated with commercial activities related to Auryxia, the timing and expenditures associated with the build-up of inventory and capacity expansion, and the timing, design and conduct of any further clinical trials for ferric citrate. As a result of these factors, we may need to seek additional financing to provide the cash necessary to execute our current operations, including working capital needs. Our capital raising activities may include, but may not be limited to, one or more of the following: the issuance of common stock or other securities via private placement or public offerings, including the potential future sales of our common stock under the Sales Agreement; the issuance of debt, including potential working capital lines of credit and/or asset-based credit facilities; or possible business combinations. Under the terms of the New Notes, we may secure an up to a $40 million asset-based credit facility, for which we have a commitment from a lender, however, we may not be able to successfully negotiate and enter into definitive agreements with respect to the asset-based credit facility and the borrowing base we may utilize at any one time under the asset-based credit facility, if successfully entered into, may be significantly lower than the total commitment under such facility. Additionally, while we may seek capital through a number of means, there can be no assurance that additional financing will be available on acceptable terms, if at all, and our negotiating position in capital-raising efforts may worsen as existing resources are used. Additional equity financings may be dilutive to our stockholders; and debt financing, if available may involve significant cash payment obligations and covenants that restrict our ability to operate as a business. 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.”

Net cash used in operating activities for the three months ended March 31, 2018 was $33.4 million as compared to $26.0 million net cash used in operating activities for the same period in 2017. This increase in net cash used in operating activities was primarily related to an increase in cash outflows arising from changes in our operating assets and liabilities, in particular purchases of inventory, partially offset by a decrease in our net loss after non-cash adjustments.

Net cash used in investing activities for the three months ended March 31, 2018 was $0.1 million as compared to zero net cash used in investing activities for the same period in 2017. The net cash used in investing activities for the three months ended March 31, 2018 relates to purchases of property, plant and equipment.

Net cash provided by financing activities for the three months ended March 31, 2018 was $0.1 million as compared to $5.1 million for the same period in 2017. Net cash provided by financing activities for the three months ended March 31, 2017 is attributable to the net proceeds from the issuance of common stock under the Sales Agreement, and we did not have such activity in the 2018 period.

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OBLIGATIONS AND COMMITMENTS

As of March 31, 2018, 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.

As of March 31, 2018, 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, 2017. See Note 14 - Subsequent Events and Management's Discussion and Analysis--Liquidity and Capital Resources for additional discussion regarding commitments that were entered into subsequent to the balance sheet date.

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 the Financial Accounting Standards Board's Accounting Standards Codification 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 March 31, 2018, 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 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 March 31, 2018, 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 March 31, 2018, management carried out, under the supervision and with the participation of our Interim 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 Interim Chief Executive Officer and Chief Financial Officer concluded that, as of March 31, 2018, our disclosure controls and procedures were effective.

CHANGES IN INTERNAL CONTROLS OVER FINANCIAL REPORTING

During the three months ended March 31, 2018, we implemented certain internal controls in connection with our adoption of ASU 2014-09, Revenue from Contracts with Customers. There were no other changes in our internal control over financial reporting that occurred during the fiscal quarter covered by this report that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

LIMITATIONS ON EFFECTIVENESS OF CONTROLS

Our management, including our Interim 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 13 – 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

You should carefully consider the following risks and uncertainties. If any of the following occurs, our business, financial condition and/or operating results could be materially harmed. These factors could cause the trading price of our common stock to decline, and you could lose all or part of your investment.

Risks related to our business and industry

We rely on third parties to manufacture and analytically test our drug. If these third parties do not successfully manufacture and test our drug, our business will be harmed.

We have limited experience in manufacturing products for clinical or commercial purposes. We intend to continue, in whole or in part, to use third parties to manufacture and analytically test our drug, Auryxia, for commercial distribution and use in clinical trials. We may not be able to enter into future contract agreements with these third-parties on terms acceptable to us, if at all.

Our ability to conduct clinical trials, manufacture and commercialize our drug will depend on the ability of such third parties to manufacture our drug on a large scale at a competitive cost and in accordance with the current good manufacturing practice, or cGMPs, and other regulatory requirements, including requirements from federal, state and local regulatory agencies and foreign regulatory requirements, if applicable. Significant scale-up of manufacturing may result in unanticipated technical challenges and will require validation studies that are subject to inspection by the U.S. Food and Drug Administration, or FDA. Scale-up and technology transfer activities can be complex, and insufficient process knowledge can result in a poorly scaled up process with inadequate process control. A lack of process control can lead to increased deviations during the manufacturing process, out of specification test results, batch rejection and the possible distribution of drug products that do not conform to predetermined specifications. In addition, a variety of factors can affect a contract manufacturer’s qualifications to produce acceptable product, including deficiencies in the contractor’s quality unit, lack of training, a shortage of qualified personnel, capacity constraints and changes in the contractor’s commercial or quality related priorities. Any of these difficulties, if they occur, and are not overcome to the satisfaction of the FDA or other regulatory agency, could lead to an interruption in the supply of our drug to the market, particularly given that some of the third parties we employ in the manufacturing process are single source providers. As a result of the large quantity of materials required for Auryxia production and the large quantities of Auryxia that is required for our commercial success, the commercial viability of Auryxia will also depend on adequate supply of starting materials that meet quality, quantity and cost standards and the ability of our contract manufacturers to continually produce the active pharmaceutical ingredient, or API, and finished drug product on a commercial scale. Failure to achieve and maintain these levels of supply can jeopardize and prevent the successful commercialization of the product. Moreover, issues that may arise in our scale-up and technology transfer of Auryxia and continued commercial scale manufacture of Auryxia may lead to significant delays in our development and commercial timelines and negatively impact our financial performance. For example, a production-related issue resulted in an interruption in the supply of Auryxia in the third and fourth quarters of 2016. This supply interruption negatively impacted our revenues in 2016. Although we have resolved this supply interruption and taken steps designed to prevent future interruptions in the supply of Auryxia, any additional supply interruptions would negatively and materially impact our reputation and financial condition.

We currently have multiple suppliers of Auryxia’s API and one supplier with two approved sites for the supply of Auryxia drug product. We are currently working with our drug product supplier to have a third site approved. 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.

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Our third-party manufacturers may not perform as required under the terms of our supply agreement or quality agreement with them, or may not remain in the contract manufacturing business for the time required by us to successfully manufacture and distribute our drug. In addition, our contract manufacturers will be subject to ongoing periodic and unannounced inspections by the FDA and corresponding foreign regulatory agencies to ensure strict compliance with cGMPs, as well as other governmental regulations and corresponding foreign standards. While we periodically audit our contractors for adherence to regulatory requirements, and are ultimately held responsible for their regulatory compliance, we cannot assure you that unforeseen changes at these contractors will not occur that could change their regulatory standing. The same issues apply to contract analytical services which we use for quality, impurity and release testing of our drug. We are required by law to establish adequate oversight and control over raw materials, components and finished products furnished by our third-party manufacturers, which we establish by contract, supplier qualification and periodic audits, but unforeseen circumstances could affect our third-party manufacturers' compliance with applicable regulations and standards. As we continue to scale up production, we continue to develop analytical tools for Auryxia drug substance and drug product testing. Failure to develop effective analytical tools could result in regulatory or technical delay or could jeopardize our ability to obtain and maintain FDA approval. Moreover, even with effective analytical methods available, there is no assurance that we will be able to analyze all the raw materials and qualify all impurities to the satisfaction of the FDA, possibly requiring additional analytical studies, analytical method development, or preclinical or post-approval studies, which could significantly delay our ability to receive regulatory approvals, and effect our ability to maintain any regulatory approvals, for our drug. Additionally, changes in the analytical specifications required by the FDA or other standard setting bodies, such as United States Pharmacopeial Convention, from time to time, could delay our ability to receive regulatory approvals, and affect our ability to maintain regulatory approvals, for our drug or our commercial efforts.

In addition, switching or engaging multiple third-party contractors to produce our drug substance or drug product may be difficult and time consuming because the number of potential manufacturers may be limited and the process by which multiple manufacturers make the drug substance or drug product must meet established specifications at each manufacturing facility. It may be difficult and time consuming for us to find and engage replacement or multiple manufacturers quickly and on terms acceptable to us, if at all. For Auryxia, the loss of any of our drug substance or drug product manufacturers would result in significant additional costs and delays in our development program and, as demonstrated by our 2016 interruption in the supply of Auryxia, negatively impact our sales of Auryxia.

If we do not establish or maintain manufacturing, drug development and marketing arrangements with third parties, we may be unable to commercialize our products.

