KERYX BIOPHARMACEUTICALS INC
Form 10-Q
November 08, 2018

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

FORM 10-Q

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

For the quarterly period ended September 30, 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

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 every Interactive Data File required to be submitted 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 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 102,375,926 shares of the registrant's common stock, $0.001 par value, outstanding as of October 31, 2018.

KERYX BIOPHARMACEUTICALS, INC.
FORM 10-Q
FOR THE QUARTER ENDED SEPTEMBER 30, 2018
TABLE OF CONTENTS

SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

Certain matters discussed in this report, including matters discussed under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations," may constitute forward-looking statements for purposes of the Securities Act of 1933, as amended, or the Securities Act, and the Securities Exchange Act of 1934, as amended, or the Exchange Act, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from the future results, performance or achievements expressed or implied by such forward-looking statements. The words "anticipate," "believe," "estimate," "may," "expect," "wi "project" and similar expressions are generally intended to identify forward-looking statements. Our actual results may differ materially from the results anticipated in these forward-looking statements due to a variety of factors, including, without limitation, those discussed under the 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 commercialization of Fexeric® (ferric citrate coordination complex) in the European market or otherwise create value from our European rights as well as with respect to the European approval of Fexeric, including expectations with respect to our arrangements with Panion & BF Biotech, Inc. with respect to Fexeric in Europe;
- 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 and reimbursement coverage for Auryxia;
- 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;
- expectations or ability to enter into product acquisition and in-licensing transactions; and
- expectations about our proposed strategic merger with Akebia Therapeutics, Inc.

The forward-looking statements contained in this report reflect our views and assumptions only as of the date that this report is signed and do not assume the consummation of the proposed strategic merger with Akebia Therapeutics, Inc. unless specifically stated otherwise. 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.

1

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

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 41,146	$ 93,526
Inventory	58,736	28,695
Accounts receivable, net	14,606	8,146
Other current assets	11,924	11,199
Total current assets	126,412	141,566
Property, plant and equipment, net	3,846	4,521
Goodwill	3,208	3,208
Other assets, net	18,318	9,577
Total assets	$ 151,784	$ 158,872
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 56,691	$ 45,031
Deferred lease incentive, current portion	244	244
Other current liabilities	165	145
Total current liabilities	57,100	45,420
Convertible senior notes	132,302	125,000
Loans payable	15,000	—
Deferred lease incentive, net of current portion	834	1,018
Deferred tax liability	—	635
Other liabilities	767	894
Total liabilities	206,003	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, 120,464,712 and 119,272,304 shares issued, 120,384,764 and 119,192,356 shares outstanding at September 30, 2018 and December 31, 2017, respectively)	120	119
Additional paid-in capital	1,004,349	984,681
Treasury stock, at cost, 79,948 shares	(357)	(357)
Accumulated deficit	(1,058,331)	(998,538)
Total stockholders' deficit	(54,219)	(14,095)
Total liabilities and stockholders' deficit	$ 151,784	$ 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 September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
Revenues:				
Net U.S. Auryxia product sales	$26,590	$ 13,597	$71,317	$ 38,218
License revenue	1,446	1,399	4,219	3,741
Total revenues	28,036	14,996	75,536	41,959
Costs and expenses:				
Cost of goods sold	7,506	5,856	24,535	14,508
License expense	867	838	2,531	2,244
Research and development	7,896	9,275	25,058	25,051
Selling, general and administrative	26,453	22,746	81,001	70,835
Total costs and expenses	42,722	38,715	133,125	112,638
Operating loss	(14,686)	(23,719)	(57,589)	(70,679)
Other income (expense):				
Amortization of debt discount	(2,214)	—	(3,530)	(62,965)
Other income (expense), net	(95)	241	76	693
Total other income (expense)	(2,309)	241	(3,454)	(62,272)
Loss before income taxes	(16,995)	(23,478)	(61,043)	(132,951)
Income tax expense (benefit)	—	20	(634)	60
Net loss	$(16,995)	$ (23,498)	$(60,409)	$ (133,011)
Basic and diluted net loss per common share	$(0.14)	$ (0.20)	$(0.50)	$ (1.18)
Weighted average shares used in computing basic and diluted net loss per common share	120,432,827	118,992,825	120,245,049	112,928,551

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)

	Nine months ended September 30,	
	2018	2017
Cash flows from operating activities		
Net loss	$(60,409)	$(133,011)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Stock-based compensation expense	12,517	10,707
Amortization of debt discount	3,530	62,965
Change in fair value of derivative liability	—	(225)
Depreciation and amortization	727	689
Amortization of deferred lease incentive	(184)	(184)
Write-down of inventory to net realizable value	7,081	1,671
Deferred income taxes	(635)	60
Changes in operating assets and liabilities:		
Other current assets	816	(12,382)
Accounts receivable, net	(6,460)	(3,962)
Inventory	(36,721)	(11,845)
Other assets	(8,741)	(27)
Other current liabilities	20	21
Accounts payable and accrued expenses	10,408	12,318
Other liabilities	(127)	(108)
Net cash used in operating activities	(78,178)	(73,313)
Cash flows from investing activities		
Purchases of property, plant and equipment	(52)	(1,176)
Net cash used in investing activities	(52)	(1,176)
Cash flows from financing activities		
Proceeds from issuance of common stock, net of commission	—	75,722
Proceeds from issuance of convertible senior notes	10,000	—
Proceeds from issuance of loans payable	15,000	—
Payments for common stock issuance costs	—	(102)
Proceeds from exercise of stock options	850	1,058
Net cash provided by financing activities	25,850	76,678
Net (decrease) increase in cash and cash equivalents	(52,380)	2,189
Cash and cash equivalents at beginning of the period	93,526	111,810
Cash and cash equivalents at end of the period	$41,146	$113,999
Non-cash financing activities:		
Change in fair value of conversion feature recorded as debt discount	$6,228	$—
Reclassification of derivative liability to equity	$—	$62,735

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.

On June 28, 2018, we entered into an agreement and plan of merger with Akebia Therapeutics, Inc., or Akebia, a Delaware corporation, and Alpha Therapeutics Merger Sub Inc., a Delaware corporation and wholly-owned subsidiary of Akebia, or Merger Sub, which was amended on October 1, 2018, pursuant to which we will combine our respective businesses through the merger of Merger Sub with and into us, with our company continuing after such merger as the surviving corporation and a wholly-owned subsidiary of Akebia, or the Merger. For additional details regarding the Merger, see Note 14 - Strategic Merger with Akebia Therapeutics, Inc.