We do not possess all of the capabilities to fully commercialize our product on our own. From time to time, we may need to contract with additional third parties, or renew or revise contracts with existing third parties, to:

- manufacture our drug;
- assist us in developing, testing and obtaining and maintaining regulatory approval for and commercializing our compound and technologies; and
- market and distribute our drug.

We can provide no assurance that we will be able to successfully enter into agreements with such third parties on terms that are acceptable to us, if at all. If we are unable to successfully contract with third parties for these services when needed, or if existing arrangements for these services are terminated, whether or not through our actions, or if such third parties do not fully perform under these arrangements, we may have to delay, scale back or end one or more of our drug development programs or seek to develop or commercialize our product independently, which could result in significant delays or negatively impact our financial condition. Furthermore, such failure could result in the termination of license rights to our product. If these manufacturing, development or marketing agreements take the form of a partnership or strategic alliance, such arrangements may provide our collaborators with significant discretion in determining the efforts and resources that they will apply to the development and commercialization of our product. We cannot predict the form or scope that any such collaboration might take, and we may pursue other strategic alternatives if terms or proposed collaborations are not attractive. To the extent that we rely on third parties to research, develop or commercialize our product, we are unable to control whether such product will be

scientifically or commercially successful. Additionally, if these third parties fail to perform their obligations under our agreements with them or fail to perform their work in a satisfactory manner, in spite of our efforts to monitor and ensure the quality of such work, we may face decreased sales and/or delays in achieving the business or regulatory milestones required for additional commercialization of our current drug and any future drug candidate. For additional risks associated with our ability to partner the commercialization of Fexeric in Europe, see the risks described under "Approval of Fexeric (ferric citrate coordination complex) in the European Union does not ensure successful commercialization and reimbursement." below.

We have a limited operating history as a commercial-stage company and have incurred substantial operating losses since our inception. We expect to continue to incur losses in the future and may never become profitable.

We have a limited operating history as a commercial-stage company. You should consider our prospects in light of the risks and difficulties frequently encountered by early commercial-stage companies. In addition, we have incurred substantial operating losses since our inception and expect to continue to incur operating losses for the foreseeable future and may never become profitable. As of March 31, 2018, we had an accumulated deficit of $1.0 billion. As we continue our research and development and commercial efforts, we may incur increasing losses. We may continue to incur substantial operating losses even after we begin to generate meaningful revenues from our drug. Our ability to achieve profitability depends on a number of factors, including our ability to complete our development efforts, obtain any additional regulatory approvals that we may seek for our drug, successfully complete any post-approval regulatory obligations and successfully manufacture and commercialize our drug.

We are highly dependent on the commercial success of Auryxia in the United States for the foreseeable future and as a result we may be unable to attain profitability and positive cash flow from operations.

In September 2014, the FDA approved Auryxia for the control of serum phosphorus levels in patients with chronic kidney disease, or CKD, on dialysis and in November 2017, the FDA approved Auryxia for the treatment of iron deficiency anemia in adults with CKD, not on dialysis. The commercial success of Auryxia in the United States will depend on a number of factors, including:

- the effectiveness of Auryxia as a treatment for adult patients with CKD on dialysis and for iron deficiency anemia in adults with CKD, not on dialysis;
- the adoption of Auryxia by physicians, which depends on whether physicians view it as a safe and effective treatment for their patients;
- our ability to successfully launch and then effectively continue to commercialize Auryxia in the newly approved indication of iron deficiency anemia in adults with CKD, not on dialysis;
- the effectiveness of the sales, managed markets and marketing efforts by us and our competitors;
- our ability to continue to supply Auryxia to the market without interruption;
- our ability to identify reliable suppliers and successfully manufacture Auryxia;
- our ability to continue to grow Auryxia product sales following the resupply of Auryxia to the market following the 2016 interruption in its supply;
- the size of the treatable patient population;
- our ability to both secure and maintain adequate reimbursement for, and optimize patient access to Auryxia by providing third-party payers with a strong value proposition and the benefits of Auryxia to patients;
- our mix of business between private commercial payers and government-sponsored plans;
- the occurrence of any side effects, adverse reactions or misuse, or any unfavorable publicity in these areas, associated with Auryxia;
- our ability to obtain and maintain strong intellectual property protection for Auryxia; and
- the development or commercialization of competing products, including generic versions of our drug.

Our revenues from the commercialization of Auryxia are subject to these and other factors, including those set forth under “Risks related to our intellectual property and third-party contracts” below, and therefore may be unpredictable from quarter-to-quarter and year-to-year. Ultimately, we may never generate sufficient revenues from Auryxia to reach or maintain profitability or sustain our anticipated levels of operations.

We have limited experience as a company in sales and marketing, and with respect to pricing and obtaining adequate third-party reimbursement and as a result we may be unable to effectively market our product and retain market access.

We currently have limited experience as a company in sales and marketing and with respect to pricing and obtaining adequate third-party reimbursement for drugs. In order to market Auryxia, including in the newly approved indication of iron deficiency anemia in adults with CKD, not on dialysis, we intend to continue to invest in our sales and marketing, which will require substantial effort and significant management and financial resources. We will need to devote significant effort, in particular, to recruiting individuals with experience in the sales and marketing of pharmaceutical products. Competition for personnel with these skills is intense and may be particularly difficult for us as no oral drug has previously been specifically marketed for the treatment of iron deficiency anemia in patients with CKD, not on dialysis.

Approval of Fexeric (ferric citrate coordination complex) in the European Union does not ensure successful commercialization and reimbursement.

On September 23, 2015, the European Commission, or EC, approved Fexeric (ferric citrate coordination complex) for the control of elevated serum phosphorus levels, or hyperphosphatemia, in adult patients with CKD, including pre-dialysis and dialysis patients. The EC also considered ferric citrate coordination complex as a New Active Substance, or NAS, which provides 10 years of data and marketing exclusivity in the European Union, or EU.

We are not currently marketing Fexeric in the EU and do not intend to commercialize Fexeric in the EU on our own. We have not been successful in finding a suitable commercialization partner for Fexeric in the EU to date. We cannot assure you that we will be able to find a suitable commercialization partner in the EU or otherwise create value from our European rights. If we do not begin to market Fexeric in the EU by September 23, 2018, we believe the EC will likely revoke its approval of Fexeric.

The commercial success of Fexeric is subject to the same types of risks we face with commercializing Auryxia in the United States. In addition, in European countries, pricing and payment of prescription pharmaceuticals is subject to more extensive governmental control than in the United States. Pricing negotiations with European governmental authorities can take six to 12 months or longer after the receipt of regulatory approval and product launch. If reimbursement for Fexeric is unavailable in any country in which reimbursement is sought, limited in scope or amount, or if pricing is set at or reduced to unsatisfactory levels, our ability or any potential partner's ability to successfully commercialize Fexeric in such a country would be impacted negatively. Furthermore, if these measures prevent us or any potential partner from selling Fexeric on a profitable basis in a particular country, they could prevent the commercial launch or continued sale of Fexeric in that country.

Our potential revenues from the commercialization of Fexeric in the EU are subject to these and other factors, including those set forth under "Risks related to our intellectual property and third-party contracts" below, and therefore we may never commercialize Fexeric in the EU or reach or maintain profitability with respect Fexeric in the EU.

Auryxia may cause undesirable side effects or have other properties that could limit its commercial potential.

The most commonly reported adverse reactions in the clinical trials that supported the approval of Auryxia for CKD on dialysis in the United States included diarrhea (21%), discolored feces (19%), nausea (11%), constipation (8%), vomiting (7%), and cough (6%). Gastrointestinal adverse reactions were the most common reason for discontinuing Auryxia (14%) in clinical trials for that indication. The most commonly reported adverse reactions in the clinical trials that supported the approval of Auryxia in the United States for iron deficiency anemia in adults with CKD, not on dialysis included discolored feces (22%), diarrhea (21%), constipation (18%), nausea (10%), abdominal pain (5%) and hyperkalemia (5%). Diarrhea was the most common reason for discontinuing Auryxia (2.6%) in clinical trials for the iron deficiency anemia in adults with CKD, not on dialysis indication. If we or others identify previously unknown side effects, if known side effects are more frequent or severe than in the past, if we or others detect unexpected safety signals for Auryxia or any products perceived to be similar to Auryxia, or if any of the foregoing are perceived to have occurred, then:

- sales of Auryxia may be impaired;

- regulatory approvals for Auryxia may be restricted or withdrawn;

- we may decide to, or be required to, send drug warnings or safety alerts to physicians, pharmacists and hospitals (or FDA or other government agency may choose to issue such alerts), or we may decide to conduct a product recall or be requested to do so by FDA or other government agency;
- reformulation of the product, additional nonclinical or clinical studies, changes in labeling or changes to or re-approvals of manufacturing facilities may be required;
- we may be precluded from pursuing additional development opportunities to enhance the clinical profile of Auryxia within its indicated populations, as well as be precluded from studying Auryxia in additional indications and populations or in new formulations; and
- government investigations or lawsuits, including class action suits, may be brought against us.