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 and nine months ended September 30, 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, we adopted Accounting Standards Update, or ASU, No. 2014-09, Revenue from Contracts with Customers (Topic 606), using the modified retrospective transition method. Under this transition method, we will not revise our 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 ASU No. 2014-09 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 revenue 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 revenue 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 revenue and 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 we 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 and nine months ended September 30, 2018 and 2017 were offset by provisions for allowances and accruals as set forth in the tables below.

(in thousands)	Three months ended September 30, 2018	Percent of gross Auryxia product sales	Three months ended September 30, 2017	Percent of gross Auryxia product sales
Gross Auryxia product sales	$ 53,496		$ 30,620	
Less provision for product sales allowances and accruals:				
Trade allowances	5,557	10%	2,894	9%
Rebates, chargebacks and discounts	19,328	36%	13,251	43%
Product returns	808	2%	592	3%
Other incentives[(1)]	1,213	2%	286	1%
Total	26,906	50%	17,023	56%
Net U.S. Auryxia product sales	$ 26,590		$ 13,597	

(1) Includes co-pay assistance for the 2018 period and co-pay assistance and voucher rebates for the 2017 period.

(in thousands)	Nine months ended September 30, 2018	Percent of gross Auryxia product sales	Nine months ended September 30, 2017	Percent of gross Auryxia product sales
Gross Auryxia product sales	$ 141,456		$ 74,603	
Less provision for product sales allowances and accruals:				
Trade allowances	14,696	10%	7,122	10%
Rebates, chargebacks and discounts	50,256	36%	27,365	37%
Product returns	1,544	1%	870	1%
Other incentives[(1)]	3,643	3%	1,028	1%
Total	70,139	50%	36,385	49%
Net U.S. Auryxia product sales	$ 71,317		$ 38,218	

(1) Includes co-pay assistance for the 2018 period and co-pay assistance and voucher rebates for the 2017 period.

7

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)	September 30, 2018	September 30, 2017
Options to purchase common stock	10,726	12,135
Shares issuable upon conversion of convertible senior notes	35,582	33,422
Shares issuable under Notes Conversion Agreement[(1)]	4,000	—
	50,308	45,557

[(1)] See Note 14 - Strategic Merger with Akebia Therapeutics, Inc.

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 September 30, 2018, approximately $30.9 million of our total $41.1 million cash and cash equivalents balance was invested in institutional money market funds. See Note 3 – Fair Value Measurements.

Our accounts receivable, net at September 30, 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 September 30, 2018 and December 31, 2017.

	September 30, 2018		December 31, 2017	
McKesson Corporation	33	%	17	%
Cardinal Health, Inc.	31	%	25	%
AmerisourceBergen Drug Corporation	28	%	20	%
Fresenius Medical Care Rx	5	%	34	%

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.

Adopted Standards

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 No. 2014-09, or collectively, the new revenue standards.

8

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 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 consolidated statements of cash flows upon adoption.

Standards Not Yet Effective

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, with certain practical expedients available pursuant to ASU No. 2018-10, Codification Improvements to Topic 842, Leases, issued in July 2018. The FASB also issued ASU No. 2016-11, Leases (Topic 842): Targeted Improvements, in July 2018 which provides an additional transition method to adopt the new leasing standard. Under this new transition method, an entity initially applies the new leasing standard by recognizing a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption but will continue to report comparative periods under existing guidance. We are in the final stages of reviewing contracts with our contract manufacturers to determine whether these agreements contain any potential embedded leases. 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 related 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.

NOTE 3 – FAIR VALUE MEASUREMENTS

The following table provides the fair value measurements of applicable financial assets as of September 30, 2018 and December 31, 2017:

	Financial assets at fair value as of September 30, 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)]	$ 30,896	$ —	$ —	$ 1,895	$ —	$ —
Total assets	$ 30,896	$ —	$ —	$ 1,895	$ —	$ —

(1) Cash equivalents as of September 30, 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 Old Notes, in a private financing to funds managed by Baupost Group Securities, L.L.C., or Baupost. 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) the Old Notes, and (b) an additional investment of $10.0 million in cash. As of December 31, 2017, the fair value of the Old Notes was $155.4 million and, as of September 30, 2018, the fair value of the New Notes was $121.0 million, not including the additional 4.0 million shares that may be issued under the Notes Conversion Agreement, which in each case differs from their carrying value. The fair value of these notes is influenced by our stock price and stock price volatility. See Note 10 – Debt and Note 14 – Strategic Merger with Akebia Therapeutics, Inc. for additional information on our debt obligations.

NOTE 4 – INVENTORY

Inventory consists of the following at September 30, 2018 and December 31, 2017:

(in thousands)	September 30, 2018	December 31, 2017
Raw materials	$ 1,947	$ 469
Work in process	51,299	25,160
Finished goods	5,490	3,066
Total inventory	$ 58,736	$ 28,695

We wrote off approximately $1.8 million and $1.1 million of inventory that was determined to no longer be suitable for commercial manufacture, which was recorded to cost of goods sold during the three months ended September 30, 2018 and September 30, 2017, respectively, and $7.1 million and $1.7 million during the nine months ended September 30, 2018 and September 30, 2017, respectively.

NOTE 5 – OTHER ASSETS

Other current assets

Other current assets consisted of the following at September 30, 2018 and December 31, 2017:

(in thousands)	September 30, 2018	December 31, 2017
Prepaid manufacturing costs	$ 6,505	$ 7,646
Prepaid selling, general and administrative expenses	4,607	2,265
Prepaid research and development expenses	812	1,288
Total other current assets	$ 11,924	$ 11,199

Prepaid manufacturing costs as of September 30, 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 September 30, 2018 and December 31, 2017:

(in thousands)	September 30, 2018	December 31, 2017
Deferred manufacturing costs	$ 16,069	$ 7,338
Deposits	1,109	1,099
Long-term prepaid manufacturing costs	1,000	1,000
Deferred registration fees	140	140
Total other long-term assets	$ 18,318	$ 9,577

Deferred manufacturing costs consisted of amounts paid or payable under contract manufacturing agreements, including $10.0 million and $5.0 million in milestones related to a facility construction agreement as of September 30, 2018 and December 31, 2017, respectively, and $2.6 million and $2.3 million in product premiums paid or payable by us to our contract manufacturer as of September 30, 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 other assets 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 to cost of goods sold ratably over the relevant supply periods based on anticipated product to be received from the facilities. At September 30, 2018 and December 31, 2017, $5.2 million and $7.3 million, respectively, included in deferred manufacturing costs were also recorded as a liability on our consolidated balance sheets as they had not yet been paid.

NOTE 6 – STOCKHOLDERS' DEFICIT

Change in Stockholders' Deficit

Total stockholders' deficit was $54.2 million at September 30, 2018, which is an increase of $40.1 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 $60.4 million for the nine months ended September 30, 2018, partially offset by $12.5 million related to stock-based compensation expense, $6.2 million related to the recognition of an additional debt discount recorded in connection with the modification of our convertible senior notes and $0.6 million related to an adjustment to accumulated deficit as of January 1, 2018 upon the adoption of ASU No. 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 September 30, 2018, a total of 6,101,644 shares were available for the issuance of stock options or other stock-based awards under our 2018 equity incentive plan.

Stock Options

The following table summarizes stock option activity for the nine months ended September 30, 2018:

	Number of shares	Weighted average exercise price
Outstanding at December 31, 2017	11,967,815	$ 6.73
Granted	1,030,000	4.08
Exercised	(225,689)	3.77
Forfeited or Expired	(2,046,033)	5.91
Outstanding at September 30, 2018	10,726,093	$ 6.69
Vested and expected to vest at September 30, 2018	8,895,564	$ 6.92
Exercisable at September 30, 2018	6,408,820	$ 7.66

Upon the exercise of stock options, we issue new shares of our common stock. As of September 30, 2018, 2,522,500 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 nine months ended September 30, 2018:

	Number of shares	Weighted average grant date fair value
Outstanding at December 31, 2017	1,884,297	$ 6.39
Granted	1,548,400	4.44
Vested	(735,204)	5.52
Forfeited	(581,681)	4.87
Outstanding at September 30, 2018	2,115,812	$ 5.68

As of September 30, 2018, 310,000 shares of restricted stock issued to employees are unvested, performance-based shares.

Stock-Based Compensation Expense

We incurred $3.9 million and $3.4 million of stock-based compensation expense related to equity incentive grants during the three months ended September 30, 2018 and 2017, respectively, and $12.5 million and $10.7 million during the nine months ended September 30, 2018 and 2017, respectively. The following table reflects stock-based compensation expense for the three and nine months ended September 30, 2018 and 2017:

	Three months ended September 30,		Nine months ended September 30,	
(in thousands)	2018	2017	2018	2017
Cost of goods sold	$31	$37	$74	$125
Research and development	389	468	1,700	1,529
Selling, general and administrative	3,443	2,867	10,742	9,053
Total stock-based compensation expense	$3,863	$3,372	$12,516	$10,707

Stock-based compensation costs capitalized as part of inventory were immaterial for the three and nine months ended September 30, 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 September 30, 2018 and 2017 was $2.25 and $5.14 per share, respectively, and during the nine months ended September 30, 2018 and 2017 was $2.84 and $3.91 per share, respectively. We use historical information to estimate forfeitures of stock-based awards. As of September 30, 2018, there was $7.2 million and $6.8 million of total unrecognized compensation cost related to unvested stock options and restricted stock, respectively, which is expected to be recognized over weighted-average periods of 1.9 years and 1.8 years, respectively. These amounts do not include 2,522,500 unvested options and 310,000 shares of unvested restricted stock as of September 30, 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 marketed 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 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 No. 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 September 30, 2018 and 2017, we recorded $1.4 million in license revenue related to royalties earned on net sales of Riona in Japan. For the nine months ended September 30, 2018 and 2017, we recorded $4.2 million and $3.7 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 to 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 September 30, 2018 and 2017, we recorded $0.9 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. For the nine months ended September 30, 2018 and 2017, we recorded $2.5 million and $2.2 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 September 30, 2018 and December 31, 2017:

(in thousands)	September 30, 2018	December 31, 2017
Commercial rebates and fees	$ 23,461	$ 16,362
Accounts payable	15,090	6,474
Professional, license, and other fees and expenses	8,697	5,257
Accrued compensation and related liabilities	5,840	7,504
Accrued manufacturing expenses	3,603	9,434
Total accounts payable and accrued expenses	$ 56,691	$ 45,031

NOTE 10 – DEBT

Convertible Senior Notes

In October 2015, we completed the sale of $125 million of the Old Notes, in a private placement, or the Private Placement, to funds managed by Baupost pursuant to a Notes Purchase Agreement dated October 14, 2015. The Old 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 subjected us to certain financial and business covenants and contained restrictions on the payments of cash dividends.

The Indenture contained customary terms and events of default. If an event of default (other than certain events of bankruptcy, insolvency or reorganization involving us) occurred and was continuing, the Trustee by notice to us, or the holders of at least 25% in aggregate principal amount of the outstanding Old Notes by written notice to us and the Trustee, could have declared 100% of the principal on all of the Old Notes to be due and payable. Upon such a declaration of acceleration, such principal would 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 Old Notes would have become due and payable automatically.

Further, in connection with the Private Placement, we entered into a Registration Rights Agreement with the purchasers of the Old 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 Old Notes and the underlying common stock into which the Old Notes were 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 Old Notes, to cause the SEC to declare the Resale Registration Statement effective. Further, the Registration Rights Agreement permitted 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 could be conducted upon written request from Baupost. Finally, the Registration Rights Agreement afforded Baupost certain piggyback registration rights.

The Old Notes were 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 represented the last reported sale price of our stock on October 14, 2015. The conversion rate was subject to adjustment from time to time upon the occurrence of certain events. Further, upon the occurrence of certain fundamental changes involving us, Baupost could have required us to repurchase for cash all or part of their Old Notes at a repurchase price equal to 100% of the principal amount of the Old Notes to be repurchased.

At issuance, a portion of the Old 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 Old 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 Old Notes with the conversion option and the fair value of the Old Notes without the conversion option. The fair value of the derivative liability was recognized as a debt discount and the carrying amount of the Old Notes represented the difference between the proceeds from the issuance of the Old 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 Old 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 Old 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 Old Notes were 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 Old Notes was convertible into shares of our common stock.

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 Old 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 Old Notes with the conversion option and the fair value of the Old Notes without the conversion option. The fair value of the derivative liability was recognized as a debt discount and the carrying amount of the Old Notes represented the difference between the principal amount of the Old 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 Old Notes were contingently convertible into cash.