Any of the above occurrences would harm or prevent sales of Auryxia, likely increase our expenses and impair our ability to successfully commercialize Auryxia.

Furthermore, as we explore development opportunities to enhance the clinical profile of Auryxia, any clinical trials conducted, if successful, may expand the patient populations treated with Auryxia within or outside of its current indications or patient populations, which could result in the identification of previously unknown side effects, increased frequency or severity of known side effects, or detection of unexpected safety signals. In addition, as Auryxia is commercialized, it will be used in wider populations and in less rigorously controlled environments than in clinical studies. As a result, regulatory authorities, healthcare practitioners, third-party payers or patients may perceive or conclude that the use of Auryxia is associated with serious adverse effects, undermining our commercialization efforts.

We will incur significant liability if it is determined that we are promoting any “off-label” use of Auryxia.

Physicians are permitted to prescribe drug products for uses that are not described in the product’s labeling and that differ from those approved by the FDA or other applicable regulatory agencies. Such “off-label” uses are common across medical specialties. Although the FDA and other regulatory agencies do not regulate a physician’s choice of treatments, the FDA and other regulatory agencies do restrict communications on the subject of off-label use. Companies are not permitted to promote drugs for off-label uses or promote drugs using marketing claims that are not otherwise consistent with the FDA-approved labeling, including comparative or superiority claims that are not consistent with the FDA-approved labeling or supported by substantial evidence. Accordingly, we may not promote Auryxia in the United States for use in any indications other than for the control of serum phosphorus levels in patients with CKD on dialysis and for the treatment of iron deficiency anemia in adults with CKD, not on dialysis, and all promotional claims must be consistent with the FDA-approved labeling for Auryxia. The FDA and other regulatory and enforcement authorities actively enforce laws and regulations prohibiting promotion of off-label uses and the promotion of products for which marketing approval has not been obtained as well as the false advertising or misleading promotion of drugs. A company that is found to have improperly promoted off-label uses or to have otherwise engaged in false or misleading promotion of drugs will be subject to significant liability, including civil and administrative remedies as well as criminal sanctions.

Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific exchange concerning their products in certain circumstances. We intend to engage in medical education activities and communicate with healthcare providers in compliance with all applicable laws, regulatory guidance and industry best practices. Although we believe we have put in place a robust compliance program designed to ensure that all such activities are performed in a legal and compliant manner, Auryxia is our first commercial product, so our implementation of our compliance program in connection with commercialization activities is still relatively new.

The status of reimbursement from third-party payers for newly approved health care drugs is uncertain and failure to obtain adequate reimbursement could limit our ability to generate revenue.

Our ability to commercialize pharmaceutical products may depend, in part, on the extent to which reimbursement for the products will be available from:

- government and health administration authorities;

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- private health insurers;
- managed care programs; and
- other third-party payers.

Significant uncertainty exists as to the coverage and reimbursement status of newly approved health care products, as well as the timing of coverage and reimbursement decisions by third-party payers. Third-party payers, including Medicare and Medicaid, are challenging the prices charged for medical products and services. Government and other third-party payers increasingly are attempting to contain health care costs by limiting both coverage and the level of reimbursement for new drugs and by refusing, in some cases, to provide coverage for uses of approved products for disease indications for which the FDA has not granted labeling approval. In 2003, Congress passed the Medicare Prescription Drug, Improvement and Modernization Act of 2003, which for the first time established prescription drug coverage for Medicare beneficiaries, under Medicare Part D. Under this program, beneficiaries purchase insurance coverage from private insurance companies to cover the cost of their prescription drugs. Likewise, current and future legislative or regulatory efforts to control or reduce healthcare costs or reform government healthcare programs, such as the Patient Protection Affordable Care Act, or PPACA, and the Health Care and Education Reconciliation Act of 2010, could result in lower prices or rejection of coverage and reimbursement for our drug. In addition, third-party insurance coverage may not be available to patients for our product. If government and other third-party payers do not provide adequate coverage and reimbursement levels for our product, Auryxia's market acceptance may be significantly reduced. In addition, the mix of our business that is reimbursed by different payers can negatively impact our net U.S. Auryxia product sales on a year-to-year and quarter-to-quarter basis with a larger mix of government payers generally increasing our adjustments to gross Auryxia sales in the particular period resulting in lower net U.S. Auryxia product sales.

If we fail to comply with healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

As a manufacturer of pharmaceuticals, even though we do not (and do not expect in the future to) control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payers, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We are subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. These regulations include:

- federal healthcare program anti-kickback laws, which prohibit, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent, and which may apply to entities like us which provide coding and billing advice to customers;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- the Federal Food, Drug, and Cosmetic Act, or FDCA, which among other things, strictly regulates drug product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples;
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain

circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts;

- the federal Foreign Corrupt Practices Act which prohibits corporations and individuals from paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity; and
- the federal Physician Payments Sunshine Act, which was passed as part of the PPACA, and similar state laws in certain states, that require pharmaceutical and medical device companies to monitor and report certain payments and transfers of value made to physicians and teaching hospitals.

If our operations are found to be in violation of any of the laws described above or any other laws, rules or regulations that apply to us, we will be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results.

We have assembled an experienced compliance team and implemented a compliance program based on industry best practices designed to ensure our commercialization of Auryxia complies with all applicable laws, regulations and industry standards. We also hire, manage and incentivize our employees around a culture of compliance, trust, respect and ownership. Because our compliance program is relatively new and the requirements in this area are constantly evolving, we cannot be certain that our compliance program will eliminate all areas of potential exposure. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business, as well as damage our business or reputation. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security, fraud and reporting laws may prove costly.

If our competitors develop and market products that are less expensive, have a reduced pill burden, are or are promoted as more effective or safer than our drug product, or our drug product does not achieve market acceptance vis-à-vis existing treatments, our commercial opportunities may be reduced or eliminated.

The pharmaceutical industry is highly competitive. Our competitors include pharmaceutical companies and biotechnology companies, as well as universities and public and private research institutions. In addition, companies that are active in different but related fields represent substantial competition for us. Many of our competitors have significantly greater capital resources, larger research and development staffs and facilities and greater experience in drug development, regulation, manufacturing and marketing drugs than we do. These organizations also compete with us to recruit qualified personnel, attract partners for joint ventures or other collaborations, and license technologies that are competitive with ours. As a result, our competitors may be able to more easily develop technologies and products that could render our drug product obsolete or noncompetitive. To compete successfully in this industry, we must identify novel and unique drugs or methods of treatment and then acquire and/or complete the development of those drugs as treatments in advance of our competitors.

Auryxia is competing in the United States with other FDA-approved phosphate binders such as Renagel (sevelamer hydrochloride) and Renvela (sevelamer carbonate), both marketed by Genzyme Corporation (a wholly-owned subsidiary of Sanofi), PhosLo (calcium acetate), marketed by Fresenius Medical Care, Fosrenol (lanthanum carbonate), marketed by Shire Pharmaceuticals Group plc, and Velphoro (sucroferric oxyhydroxide), marketed by Fresenius Medical Care North America, as well as over-the-counter calcium carbonate products such as TUMS and metal-based options such as aluminum and magnesium. Our strategy to compete against these existing treatments depends in part on physicians and patients accepting that Auryxia is differentiated in the marketplace versus these FDA-approved phosphate binders.