On May 8, 2018, we entered into a Notes Exchange Agreement with funds managed by Baupost pursuant to which, on May 9, 2018, we issued $164.746 million of the New Notes to Baupost in exchange for (a) the Old Notes and (b) an additional investment of $10.0 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 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 of our common stock the day before entering into the Notes Exchange Agreement. The principal amount of the New Notes initially converts into a total amount of shares of our common stock approximately equal to the 33.4 million shares into which the Old 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 $40.0 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 Old 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 of our common stock 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 Trustee was discharged in connection with the cancellation of the Old Notes.

In accordance with accounting guidance for debt modifications and exchanges, we assessed the terms of the Notes Exchange Agreement and New Indenture and determined that they resulted in a modification of our then-existing convertible senior notes. During the three months ended June 30, 2018, we recognized a debt discount of approximately $36.0 million in connection with the modification. The excess of the principal amount of the New Notes over its carrying amount, or debt discount, will be amortized to interest expense using the effective interest method over the expected life of the debt. At issuance of the New Notes, we determined the expected life was equal to the period through the maturity date of the New Notes, or October 2021.

In the three months ended September 30, 2018 and 2017, $2.2 million and zero, respectively, of interest expense was recognized related to these notes and $3.5 million and $63.0 million, was recognized during the nine months ended September 30, 2018 and 2017, respectively. As of September 30, 2018 and December 31, 2017, the carrying value of these notes was $132.3 million and $125.0 million, respectively, and the fair value of the Notes was $121.0 million and $155.4 million, respectively.

See Note 14 - Strategic Merger with Akebia Therapeutics, Inc. for additional information with respect to the New Notes, and the conversion thereof (including entering into the First Supplemental Indenture to the New Indenture), related to the Merger.

Revolving Loan Facility

On July 18, 2018, we entered into a Loan and Security Agreement with Silicon Valley Bank, or SVB, pursuant to which SVB made a revolving line of credit available to us in an aggregate amount of up to $40.0 million, or the Revolving Loan Facility. Availability under the Revolving Loan Facility is subject to a borrowing base comprised of eligible receivables and eligible inventory as set forth in the Loan and Security Agreement. As of September 30, 2018, we had an approximately $20.0 million available borrowing base under the Revolving Loan Facility, of which $15.0 million had been drawn down. Proceeds from the Revolving Loan Facility may be used for working capital and general business purposes. The Revolving Loan Facility is secured by substantially all of our assets other than intellectual property. The Revolving Loan Facility restricts our ability to grant any interest in our intellectual property other than certain permitted licenses and permitted encumbrances set forth in the Revolving Loan Facility.

The principal amount outstanding under the revolving line bears interest at a floating rate per annum equal to the greater of (i) 2.0% above the “prime rate,” as reported in The Wall Street Journal and (ii) 6.75%, which interest is payable monthly. Principal amounts borrowed under the revolving line of credit may be repaid and, prior to the maturity date, re-borrowed, subject to the terms and conditions set forth in the Revolving Loan Facility. The Revolving Loan Facility will mature on the date that is two years after the effective date of the Loan and Security Agreement. Upon entry into the Loan and Security Agreement (payable in installments and subject to certain conditions), and at the one year anniversary thereof, we must pay to SVB a fee equal to 1.00% of the Revolving Loan Facility. We are also required to pay on a quarterly basis a fee equal to 0.25% per annum of the average unused portion of the revolving line. We must pay a termination fee of 2.00% of the Revolving Loan Facility, if the revolving line is terminated prior to the maturity date, subject to certain exceptions.

During the three months ended September 30, 2018, we drew down $15.0 million from the Revolving Loan Facility. As of September 30, 2018, the outstanding principal balance for the Revolving Loan Facility under the Loan and Security Agreement was $15.0 million. During the three months ended September 30, 2018, $56,000 of interest expense was recognized related to the Revolving Loan Facility and amortization of additional fees, recognized as interest expense, were $88,000.

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 nine months ended September 30, 2018 to fully offset the net deferred tax liability that was recorded on our consolidated balance sheets. 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 (EXPENSE), NET

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

	Three months ended September 30,		Nine months ended September 30,	
(in thousands)	2018	2017	2018	2017
Interest income	$79	$240	$460	$475
Interest expense	(144)	—	(144)	—
Other income (expense)	(30)	1	(240)	(7)
Fair value adjustment to derivative liability	—	—	—	225
	$(95)	$241	$76	$693

NOTE 13 – COMMITMENTS AND CONTINGENCIES

Commitments

As of September 30, 2018, our contractual obligations and commitments primarily consist of our obligations under non-cancelable leases, the New 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.

Securities Litigation

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. By order dated July 19, 2018, the Court granted in part and denied in part Defendants' motion to dismiss the complaint. The parties are presently engaged in discovery. 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 and Michael Rogers) and our former directors (Michael P. Tarnok, Joseph Feczko, Jack Kaye Wyche Fowler, Jr. and John P. Butler), 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.

Litigation Relating to the Merger

On October 16, 2018, a putative shareholder class action was filed against us and the members of our Board challenging the disclosures made in connection with the Merger. The lawsuit is captioned Corwin v. Keryx Biopharmaceuticals, Inc., et al., No. 1:18-cv-01589, and is pending in the United States District Court for the District of Delaware. On October 23, 2018, a putative shareholder class action was filed against us, the members of our Board, Merger Sub, and Akebia also challenging the disclosures made in connection with the Merger. The lawsuit is captioned Rosenblatt v. Keryx Biopharmaceuticals, Inc., et al., No. 1:18-cv-12205, and was filed in the United States District Court for the District of Massachusetts. On October 24, 2018, another putative shareholder action was filed against us and the members of the Keryx Board challenging the disclosures made in connection with the Merger. The lawsuit is captioned Van Hulst v. Keryx Biopharmaceuticals, Inc., et al., No. 1:18-cv-01656, and is pending in the United States District Court for the District of Delaware. On November 1, 2018, another putative shareholder class action was filed against us and the members of the Keryx Board challenging the disclosures made in connection with the Merger. The lawsuit is captioned Andreula v. Keryx Biopharmaceuticals, Inc., et al., No. 1:18-cv-01721, and is pending in the United States District Court for the District of Delaware.