In addition, we may have to compete against existing treatments on price, which becomes more challenging as generic versions of these existing treatments come to market. Manufacturers of branded products face commercial challenges from generic pharmaceutical manufacturers. For example, there are several parties that have received approval of Abbreviated New Drug Applications, or ANDAs, for generic Renvela with the FDA and launched the generic form in

the United States. A generic formulation of PhosLo was launched in the United States in October 2008, and there are now numerous, FDA-approved generic version of PhosLo on the market. In addition, the first generic formulation of Fosrenol was approved by FDA in August

2017. Generic competitors often operate without large research and development expenses, as well as without costs of conveying medical information about products to the medical community. The FDA approval process also exempts generics from costly and time-consuming clinical trials to demonstrate their safety and efficacy, allowing generic manufacturers, if any, to rely on the safety and efficacy data of the innovator branded product. As a result, the generic formulations of these brand name drugs could have a further material effect on the pricing of phosphate binders. Additionally, we expect interest in making a generic version of Auryxia. The date at which generic competition in the marketplace may commence can vary and may be different from the date that patent or regulatory exclusivity expires. However, upon the expiration or loss of patent protection for Auryxia, or upon an "at-risk" launch (despite pending patent infringement litigation against the generic product) by a generic manufacturer of a generic version of Auryxia, the resulting price competition may cause us to lose significant revenues for Auryxia in a very short period of time, which could adversely affect our business. In addition, generic competitors may challenge the patents covering Auryxia before their expiration. Auryxia is also competing in the United States with other FDA-approved treatments for iron deficiency anemia, such as Venofer® (iron sucrose) and Injactafer® (ferric carboxymaltose), both marketed by American Regent (a registered trademark of Luitpold Pharmaceuticals, Inc., a member of the Daiichi Sankyo Group), Feraheme® (ferumoxytol), marketed by AMAG Pharmaceuticals, Inc., Triferic® (ferric pyrophosphate citrate), marketed by Rockwell Medical, Inc., over-the-counter iron supplement products, as well as Erythropoiesis-stimulating agents, or ESAs, including Procrit® (epoetin alfa), marketed by Janssen Products, LP (a wholly-owned subsidiary of Johnson & Johnson) and Aranesp® (darbepoetin alfa), marketed by Amgen Inc. and may have to compete with other treatments currently in development if they are approved, such as Feraccru® in development by Shield Therapeutics PLC.

Furthermore, our commercial opportunities may be reduced or eliminated if our competitors develop and market products that are less expensive, more effective or safer than our drug product. Other companies have drug candidates in various stages of pre-clinical or clinical development to treat diseases for which we are marketing our drug and also seeking to acquire and develop other drug products. Even if we are successful in developing effective drugs, our product(s) may not compete successfully with products produced by our competitors.

Recent changes in our executive management team, additional changes in our key personnel or our inability to attract and retain additional personnel, could be disruptive to our operations and harmful to our business.

As of March 31, 2018, we had 207 full and part-time employees. To successfully develop and commercialize our drug and any drug candidates we may in-license or acquire, we must be able to attract and retain highly skilled personnel. Our limited resources may hinder our efforts to attract and retain highly skilled personnel. In addition, if we lose the services of our current personnel our ability to continue to execute on our business plan could be materially impaired. In addition, on April 27, 2018, Gregory P. Madison resigned as our President and Chief Executive Officer and as a member of our Board of Directors and we appointed Jodie Morrison, a member of our Board of Directors, as our Interim Chief Executive Officer while we perform a search for a permanent Chief Executive Officer. In connection with Ms. Morrison's appointment as Interim Chief Executive Officer, fellow director Kevin Cameron replaced Ms. Morrison on the Audit Committee of our Board of Directors. These changes in our executive management team and to the membership on our Board of Directors and its committees, may be disruptive to, or cause uncertainty in, our business, and any additional changes to the executive management team or the Board of Directors could have a negative impact on our ability to manage and grow our business effectively. In addition, if we are not effective in succession planning, there may be a negative impact on our ability to successfully hire for key executive management roles, including the permanent Chief Executive Officer position, in a timely manner. Any such disruption or uncertainty or difficulty in efficiently and effectively filling key roles could have a material adverse impact on our results of operations and the price of our common stock.

Although we have employment agreements with Ms. Morrison and the other members of our executive management team, John F. Neylan, M.D., Scott Holmes and Christine Carberry, these agreements do not prevent them from terminating their employment with us.

Risks associated with our product development efforts

If we are unable to successfully complete our clinical trial programs, or if such clinical trials take longer to complete than we project, our ability to execute our current business strategy will be adversely affected.

Although we are not currently conducting registration trials for Auryxia, we continue to conduct clinical trials and post-marketing testing of Auryxia. We also may have to complete the development of any product candidate that we develop, in-license or acquire in the future. As a result, the continued marketing of Auryxia and the clinical development of any other

product is subject to the risks associated with the pre-clinical and clinical development of pharmaceutical products. Failure to fulfill our obligations with respect to post-approval testing could result in the FDA levying penalties up to and including withdrawal of the drug from the market. For example, in connection with the approvals of Auryxia, we committed to the FDA to conduct certain post-approval pediatric studies of Auryxia under the Pediatric Research Equity Act. With regards to our indication for the treatment for hyperphosphatemia in adult patients on dialysis, we committed to completing the post-approval pediatric study and submitting a final report by December 31, 2019. We do not expect to complete this study and submit a final report by this date and we are in discussions with the FDA regarding an extension of the timeframe to complete the study and submit the final report. With regards to our indication for the treatment of iron deficiency anemia in chronic kidney disease patients, not on dialysis, we committed to completing the post-approval pediatric study and submitting a final report by January 31, 2023.

Whether or not and how quickly we complete our clinical trials is dependent in part upon the rate at which we are able to engage clinical trial sites and, thereafter, the rate of enrollment of patients, and the rate we collect, clean, lock and analyze the clinical trial database. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study, the existence of competitive clinical trials, and whether existing or new drugs are approved for the indication we are studying. We are aware that other companies are currently conducting or planning clinical trials that seek to enroll patients with the same disease that we are studying. If we experience delays in identifying and contracting with sites and/or in-patient enrollment in our clinical trial programs, we may incur additional costs and delays in our development programs, and may not be able to complete our clinical trials in a cost-effective or timely manner or at all. In addition, conducting multi-national studies adds another level of complexity and risk. As a result, we may be subject to events affecting countries outside the United States.

Negative or inconclusive results from the clinical trials we conduct, or unanticipated adverse medical events could cause us to have to repeat or terminate the clinical trials. For example, in May 2012, we abandoned our development efforts and terminated our license for KRX-0401 (perifosine) following negative results from the Phase 3 trial for KRX-0401. We may also opt to change the delivery method, formulation or dosage which could affect efficacy results for the drug. Accordingly, we may not be able to complete our current or future clinical trials within an acceptable time frame, if at all.

Pre-clinical testing and clinical development are long, expensive and uncertain processes.

Pre-clinical testing and clinical development are long, expensive and uncertain processes. Satisfaction of regulatory requirements typically depends on the nature, complexity and novelty of the product. It requires the expenditure of substantial resources. Data obtained from pre-clinical and clinical tests can be interpreted in different ways, which could delay, limit or prevent regulatory approval. The FDA may pose additional questions or request further toxicological, drug-drug interaction, pre-clinical or clinical data or substantiation. Negative, inconclusive, or insufficient results or medical events during a pre-clinical or clinical trial could cause us to delay or terminate our development efforts. Furthermore, interim results of pre-clinical or clinical studies do not necessarily predict their final results, and acceptable results in early studies might not be obtained in later studies.

Drug candidates in the later stages of clinical development may fail to show the desired traits of safety and efficacy despite positive results in earlier clinical testing. The risk also remains that a clinical program conducted by one of our partners may raise efficacy or safety concerns that may prevent approval of the drug. In addition, qualitative, quantitative and statistical interpretation of any of the prior pre-clinical and clinical safety and efficacy data of our drug may be viewed as flawed by the FDA. In addition, there can be no assurance that safety and/or efficacy concerns from the prior data were not overlooked or misinterpreted by us or our consultants, which in subsequent, larger studies might appear and prevent approval of such drug candidate.

Clinical trials have a high risk of failure. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in advanced clinical trials, even after achieving what appeared to be promising results in earlier trials. We experienced such a setback with our Phase 3 KRX-0401 (perifosine) trial results in April 2012, and we can provide no assurance that we will not experience such setbacks with ferric citrate or any other drug candidate we develop or acquire. If we experience delays in the testing or approval process for any drug we may commercialize or develop or if we need to perform more or larger clinical trials than

originally planned, our financial results and the commercial prospects for our drug may be materially impaired. In addition, we have limited experience in conducting and managing the clinical trials necessary to obtain and maintain regulatory approval. Accordingly, we may encounter unforeseen problems and delays in the approval process. Although we engage, from time to time, clinical research organizations, or CROs, with experience in conducting regulatory trials, errors in the conduct, monitoring, data capture and analysis, and/or auditing could potentially invalidate the results.

Because all of our proprietary technologies are licensed or sublicensed to us by third parties, termination of these license rights would prevent us from developing and further commercializing Auryxia.

We do not own our drug, Auryxia. We have licensed and sublicensed the rights, patent or otherwise, to Auryxia from a third-party, Panion & BF Biotech, Inc., or Panion, who in turn licenses certain rights to Auryxia from one of the inventors of Auryxia. The license agreement with Panion requires us to meet development milestones and imposes development and commercialization due diligence requirements on us. In addition, under the agreement, we must pay royalties based on a mid-single digit percentage of net sales of product resulting from the licensed technologies (including Auryxia) and pay the patent filing, prosecution and maintenance costs related to the license. If we do not meet our obligations in a timely manner or if we otherwise breach the terms of our license agreement (including upon certain insolvency events), Panion could terminate the agreement, and we would lose the rights to Auryxia. In addition, if Panion breaches its agreement with the inventor from whom it licenses rights to Auryxia, Panion could lose its license, which could impair or delay our ability to develop and commercialize Auryxia. From time to time, we may have disagreements with our licensors or collaborators, or they and/or we may have disagreements with the original inventors, regarding the terms of our agreements or ownership of proprietary rights, which could lead to delays in the research, development and commercialization of our current drug and any future drug candidate, could require or result in litigation or arbitration, which would be time-consuming and expensive, or could lead to the termination of a license, or force us to negotiate a revised or new license agreement on terms less favorable than the original. In addition, in the event that the owners and/or licensors of the rights we license were to enter into bankruptcy or similar proceedings, we could potentially lose our rights to our drug or drug candidates or our rights could otherwise be adversely affected, which could prevent us from developing or commercializing our drugs. Finally, our rights to develop and commercialize Auryxia, whether ourselves or with third parties, are subject to and limited by the terms and conditions of our licenses to Auryxia and the licenses and sublicenses we grant to others.

Our reliance on third parties, such as CROs, may result in delays in completing, or a failure to complete, clinical trials if such CROs fail to perform under our agreements with them.

In the course of product development, we engage CROs and other vendors to conduct and manage clinical studies and to assist us in guiding our products through the FDA review and approval process and maintain any approvals we receive. If the CROs or applicable vendors fail to perform their obligations under our agreements with them or fail to perform clinical trials in a satisfactory or timely manner, we may face significant delays in completing our clinical trials, submitting our regulatory filings, or approval, and we may not maintain any regulatory approvals or effectively commercialize one or more drug candidates. Furthermore, any loss or delay in obtaining contracts with such entities may also delay the completion of our clinical trials and the market approval of drug candidate(s).

Other risks related to our business

Any acquisitions or other strategic transaction we undertake may require a significant amount of our available cash, may dilute our stockholders and may not be scientifically or commercially successful.

As part of our business strategy, we may affect acquisitions or other strategic transactions to obtain additional businesses, products, technologies, capabilities and personnel. If we make one or more significant acquisitions or other strategic transactions in which the consideration includes cash, we may be required to use a substantial portion of our available cash. In addition, if we issue our equity securities as consideration in any acquisition or other strategic transaction, the ownership interests of our stockholders will be diluted.

Acquisitions and other strategic transactions involve a number of operational risks, including:

- difficulty and expense of assimilating the operations, technology and personnel of the acquired business;
- our inability to retain the management, key personnel and other employees of the acquired business;
- our inability to maintain the acquired company’s relationship with key third parties, such as alliance partners;
- exposure to legal claims for activities of the acquired business prior to the acquisition;
- the diversion of our management’s attention from our core business; and

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- the potential impairment of goodwill and write-off of in-process research and development costs, adversely affecting our reported results of operations.

If we do not successfully integrate any such additional businesses, products, technologies, capabilities or personnel into our business, our financial condition and operating results could be materially and negatively impacted.

Health care reform measures could adversely affect our business.

The business prospects and financial condition of pharmaceutical and biotechnology companies are affected by the efforts of governmental and third-party payers to contain or reduce the costs of health care. In the United States and in foreign jurisdictions there have been, and we expect that there will continue to be, a number of legislative and regulatory proposals aimed at changing the health care system, such as proposals relating to the pricing of healthcare products and services in the United States or internationally, the importation of drugs into the United States from other countries (where they are then sold at a lower price), and the amount of reimbursement available from governmental agencies or other third-party payers. For example, drug manufacturers are required to have a national rebate agreement with the Department of Health and Human Services, or HHS, in order to obtain state Medicaid coverage, which requires manufacturers to pay a rebate on drugs dispensed to Medicaid patients. On January 27, 2012, the Centers for Medicare and Medicaid Services, or CMS, issued a proposed regulation covering the calculation of Average Manufacturer Price, or AMP, which is the key variable in the calculation of these rebates.

Furthermore, in the United States, health care reform legislation titled the PPACA was signed into law in March 2010. The impact of this legislation on our business is inherently difficult to predict as many of the details regarding the implementation of this legislation have not been determined. In a decision issued on June 29, 2012, the United States Supreme Court upheld the majority of PPACA. The Court's decision allows implementation of key provisions impacting drug and device manufacturers to go forward. This includes PPACA changes to the Medicare Part D Program (including closing the "donut hole"), Medicaid Drug Rebate Program (including the definition of AMP), and expansion of the 340B Drug Discount Program. The decision also allows the FDA and CMS to continue with implementation efforts, including related to the Biologics Price Competition and Innovation Act and the Physician Payments Sunshine Act, both of which were enacted as part of the PPACA. Regulations to implement PPACA could result in a decrease in our stock price or limit our ability to raise capital or to obtain strategic partnerships or licenses. Government-financed comparative efficacy research could also result in new practice guidelines, labeling or reimbursement policies that discourages use of our product.

For example, in July 2010, CMS released its final rule to implement a bundled prospective payment system for end-stage renal disease facilities as required by the Medicare Improvements for Patients and Providers Act, or MIPPA. The final rule delayed the inclusion of oral medications without intravenous equivalents, such as phosphate binders, in the bundle until January 1, 2014; however, on January 3, 2013, the United States Congress passed legislation known as the American Taxpayer Relief Act of 2012, which, among other things, delayed by two years the implementation of oral-only end-stage renal disease related drugs, including phosphate binders, in the bundled end stage renal disease, or ESRD, prospective payment system, until January 1, 2016. In April 2014, the United States Congress passed legislation known as Protecting Access to Medicare Act of 2014, which, among other things, delays by eight years the implementation of oral-only ESRD related drugs, including phosphate binders, in the bundled ESRD prospective payment system, until January 1, 2025. If phosphate binders are included in the bundle beginning in 2025, or earlier, separate Medicare reimbursement will no longer be available for phosphate binders, as it is today under Medicare Part D. While it is too early to project the impact bundling may have on the phosphate binder industry, the impact could potentially cause dramatic price reductions for phosphate binders, which could significantly reduce the commercial potential of Auryxia.

On September 27, 2007, the Food and Drug Administration Amendments Act of 2007 was enacted, giving the FDA enhanced post-market authority, including the authority to require post-marketing studies and post-marketing clinical trials related to serious risks, labeling changes based on new safety information, and compliance with risk evaluation and mitigation strategies approved by the FDA. The FDA's exercise of this authority may result in delays or increased costs during the period of product development, clinical trials and regulatory review and approval, which may also increase costs related to complying with new post-approval regulatory requirements, and increase potential FDA

restrictions on the sale or distribution of approved products. On July 9, 2012, the Food and Drug Administration Safety and Innovation Act was enacted to, among other things, renew the drug user fee program, expand the FDA's inspection records access and require manufacturers to establish appropriate oversight and controls over their suppliers and the supply chain, including raw material suppliers and contract manufacturers, as a part of cGMP compliance. On November 27, 2013, the Drug Quality and Security Act, which includes the

Drug Supply Chain Security Act, was signed into law to, among other things, build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States. Requirements for the tracing of products through the pharmaceutical distribution supply chain took effect on January 1, 2015 for manufacturers and building and maintaining internal systems to ensure compliance with this law requires dedication of resources. In addition, this law requires engaging in transactions only with authorized trading partners and could limit our pool of available trading partners.

We face product liability risks and may not be able to obtain adequate insurance.

The use of our drug commercially and in clinical trials exposes us to liability claims. In addition, the use of any other drug candidate we develop or acquire in clinical trials, the future sale of any other approved drug and the use of new technology will also expose us to liability claims. Although we are not aware of any historical or anticipated product liability claims against us, if we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to cease clinical trials of our drug product or limit commercialization of any approved product.