The complaints generally allege that the Registration Statement filed in connection with the Merger fails to disclose certain allegedly material information in violation of Section 14(a) and 20(a) of the Exchange Act and Rule 14a-9 promulgated thereunder. The alleged omissions relate to (i) certain financial projections for us and Akebia and certain financial analyses performed by our advisors; (ii) certain terms relating to the engagement of one of our advisors; and (iii) any alleged negotiations that may have taken place regarding which individuals would serve on the Board of the combined company as well as future employment of officers. Each of the plaintiffs seek to enjoin the defendants from proceeding with the Merger and seek damages in the event the transaction is consummated.

We, together with Akebia, are reviewing the complaints and have not yet formally responded to them, but believe that each Plaintiff's allegations are without merit and intend to defend against them vigorously. However, litigation is inherently uncertain and there can be no assurance regarding the likelihood that our or Akebia's defense of the actions will be successful. Additional lawsuits arising out of the Merger may also be filed in the future.

NOTE 14 – STRATEGIC MERGER WITH AKEBIA THERAPEUTICS, INC.

Agreement and Plan of Merger

On June 28, 2018, we entered into an agreement and plan of merger, which was amended on October 1, 2018, or the Merger Agreement, with Akebia and Merger Sub, pursuant to which we will combine our respective businesses through the merger of Merger Sub with and into us, with our Company continuing after the Merger as the surviving corporation and a wholly-owned subsidiary of Akebia. The Merger Agreement has been approved by our Board of Directors and the board of directors of Akebia.

At the effective time of the Merger, (i) each share of our common stock issued and outstanding immediately prior to the effective time of the Merger (other than the shares that are held by Akebia, Merger Sub, any subsidiary of Akebia or us, or held by us as treasury shares) will be converted into and become 0.37433 fully paid and non-assessable shares of common stock of Akebia, $0.00001 par value per share, each, an Akebia Share, such that the pre-Merger stockholders of us and Akebia will each own approximately 50% of the voting power of the combined company upon the closing of the Merger, which we refer to as the Combined Company, based on each of the companies' fully diluted market capitalizations as of signing and before taking into account the 4.0 million additional shares issuable to Baupost described below.

The Merger Agreement provides that, at the effective time of the Merger, each of our outstanding restricted shares issued under our equity incentive plans, which we refer to as Restricted Shares, other than those Restricted Shares that accelerate or lapse as a result of the Merger, will be canceled and converted into restricted stock unit awards of Akebia, the number of which will be adjusted in accordance with the terms of the Merger Agreement. Each of those Restricted Shares whose restrictions (including vesting) accelerate or lapse as a result of the Merger, will be canceled and converted into the right to receive 0.37433 Akebia Shares. In addition, each outstanding and unexercised option to acquire shares of our common stock granted under our equity incentive plans will be canceled and converted into an option to acquire Akebia Shares, with the number of shares and exercise price adjusted for the exchange ratio in accordance with the terms of the Merger Agreement.

The Combined Company is expected to have a board of directors consisting initially of ten directors, comprised of: (i) four directors designated by the current board of directors of Akebia, each of whom will be a director of Akebia immediately prior to the effective time of the Merger (and who will be reasonably acceptable to us), referred to as the Akebia Directors; (ii) five directors designated by our current Board of Directors, each of whom will be a director of ours immediately prior to the effective time of the Merger (and who will be reasonably acceptable to Akebia), referred to as the Keryx Directors; and (iii) one additional independent director to be designated by our Board of Directors and the board of directors of Akebia, who is neither a member of the board of directors of Akebia nor a member of our Board of Directors prior to the effective time of the Merger, referred to as the Additional Director. The Additional Director will serve as chairperson of the Combined Company's board of directors as of the effective time of the Merger. As of the effective time of the Merger, the directors shall be allocated among three classes of directors on the board of directors of the Combined Company as follows:

•Class II (up for re-election in 2019): 1 Akebia Director, 2 Keryx Directors;
•Class III (up for re-election in 2020): the Additional Director, 1 Akebia Director, 1 Keryx Director; and
•Class I (up for re-election in 2021): 2 Akebia Directors, 2 Keryx Directors.

We and Akebia each made certain representations and warranties, and agreed to certain covenants, in the Merger Agreement, including covenants by Akebia and us to conduct the respective businesses in the ordinary course during the period between the execution of the Merger Agreement and consummation of the Merger, to refrain from taking certain actions specified in the Merger Agreement and to use reasonable best efforts to cause the conditions of the Merger to be satisfied.

The consummation of the Merger is subject to customary closing conditions, including: (i) approval of the issuance of Akebia Shares in connection with the Merger by the affirmative vote of the majority of Akebia Shares cast at the Akebia shareholders' meeting in favor of the issuance of Akebia Shares in connection with the Merger; (ii) the adoption of the Merger Agreement by the affirmative vote of the holders of a majority of all outstanding shares of Keryx common stock entitled to vote thereon; (iii) the absence of any adverse law or order promulgated, entered, enforced, enacted or issued by any governmental entity that prohibits, restrains or makes illegal the consummation of

the Merger; (iv) the Akebia Shares to be issued in the Merger being approved for listing on the Nasdaq Global Market; (v) the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, which waiting period was terminated by the U.S. Federal Trade Commission on August 21, 2018, and other material government approvals; (vi) subject to certain materiality exceptions, the accuracy of certain representations and warranties of each of us and Akebia contained in the Merger Agreement and the

compliance by each party with the covenants contained in the Merger Agreement; and (vii) the absence of a material adverse effect with respect to each of us and Akebia. Akebia's obligation to consummate the Merger is also subject to the conversion of the New Notes into shares of our common stock before the closing of the Merger pursuant to the Notes Conversion Agreement described below. We and Akebia have filed definitive proxy materials with the SEC in connection with our respective special meetings of stockholders to approve the Merger. The special meetings of stockholders are scheduled to be held on December 11, 2018, and, if the Merger is approved by each company's stockholders, we expect the merger will be completed shortly thereafter.

The Merger Agreement contains certain termination rights for both us and Akebia, including for the failure to consummate the Merger by December 28, 2018, the enactment, promulgation or issuance of any injunction, order or ruling which has become final and non-appealable and makes the consummation of the Merger illegal or otherwise prohibits consummation of the Merger, failure of either our stockholders or Akebia's stockholders to approve the Merger and related transactions, or breaches of representations, warranties or covenants by a party that result in the failure of certain conditions to closing being satisfied. In addition, each of us and Akebia have the right to terminate the Merger Agreement in order to enter into a "Superior Proposal" (as defined in the Merger Agreement). Upon termination of the Merger Agreement under certain specified circumstances Akebia or we may be required to pay the other party a termination fee of $22.0 million.

Notes Conversion Transactions

In connection with the Merger, we entered into a Notes Conversion Agreement, or the Conversion Agreement, with Baupost and, with respect to certain sections only, Akebia. Pursuant to the terms of the Conversion Agreement, Baupost has agreed to convert the New Notes into the 35.6 million shares of our common stock into which the New Notes are currently convertible, immediately prior to the effective time of the Merger, conditioned upon our issuance to Baupost of an additional 4.0 million shares of our common stock. On November 8, 2018, in furtherance of the Conversion Agreement, we entered into a First Supplemental Indenture with The Bank of New York Mellon Trust Company, N.A. to facilitate the conversion of the New Notes into shares of our common stock immediately prior to the effective time of the Merger.

NOTE 15 – SUBSEQUENT EVENTS

Amendment to Merger Agreement

On October 1, 2018, we entered into the First Amendment to our previously disclosed Merger Agreement with Akebia and Merger Sub. The First Amendment amended the Merger Agreement to provide that, as of the effective time of the Merger, Akebia must take all necessary corporate action to cause an increase in the size of the board of directors of Akebia, or the Akebia Board, to ten (10) directors, comprising (i) four (4) directors designated by the Akebia Board, each of whom shall be a director of Akebia prior to the effective time of the Merger and be reasonably acceptable to us (referred to as the Akebia Directors), (ii) five (5) directors designated by our Board of Directors, each of whom shall be a director of ours prior to the effective time of the Merger and be reasonably acceptable to Akebia (referred to as the Keryx Directors), and (iii) one (1) additional independent director to be designated by the board of directors of Akebia and our Board of Directors (referred to as the Additional Director), who is neither a member of the board of directors of Akebia nor a member of our Board of Directors prior to the effective time of the Merger. The Additional Director shall serve as chairperson of the Combined Company's board of directors as of the effective time of the Merger. Pursuant to the First Amendment, we and Akebia shall designate the Akebia Directors, the Keryx Directors and the Additional Director, as applicable, as soon as practicable, but no later than immediately prior to the effective time of the Merger. The First Amendment also provides that, as of the effective time of the Merger, the Akebia Directors, the Keryx Directors and the Additional Director shall be allocated among three classes of directors of the Combined Company as follows:

•Class II (up for re-election in 2019): 1 Akebia Director, 2 Keryx Directors;
•Class III (up for re-election in 2020): the Additional Director, 1 Akebia Director, 1 Keryx Director; and
•Class I (up for re-election in 2021): 2 Akebia Directors, 2 Keryx Directors.

Other than as expressly modified pursuant to the First Amendment, the Merger Agreement remains in full force and effect as originally executed on June 28, 2018. The foregoing description of the First Amendment is not complete and is subject to and qualified in its entirety by reference to the First Amendment.

18

Employment Agreement with Jodie Morrison

On November 2, 2018, we entered into an Amendment, effective October 31, 2018, or the Amendment, to our Employment Agreement, or the Employment Agreement, with Jodie Morrison, our Interim Chief Executive Officer, to extend the term of the Employment Agreement to the earlier of the closing of a Change of Control (as defined in the Employment Agreement) or December 31, 2018. The Amendment also provides for, among other things, (i) continued payment to Ms. Morrison of her salary through the term of her employment, (ii) conversion of the prorated bonus contemplated by the Employment Agreement to a full annualized bonus, (iii) a $150,000 cash payment payable as of October 31, 2018 in recognition of the considerable efforts undertaken by Mr. Morrison in her role as Interim Chief Executive Officer, and (iv) a $200,000 cash retention payment to be made on the earlier of December 31, 2018 and the closing of a Change of Control, subject to Ms. Morrison's continued employment with us through such date. As disclosed in the joint proxy statement/prospectus filed by us and Akebia on October 30, 2018, the proposed business combination between us and Akebia pursuant to the Merger Agreement will constitute a Change of Control under the Employment Agreement, including the Amendment.

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.

On June 28, 2018, we entered into an agreement and plan of merger with Akebia Therapeutics, Inc., or Akebia, a Delaware corporation, and Alpha Therapeutics Merger Sub Inc., a Delaware corporation and wholly-owned subsidiary of Akebia, or Merger Sub, which was amended on October 1, 2018, pursuant to which we will combine our respective businesses through the merger of Merger Sub with and into us, with our company continuing after such merger as the surviving corporation and a wholly-owned subsidiary of Akebia, or the Merger. For additional details regarding the Merger, see Note 14 - Strategic Merger with Akebia Therapeutics, Inc. to our condensed consolidated financial statements included in this report.

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.

Agreement and Plan of Merger with Akebia Therapeutics, Inc.

On June 28, 2018, we entered into an agreement and plan of merger, or the Merger Agreement, with Akebia, and Merger Sub, which was amended on October 1, 2018, pursuant to which we will combine our respective businesses through the merger of Merger Sub with and into us, with our company continuing after the merger as the surviving corporation and a wholly-owned subsidiary of Akebia. At the effective time of the Merger, (i) each share of our common stock issued and outstanding immediately prior to the effective time of the Merger (other than the shares that are held by Akebia, Merger Sub, any subsidiary of Akebia or us, or held by us as treasury shares) will be converted into and become 0.37433 fully paid and non-assessable shares of common stock of Akebia, such that the pre-Merger stockholders of us and Akebia will each own approximately 50% of the voting power of the combined company upon the closing of the Merger, based on each of the companies' fully diluted market capitalizations as of signing of the Merger Agreement and before taking into account the 4.0 million additional shares issuable to funds managed by Baupost Group Securities, L.L.C., or Baupost, described below.

In connection with the Merger, we entered into a Notes Conversion Agreement, or the Conversion Agreement, with Baupost and, with respect to certain sections only, Akebia. Pursuant to the terms of the Conversion Agreement, Baupost has agreed to convert the total outstanding amount of our $164.746 million of Convertible Senior Notes due 2021, or the New Notes, issued to Baupost in May 2018 into the 35.6 million shares of our common stock into which the New Notes are currently convertible, immediately prior to the effective time of the Merger, conditioned upon our issuance to Baupost of an additional 4.0 million shares of our common stock. On November 8, 2018, in furtherance of the Conversion Agreement, we entered into a First Supplemental Indenture with The Bank of New York Mellon Trust Company, N.A. to facilitate the conversion of the New Notes into shares of our common stock immediately prior to the effective time of the Merger.