We have insurance coverage for the commercial sale of Auryxia; however, insurance coverage is becoming increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost. We also may not be able to obtain additional insurance coverage that will be adequate to cover product liability risks that may arise. Regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand for a product;
- injury to our reputation;
- our inability to continue to develop a drug candidate;
- withdrawal of clinical trial volunteers; and
- loss of revenues.

Consequently, a product liability claim or product recall may result in losses that could be material to our business.

Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our suppliers and business partners, as well as personally identifiable information of Auryxia patients, clinical trial participants and employees. We also have outsourced elements of our information technology structure, and as a result, we are managing independent vendor relationships with third parties who may or could have access to our confidential information. Similarly, our business partners and other third-party providers possess certain of our sensitive data. The secure maintenance of this information is critical to our operations and business strategy. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. We, our partners, vendors and other third-party providers could be susceptible to third-party attacks on our, and their, information security systems, which attacks are of ever increasing levels of sophistication and are made by groups and individuals with a wide range of motives and expertise, including criminal groups. Any such breach could compromise our, and their, networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, disrupt our operations, and damage our reputation, any of which could adversely affect our business.

Risks related to our financial condition

Our existing capital resources may not be adequate to finance our operating cash requirements for the length of time that we have estimated.

The actual amount of cash that we will need to operate our business 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 any further clinical trials for ferric citrate. As a result of

these factors, we will need to seek additional financing, in addition to our borrowings from The Baupost Group, L.L.C. to provide the cash necessary to execute our current operations, including beyond the continued commercialization of Auryxia, and to develop and commercialize any

drugs or drug candidates we may in-license or acquire. Although our Convertible Senior Notes due 2021 issued to a fund affiliated with The Baupost Group, L.L.C. on May 9, 2018 allow us to secure an up to a $40 million asset-based credit facility, for which we have a commitment from a lender, we may not be able to successfully negotiate and enter into definitive agreements with respect to the asset-based credit facility and the borrowing base we may utilize at any one time under the asset-based credit facility, if successfully entered into, may be significantly lower than the total commitment under such facility.

Our forecast of the period of time through which our existing capital resources will be adequate to support our current operations is a forward-looking statement that involves risks and uncertainties. The actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control. These factors include, but are not limited to, the following:

- our ability to successfully market Auryxia as a drug for adults with CKD on dialysis and for the treatment of iron deficiency anemia in adults with CKD, not on dialysis;
- 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;
- our ability to continue to supply Auryxia to the market without interruption;
- our ability to continue to grow Auryxia product sales following the resupply of Auryxia to the market following the 2016 interruption in its supply;
- the timing, design and conduct of, and results from, clinical trials that we may conduct;
- the timing of expenses associated with manufacturing and product development of Auryxia and those proprietary drug candidates that may be in-licensed, partnered or acquired;
- the timing of the in-licensing, partnering and acquisition of new product opportunities;
- the timing and expenditures associated with commercial activities related to launching Fexeric in Europe, through a commercialization partner or by us if we decide to commercialize in Europe on our own, or other expenses incurred in connection with our Fexeric marketing rights in Europe;
- the progress of the development efforts of parties with whom we have entered, or may enter, into research and development agreements;
- our ability to achieve our milestones under our licensing arrangement;
- the timing and expenses associated with capital expenditures to expand our manufacturing capabilities;
- the timing and expenses associated with building our own commercial infrastructure to manufacture, market and sell our drug and those that may be in-licensed, partnered or acquired; and
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights, defending against post-grant proceedings initiated by third parties attempting to limit or cancel our intellectual property rights in the United States and elsewhere, such as U.S. inter partes review proceedings and/or European oppositions, or defending against claims of infringement initiated by third parties in respect of their intellectual property rights.

If our cash is insufficient to meet our future operating requirements, we will have to raise additional funds. If we are unable to obtain additional funds on terms favorable to us, or at all, we may be required to cease or reduce our operating activities or sell or license to third parties some or all of our intellectual property.

If we raise additional funds by selling additional shares of our capital stock, including pursuant to our Controlled Equity Offering[SM] Sales Agreement, or Sales Agreement, with Cantor Fitzgerald & Co., or Cantor Fitzgerald, the ownership interests of our stockholders will be diluted. If we need to raise additional funds through the sale or license of our intellectual property, we may be unable to do so on terms favorable to us, if at all.

Risks related to our intellectual property and third-party contracts

If we are unable to adequately protect our intellectual property, third parties may be able to use our intellectual property, which could adversely affect our ability to compete in the market.

Our commercial success will depend in part on our ability, and the ability of our licensors, to obtain and maintain patent protection on our drug product and technologies, and to successfully defend these patents against third-party challenges. We seek to protect our proprietary products and technology by filing patent applications in the United States and certain foreign jurisdictions. The process for obtaining patent protection is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications in a cost effective or timely manner. In addition, we may fail to identify patentable subject matter before it is too late to obtain patent protection. Further, license agreements with third parties may not allow us to control the preparation, filing and prosecution of patent applications, or the maintenance or enforcement of patents. Such third parties may decide not to enforce such patents or enforce such patents without our involvement. Thus, these patent applications and patents may not under these circumstances be prosecuted or enforced in a manner consistent with the best interests of the company.

Our pending patent applications may not issue as patents and may not issue in all countries in which we develop, manufacture or potentially sell our product(s) or in countries where others develop, manufacture and potentially sell products using our technologies. Moreover, our pending patent applications, if issued as patents, may not provide additional protection for our product.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. No consistent policy regarding the breadth of claims allowed in pharmaceutical and biotechnology patents has emerged to date. Changes in the patent laws or the interpretation of the patent laws in the United States and other jurisdictions may diminish the value of our patents or narrow the scope of our patent protection. Accordingly, the patents we own or license may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Furthermore, others may independently develop similar or alternative drug products or technologies or design around our patented drug product and technologies which may have an adverse effect on our business. If our competitors prepare and file patent applications in the United States that claim technology also claimed by us, we may have to participate in interference or derivation proceedings in front of the U.S. Patent and Trademark Office, or USPTO, to determine priority of invention, which could result in substantial cost, even if the eventual outcome is favorable to us. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that any related patent may expire prior to, or remain in existence for only a short period following commercialization, thus reducing any advantage of the patent. The patents we own or license may be challenged or invalidated or may fail to provide us with any competitive advantage. Since we have licensed or sublicensed many patents from third parties, we may not be able to enforce such licensed patents against third-party infringers without the cooperation of the patent owner and the licensor, which may not be forthcoming. In addition, we may not be successful or timely in obtaining any patents for which we submit applications.

Additionally, the laws of foreign countries may not protect our intellectual property rights to the same extent as do the laws of the United States. For example, claims in a patent application directed to methods of treatment of the human body are not patentable or are restricted in many non-U.S. countries. Further, we may not pursue or obtain patent protection in all major markets. In addition, in jurisdictions outside the United States where we own or license patent rights, we may be unable to prevent unlicensed parties from selling or importing products or technologies derived elsewhere using our proprietary technology.

Generally, the first to file a patent application is entitled to the patent if all other requirements of patentability are met. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. Since publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Moreover, the laws enacted by the Leahy-Smith America Invents Act of 2011, or the Act, which reformed certain patent laws in the

United States, introduce procedures that permit competitors to challenge our patents in the USPTO after grant, including inter partes review and post grant review. Similar laws exist outside of the United States. The laws of the European Patent Convention, for example, provide for post-grant opposition procedures that permit competitors to challenge, or oppose, our European patents administratively at the European Patent Office. We currently have two issued European patents involved in such post-grant opposition proceedings, European patent numbers 1 931 689 and 1 978 807. Patent number 1 931 689 was revoked by the European Patent Office. We filed an appeal of this decision, which is presently pending. According to European practice, the revocation of the patent is stayed until an

appeal is finally resolved. We anticipate the appeal to take several years to resolve, during which time the patent will remain in force. Opposition proceedings relating to patent number 1 978 807 are presently ongoing.

We may become involved in addressing patentability objections based on third-party submission of references, or we may become involved in defending our patent rights in oppositions, derivation proceedings, reexamination, inter partes review, post grant review, interference proceedings or other patent office proceedings or litigation, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse result in any such proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged on such a basis in the courts or patent offices in the United States and abroad. As a result of such challenges, we may lose exclusivity or freedom-to-operate or patent claims may be narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to prevent third parties from using or commercializing similar or identical products, or limit the duration of the patent protection for our products.

In addition, patents protecting our product candidate might expire before or shortly after such candidate is commercialized. Thus, our patent portfolio may not provide sufficient rights to exclude others from commercializing products similar or identical to ours.

We also rely on trade secrets and know-how to protect our intellectual property where we believe patent protection is not appropriate or obtainable. Trade secrets are difficult to protect. While we require our employees, licensees, collaborators and consultants to enter into confidentiality agreements, this may not be sufficient to adequately protect our trade secrets or other proprietary information. In addition, we share ownership and publication rights to data relating to our drug product and technologies with our research collaborators and scientific advisors. If we cannot maintain the confidentiality of this information, our ability to receive patent protection or protect our trade secrets or other proprietary information will be at risk.

The intellectual property that we own or have licensed relating to our drug, Auryxia, is limited, which could adversely affect our ability to compete in the market and adversely affect the value of Auryxia.

The patent rights that we own or have licensed relating to Auryxia are limited in ways that may affect our ability to exclude third parties from competing against us. For example, a third-party may design around our owned or licensed composition of matter patent claims or not market a product for methods of use covered by our owned or licensed patents.

Obtaining proof of direct infringement by a competitor for a method of use patent requires us to demonstrate that the competitors make and market a product for the patented use(s). Alternatively, we can prove that our competitors induce or contribute to others in engaging in direct infringement. Proving that a competitor contributes to, or induces, infringement of a patented method by another has additional proof requirements. For example, proving inducement of infringement requires proof of intent by the competitor. If we are required to defend ourselves against claims or to protect our own proprietary rights against others, it could result in substantial costs to us and the distraction of our management. An adverse ruling in any litigation or administrative proceeding could prevent us from marketing and selling Auryxia, increase the risk that a generic or other similar version of Auryxia could enter the market to compete with Auryxia, limit our development and commercialization of Auryxia, or otherwise harm our competitive position and result in additional significant costs. In addition, any successful claim of infringement asserted against us could subject us to monetary damages or injunction, which could prevent us from making or selling Auryxia. We also may be required to obtain licenses to use the relevant technology. Such licenses may not be available on commercially reasonable terms, if at all.

Moreover, physicians may prescribe a competitive identical product for indications other than the one for which the product has been approved, or “off-label” indications, that are covered by the applicable patents. Although such off-label prescriptions may directly infringe or contribute to or induce infringement of method of use patents, such infringement is difficult to prevent.

In addition, any limitations of our patent protection described above may adversely affect the value of our drug product and may inhibit our ability to obtain a corporate partner at terms acceptable to us, if at all.

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In addition to patent protection, we may utilize, if granted by the FDA, pediatric exclusivity or other provisions of the FDCA such as new chemical entity, or NCE, exclusivity, or exclusivity for a new use or new formulation, to provide non-patent market exclusivity for a drug product. As of the date of this report, we have not received NCE status for Auryxia from the FDA.

In the United States, the FDA has the authority to grant additional regulatory exclusivity protection for approved drugs where the sponsor conducts specified testing in pediatric or adolescent populations. If granted, this pediatric exclusivity may provide an additional six months which are added to the term of any non-patent exclusivity that has been awarded as well as to the regulatory protection related to the term of a relevant patent, to the extent these protections have not already expired.

The FDCA provides a five-year period of non-patent exclusivity within the United States to the first applicant to gain approval of a new drug application, or NDA, for an NCE. A drug is an NCE if the FDA has not previously approved any other new drug containing the same active moiety, which consists of the molecule(s) or ion(s) responsible for the action of the drug substance, (but not including those portions of the molecule that cause it to be a salt or ester or which are not bound to the molecule by covalent or similar bonds). During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an ANDA or 505(b)(2) NDA that references an NDA product with NCE exclusivity may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application (for example, for new indications, dosages, or strengths of an existing drug). This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. The three-year exclusivity period, unlike five-year exclusivity, does not prevent the submission of a competing ANDA or 505(b)(2) NDA. Instead, it only prevents FDA from granting final approval to such a product until expiration of the exclusivity period. Five-year and three-year exclusivity will not delay the submission (in the case of five-year exclusivity) or the approval (in the case of three-year exclusivity) of a full NDA submitted under section 505(b)(1) of the FDCA; however, an applicant submitting a full NDA would be required to conduct all of its own studies needed to independently support a finding of safety and effectiveness for the proposed product, or have a full right of reference to all studies not conducted by the applicant.

We cannot assure that Auryxia or any drug candidates we may acquire or in-license will obtain such pediatric exclusivity, NCE exclusivity or any other market exclusivity in the United States, EU or any other territory, or that we will be the first to receive the respective regulatory approval for such drugs so as to be eligible for any market exclusivity protection. We also cannot assure that Auryxia or any drug candidates we may acquire or in-license will obtain patent term extension.

Litigation or third-party claims could require us to spend substantial time and money defending such claims and adversely affect our ability to develop and commercialize our product.

We may be forced to initiate litigation to enforce our contractual and intellectual property rights, or we may be sued by third parties asserting claims based on contract, tort or intellectual property infringement. In addition, third parties may have or may obtain patents in the future and claim that Auryxia or any other technologies infringe their patents. If we are required to defend against suits brought by third parties, or if we sue third parties to protect our rights, we may be required to pay substantial litigation costs, and our management’s attention may be diverted from operating our business. In addition, any legal action against our licensor or us that seeks damages or an injunction of our commercial activities relating to Auryxia or other technologies could subject us to monetary liability, a temporary or permanent injunction preventing the development, marketing and sale of Auryxia or such technologies, and/or require our licensor or us to obtain a license to continue to use Auryxia or other technologies. We cannot predict whether our licensor or we would prevail in any of these types of actions or that any required license would be made available on commercially acceptable terms, if at all.

We may be subject to claims by third parties asserting that we or our employees have misappropriated their intellectual property or claiming ownership of what we regard as our own intellectual property.

A number of our employees were previously employed at universities, or pharmaceutical or biotechnology companies, some of which may be a competitor or potential competitor. We try to ensure that our employees do not use the proprietary information or know-how of third parties in their work for us. Nonetheless, we may be subject to claims that we, or these employees, have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. As a result, litigation may be necessary to defend against these claims.

In addition, although we typically require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Such assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

In the event that we fail in prosecuting or defending any such claims, we may need to pay monetary damages as well as lose valuable intellectual property rights or personnel. However, regardless of the success in prosecuting or defending against such claims, such litigation may result in substantial costs and distract management.

Risks related to our common stock

The Baupost Group, L.L.C, or Baupost, our largest stockholder, may have significant influence over our company and may cause us to take actions that may not be, or refrain from taking actions that may be, in our best interest or the best interest of our other stockholders.

As of May 9, 2018, Baupost beneficially owns approximately 21% of our issued and outstanding common stock. If Baupost converts all of the convertible notes issued to it on May 9, 2018 into shares of our common stock, Baupost would beneficially own approximately 39% of our issued and outstanding common stock. Baupost, through its equity interests, may have significant influence over matters submitted to our stockholders for approval and other corporate actions, such as:

- election of directors;
- timing and manner in which we raise additional funds;
- timing and manner of dividend distributions;
- approval of contracts between us and Baupost or its respective affiliates, which could involve conflicts of interest;
- open market purchase programs or other purchases of our common shares;
- delay, defer or prevent a change in who controls us;
- discourage bids for our shares at a premium over the market price; and
- adversely affect the market price of our common shares.

Moreover, because large stockholders have potential power to direct or influence our corporate actions, we may be required to engage in transactions that may not be agreeable to our other stockholders or that may not be in the best interest of our other stockholders. In addition, Baupost has the right to appoint a director to our Board and also has the right to appoint an observer to our Board.

Future sales or other issuances of our common stock could depress the market for our common stock.

Sales of a substantial number of shares of our common stock, or the perception by the market that those sales could occur, could cause the market price of our common stock to decline or make it more difficult for us to raise funds through the sale of equity in the future.