For more information about the Merger and the conversion of the New Notes in connection therewith, see Note 14 - Strategic Merger with Akebia Therapeutics, Inc. to our condensed consolidated financial statements included in this report.

Loan and Security Agreement with Silicon Valley Bank

On July 18, 2018, we entered into a Loan and Security Agreement with Silicon Valley Bank, or SVB, pursuant to which SVB made a revolving line of credit available to us in an aggregate amount of up to $40 million, or the Revolving Loan Facility. Availability under the Revolving Loan Facility is subject to a borrowing base comprised of eligible receivables and eligible inventory as set forth in the Loan and Security Agreement. Proceeds from the revolving line of credit may be used for working capital and general business purposes. The Revolving Loan Facility is secured by substantially all of our personal property other than intellectual property. For more information about the Revolving Loan Facility, see Note 10 - Debt to our condensed consolidated financial statements included in this report.

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, marketing, business development, pharmacovigilance 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 No. 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 to our condensed consolidated financial statements included in this report 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 with our Distributors, 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 and 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.

23

RESULTS OF OPERATIONS

Three months ended September 30, 2018 and September 30, 2017

Net U.S. Auryxia Product Sales. For the three months ended September 30, 2018, we recognized $26.6 million in product sales of Auryxia, net of allowances, discounts, incentives, rebates and chargebacks, as compared with $13.6 million for the three months ended September 30, 2017.

(in thousands)	Three months ended September 30, 2018	Percent of gross Auryxia product sales	Three months ended September 30, 2017	Percent of gross Auryxia product sales
Gross Auryxia product sales	$ 53,496		$ 30,620	
Less provision for product sales allowances and accruals:				
Trade allowances	5,557	10%	2,894	9%
Rebates, chargebacks and discounts	19,328	36%	13,251	43%
Product returns	808	2%	592	3%
Other incentives[1]	1,213	2%	286	1%
Total	26,906	50%	17,023	56%
Net U.S. Auryxia product sales	$ 26,590		$ 13,597	

[1] Includes co-pay assistance for the 2018 period and co-pay assistance and voucher rebates for the 2017 period.

Gross Auryxia product sales increased for the three months ended September 30, 2018 as compared to the same period in 2017 as a result of an increase in patient prescriptions and related units sold. Provisions for product sales allowances and accruals as a percentage of gross Auryxia product sales for the three months ended September 30, 2018 as compared to the same period in 2017 decreased primarily as a result of a lower percentage of sales through Medicare Part D contracts and a lower effective rebate across our Medicare Part D plans. Our gross-to-net adjustments may fluctuate 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. Although we believe the vast majority of Part D prescriptions written for Auryxia today are for the treatment of hyperphosphatemia and, therefore, Auryxia will continue to be covered by Part D plans in the future, the Centers for Medicare & Medicaid Services' recent determination that Auryxia is only a Part D drug if used for hyperphosphatemia, our future revenues may decline as a result of this determination and our ability to obtain Part D coverage for Auryxia.

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 September 30, 2018 and 2017, we recognized $1.4 million 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 September 30, 2018 was recorded based on an estimate of net sales of Riona in Japan during the three months ended September 30, 2018, as compared to license revenue for the three months ended September 30, 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 and we may not be able to successfully commercialize Fexeric in Europe with our licensor Panion & BF Biotech Inc. 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 September 30, 2018, we recognized $7.5 million in cost of goods sold, as compared to $5.9 million for the three months ended September 30, 2017. This increase was primarily due to additional units sold in the 2018 period as compared to the 2017 period, as well as an increase of $0.7 million in inventory write-offs in the 2018 period as compared to the 2017, period partially offset by value added tax, or VAT, refunds of $1.6 million that were received during the three months ended September 30, 2018 which were recorded as

a reduction of cost of goods sold.

License Expense. For the three months ended September 30, 2018, we recognized $0.9 million in license expense related to royalties due to the licensor of ferric citrate relating to sales of Riona in Japan as compared to $0.8 million for the three months ended September 30, 2017. The increase was due to an increase in license revenue recorded in the 2018 period as compared to the 2017 period.

Research and Development Expenses. Research and development expenses decreased by $1.4 million to $7.9 million for the three months ended September 30, 2018, as compared to $9.3 million for the three months ended September 30, 2017. The decrease in research and development expenses was primarily due to a decrease in process development-related manufacturing costs in the 2018 period, partially offset by an increase in clinical trial costs. We expect our quarterly research and development expenses will increase slightly for the remainder of 2018 as compared to the three months ended September 30, 2018, due to continued process development-related manufacturing costs, as well as clinical trial costs.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased by $3.7 million to $26.5 million for the three months ended September 30, 2018, as compared to $22.7 million for the three months ended September 30, 2017. The increase was primarily due to business development and legal expenses related to our proposed merger with Akebia 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 quarterly selling, general and administrative costs to remain relatively consistent for the remainder of 2018 as compared to the three months ended September 30, 2018.

Other income (expense) net. For the three months ended September 30, 2018 we recognized $0.1 million in expense which represented interest expense offset by interest income whereas for the three months September 30, 2017, we recognized $0.2 million in income which primarily related to interest income.

Income Tax (Benefit) Expense. Income tax (benefit) expense for the three months ended September 30, 2018 was zero as compared to $20,000 expense for the three months ended September 30, 2017.

Nine months ended September 30, 2018 and September 30, 2017

Net U.S. Auryxia Product Sales. For the nine months ended September 30, 2018, we recognized $71.3 million in product sales of Auryxia, net of allowances, discounts, incentives, rebates and chargebacks, as compared with $38.2 million for the nine months ended September 30, 2017.

(in thousands)	Nine months ended September 30, 2018	Percent of gross Auryxia product sales	Nine months ended September 30, 2017	Percent of gross Auryxia product sales
Gross Auryxia product sales	$ 141,456		$ 74,603	
Less provision for product sales allowances and accruals:				
Trade allowances	14,696	10%	7,122	10%
Rebates, chargebacks and discounts	50,256	36%	27,365	37%
Product returns	1,544	1%	870	1%
Other incentives[(1)]	3,643	3%	1,028	1%
Total	70,139	50%	36,385	49%
Net U.S. Auryxia product sales	$ 71,317		$ 38,218	

[(1)] Includes co-pay assistance for the 2018 period and co-pay assistance and voucher rebates for the 2017 period.

Gross Auryxia product sales increased for the nine months ended September 30, 2018 as compared to the same period in 2017 as a result of an increase in patient prescriptions and related units sold. Provisions for product sales allowances and accruals as a percentage of gross Auryxia product sales for the nine months ended September 30, 2018 as compared to the same period in 2017 remained relatively consistent.