In November 2016, we filed a registration statement on Form S-3 (No. 333-214513), which the Securities and Exchange Commission, or 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 the Sales Agreement with 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. In July 2017, we filed 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. During the year ended December 31, 2017, we sold 11,937,174 shares under the Sales Agreement for aggregate net proceeds of $75.7 million, which included all of the initial $75.0 million shares issuable pursuant to the Sales Agreement. As of the date hereof, we may sell up to an additional $72.4 million under the Sales Agreement pursuant to the July 2017 prospectus supplement. The initial $75.0 million of common stock

issued pursuant to the Sales Agreement and the additional $75.0 million of common stock issuable pursuant to the Sales Agreement are included as part of the $250 million registered on the registration statement referred to above.
In October 2015, we raised $125 million through the private placement of Convertible Senior Notes due 2020, with funds managed by Baupost. The zero-coupon notes matured in October 2020 and were convertible into approximately 33,422,460 shares of our common stock in accordance with their terms. On May 9, 2018, we issued $164.7 million of Convertible Senior Notes due 2021 to a fund managed by Baupost in exchange for the old Convertible Senior Notes due 2020 and an additional $10 million in cash. The new zero-coupon notes will mature in October 2021. We do not have the right to redeem the new notes prior to maturity. The conversion price of the new notes is equal to $4.63 per share, the closing price of our common stock on the day prior entering into the notes exchange agreement on May 8, 2018, subject to certain adjustments under the terms of the new notes. As a result, the principal amount of the new notes issued in connection with the exchange of the existing notes initially converts into approximately the same number of shares (33.4 million) into which the existing notes were convertible and the principal amount of the new notes issued in connection with the additional $10 million investment initially converts into an additional approximately 2.2 million shares.
On January 21, 2015, we announced the pricing of an underwritten public offering in which we sold 10,541,667 shares of our common stock at a price of $12.00 per share for gross proceeds of approximately $126.5 million. Net proceeds from this offering were approximately $118.3 million, net of underwriting discounts and offering expenses of approximately $8.2 million. The shares were sold under registration statements (Nos. 333-201605 and 333-201639) on Form S-3 and Form S-3MEF, respectively, filed by us with the SEC.
We will need to seek additional financings to provide cash necessary to execute our current operations, including, but not limited to, beyond commercializing Auryxia, and to develop and commercialize any drugs or drug candidates we may in-license or acquire. Future issuances of common stock could depress the market for our common stock.
If we make one or more significant acquisitions or otherwise enter into one or more other strategic transactions in which the consideration includes stock or other securities, our stockholders' holdings may be significantly diluted. In addition, stockholders' holdings may also be diluted if we enter into arrangements with third parties permitting us to issue shares of common stock in lieu of certain cash payments upon the achievement of milestones.

Our stock price can be volatile, which increases the risk of litigation, and may result in a significant decline in the value of your investment.
The trading price of our common stock is likely to be highly volatile and subject to wide fluctuations in price in response to various factors, many of which are beyond our control. These factors include:

- actual or anticipated variations in quarterly or annual operating results, including, in particular with respect to net U.S. Auryxia product sales;
- announcements of technological innovations by us or our competitors;
- introductions or announcements of new products by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures, capital commitments or other strategic transactions involving us or our competitors;
- changes in financial estimates by securities analysts;
- developments relating to the marketing, safety and efficacy of our drug product, and regulatory filing and approvals for us or our competitors;
- expectations regarding our financial condition;
- expiration or termination of licenses, research contracts or other collaboration agreements;
- expectations or investor speculation regarding the strength of our intellectual property position, or the availability of other forms of regulatory exclusivity;
- conditions or trends in the regulatory climate and the biotechnology and pharmaceutical industries;
- changes in the market valuations of similar companies;

- negative comments and sentiment in the media;
- and
- additions or departures of key personnel.

In addition, equity markets in general, and the market for biotechnology and life sciences companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies traded in those markets. These broad market and industry factors may materially affect the market price of our common stock, regardless of our development and operating performance. In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation has often been instituted against that company. For example, following our August 1, 2016 announcement of the supply interruption of Auryxia, four purported class action lawsuits were filed against us and certain of our current and former executive officers alleging false and/or misleading statements concerning the company and its business operations and future prospects, and two stockholder derivative complaints were filed against certain of our current and former executive officers and members of our board of directors. These litigations and any other litigation instituted against us could cause us to incur substantial costs to defend such claims and divert management's attention and resources, which could seriously harm our business.

Certain anti-takeover provisions in our charter documents and Delaware law could make a third-party acquisition of us difficult. This could limit the price investors might be willing to pay in the future for our common stock.

Provisions in our amended and restated certificate of incorporation and bylaws could have the effect of making it more difficult for a third-party to acquire, or of discouraging a third-party from attempting to acquire, or control us. These factors could limit the price that certain investors might be willing to pay in the future for shares of our common stock. For example, our amended and restated bylaws have provisions specifying how and when stockholders may propose director nominations and other business to be brought before meetings of our stockholders and also provide that only certain parties may call a special meeting of stockholders, which could make it more difficult for stockholders to effect certain corporate actions. Any of these provisions could also have the effect of delaying or preventing a change in control.

ITEM 5. OTHER INFORMATION

Employment Agreement with Jodie Morrison

On May 10, 2018, we entered into an employment agreement with Jodie Morrison in connection with the previously announced appointment of Ms. Morrison as our Interim Chief Executive Officer effective as of April 27, 2018. Under the employment agreement, Ms. Morrison will serve as our Interim Chief Executive Officer until October 31, 2018 or the earlier appointment of a permanent Chief Executive Officer.

Ms. Morrison's base salary will be equal to $585,000 per year and she will also eligible to receive a pro-rated annual discretionary bonus, not to exceed 60% of her base salary. Under the employment agreement, Ms. Morrison is also entitled to 100,000 shares of restricted common stock, which will vest in full on October 31, 2018 if she remains Interim Chief Executive Officer on such date, provided, that in the event that a permanent Chief Executive Officer commences employment with us prior to October 31, 2018, then the shares of restricted stock shall vest in a pro rata amount based on the number of completed full months prior to the appointment of a permanent Chief Executive Officer, but in no event less than fifty percent (50%) of the shares of restricted stock. The shares of restricted stock will fully vest upon a Change in Control while she serves as Interim Chief Executive Officer. We will also reimburse Ms. Morrison for her legal fees incurred in connection with her entering into the employment agreement up to $5,000. Ms. Morrison will not receive any compensation for her service on our Board of Directors under our director compensation program while she serves as Interim Chief Executive Officer other than the annual equity awards for continuing directors.

In connection with the execution of the employment agreement, Ms. Morrison agreed to maintain our confidential information and trade secrets, as defined in the employment agreement, and also to adhere to certain covenants of non-competition while she serves as Interim Chief Executive Officer.

The foregoing summary of the Ms. Morrison's employment agreement is qualified in its entirety by the copy of such agreement filed as Exhibit 10.5 to this report and is incorporated herein by reference.

Amendment to the Product Manufacture and Supply and Facility Construction Agreement with BioVectra, Inc.

On May 5, 2018, we and BioVectra, Inc., or BioVectra, entered into Amendment No. 1 to the Product Manufacture and Supply and Facility Construction Agreement which revises certain provisions of our Product Manufacture and Supply and Facility Construction Agreement dated December 11, 2017 with BioVectra with respect to BioVectra's ability to recoup costs associated with their obligation to construct the manufacturing facility in Charlottetown, Prince Edward Island, Canada.

ITEM 6. EXHIBITS

The following exhibits are filed or furnished as part of this report:

| Exhibit Number | Exhibit Description |
|---|---|
| 10.1! | Amended and Restated License Agreement by and between Panion & BF Biotech, Inc. and Keryx Biopharmaceuticals, Inc. dated March 17, 2008. |
| 10.2 | Notes Exchange Agreement dated as of May 8, 2018, between Keryx Biopharmaceuticals, Inc. and Baupost Group Securities, L.L.C., filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on May 10, 2018 (File No. 000-30929), and incorporated herein by reference. |
| 10.3 | Indenture dated as of May 9, 2018, between Keryx Biopharmaceuticals, Inc. and The Bank of New York Mellon Trust Company, N.A., filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed on May 10, 2018 (File No. 000-30929), and incorporated herein by reference. |
| 10.4 | Registration Rights Agreement dated as of May 9, 2018, between Keryx Biopharmaceuticals, Inc. and Baupost Group Securities, L.L.C., filed as Exhibit 10.3 to the Registrant's Current Report on Form 8-K, filed on May 10, 2018 (File No. 000-30929), and incorporated herein by reference. |
| 10.5† | Employment Agreement with Jodie Morrison dated May 10, 2018. |
| 31.1 | Certification of Interim 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 May 10, 2018 |
| 31.2 | 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 May 10, 2018 |
| 32.1 | Certification of Interim Chief Executive Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated May 10, 2018 |
| 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 May 10, 2018 |
| 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. |

! Confidential treatment has been granted or is being sought with respect to the omitted portions of this exhibit.
† Indicates management contract or compensatory plan or arrangement.

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: May 10, 2018 By: /s/ Scott A. Holmes
Scott A. Holmes
Chief Financial Officer
Principal Financial and Accounting Officer