License Revenue. For the nine months ended September 30, 2018 and 2017, we recognized $4.2 million and $3.7 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 nine months ended September 30, 2018 was recorded based on an estimate of net sales of Riona in Japan during the nine months ended September 30, 2018, as compared to license revenue for

the nine months ended September 30, 2017 which was based on net sales of Riona in Japan one quarter in arrears.

Cost of Goods Sold. For the nine months ended September 30, 2018, we recognized $24.5 million in cost of goods sold, as compared to $14.5 million for the nine months ended September 30, 2017. This increase was primarily due to additional units sold in the 2018 period as compared to the 2017 period and an increase of $5.4 million in inventory write-offs in the 2018 period as compared to the 2017 period.

License Expense. For the nine months ended September 30, 2018, we recognized $2.5 million in license expense related to royalties due to the licensor of ferric citrate relating to sales of Riona in Japan as compared to $2.2 million for the nine months ended September 30, 2017. The increase was due to an increase in license revenue recorded in the 2018 period as compared to the 2017 period.

Research and Development Expenses. Research and development expenses were $25.1 million for both the nine months ended September 30, 2018 and the nine months ended September 30, 2017. This was a result of a decrease in process development-related manufacturing costs and supplemental new drug application filing fees in the 2018 period as compared to the 2017 period, offset by an increase in clinical trial costs in the 2018 period as compared to the 2017 period.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased by $10.2 million to $81.0 million for the nine months ended September 30, 2018, as compared to $70.8 million for the nine months ended September 30, 2017. The increase was primarily due to business development and legal expenses related to our proposed merger with Akebia as well as costs related to the launch of Auryxia for the treatment of iron deficiency anemia in adults with CKD, not on dialysis.

Other income (expense), net. For the nine months ended September 30, 2018, we recognized $0.1 million in income related to interest income partially offset by interest expense and foreign currency translation adjustments whereas for the nine months ended September 30, 2017, we recognized $0.7 million in income which primarily represents interest income and a fair value adjustment to the derivative liability.

Income Tax (Benefit) Expense. Income tax (benefit) expense for the nine months ended September 30, 2018 was $0.6 million (benefit) as compared to $20,000 expense for the nine months ended September 30, 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, sales of Auryxia, amounts borrowed under the Revolving Loan Facility, the upfront, milestone and royalty payments from our agreement with JT and Torii, 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.

On July 18, 2018, we entered into a Loan and Security Agreement with SVB, pursuant to which SVB made a revolving line of credit available to us in an aggregate amount of up to $40 million. Availability under the Revolving Loan Facility is subject to a borrowing base comprised of eligible receivables and eligible inventory as set forth in the Loan and Security Agreement. Proceeds from the Revolving Loan Facility may be used for working capital and general business purposes. The Revolving Loan Facility is secured by substantially all of our assets other than intellectual property. During the three months ended September 30, 2018, we drew down $15.0 million from the Revolving Loan Facility. As of September 30, 2018, the borrowing base available under the Revolving Loan Facility was approximately $20.0 million, of which $15.0 million was outstanding as of the end of the period. For more information about the Revolving Loan Facility, see Note 10 - Debt to our condensed consolidated financial statements

included in this report.

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 Old Notes, to funds managed by Baupost. See Note 10 – Debt to our condensed consolidated financial statements included in this report for a description of the Old 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 the New Notes, to Baupost in exchange for (a) the Old Notes and (b) an additional investment of $10 million in cash. See Note 10– Debt to our condensed consolidated financial statements included in this report 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 Old 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 September 30, 2018, we had $41.1 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 $52.4 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 into the first quarter of 2019. To fund our operations beyond that time, we will need to either complete the proposed merger with Akebia announced on June 28, 2018, utilize the remaining available capacity under the asset-based revolving credit facility that we entered in July 2018, and/or raise additional capital through the issuance of common stock or other securities. 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 expenditures associated with commercial activities related to Auryxia, 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 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 the asset-based credit facility with SVB; or possible business combinations, such as the proposed merger with Akebia. In addition, although we secured an up to $40.0 million revolving loan facility from SVB in July 2018, the borrowing base we may utilize at any one time under this facility or any other asset-based credit facility, if successfully entered into, may be significantly lower than the total commitment under any 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 nine months ended September 30, 2018 was $78.2 million as compared to $73.3 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 nine months ended September 30, 2018 was $0.1 million as compared to $1.2 million net cash used in investing activities for the same period in 2017. Net cash used in investing activities for the nine months ended September 30, 2018 and 2017 relates to purchases of property, plant and equipment.

Net cash provided by financing activities for the nine months ended September 30, 2018 was $25.9 million as compared to $76.7 million for the same period in 2017. Net cash provided by financing activities in 2018 was primarily related to proceeds of $10.0 million received in connection with the New Notes and proceeds of $15.0 million received in connection with the Revolving Loan Facility from SVB whereas in 2017 net cash provided by financing activities was primarily related to net proceeds of $75.7 million from the issuance of common stock under the Sales Agreement.

OBLIGATIONS AND COMMITMENTS

As of September 30, 2018, our contractual obligations and commitments primarily consist of our obligations under non-cancelable leases, the New Notes, and various agreements with third parties, including selling, general and administrative, research and development and manufacturing agreements.

The following table summarizes our contractual obligations as of September 30, 2018.

(in thousands)	Payment due by period			
Contractual obligations	Total	Less than 1 year	1-3 years	3-5 years
Convertible senior notes	$132,302	$—	$132,302	$—
Payments under the Revolving Loan Facility	15,000	—	15,000	—
Facility lease	7,483	1,648	3,379	2,456
Purchase commitments	153,705	79,318	60,622	13,765
Total	$308,490	$80,966	$211,303	$16,221

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 September 30, 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 September 30, 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 New Notes include conversion provisions that are based on the price of our common stock at conversion or at maturity of the New Notes. The fair values of the New 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 September 30, 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 September 30, 2018, our disclosure controls and procedures were effective.

CHANGES IN INTERNAL CONTROLS OVER FINANCIAL REPORTING

There were no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2018 that materially affected, or are reasonably likely to materially affect, our internal controls 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 and Item 5 "Other Information - Notice Regarding Abbreviated New Drug Application", which are 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 investmentw.

Risks related to our business anoud 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 insapection 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.

28

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 September 30, 2018, we had an accumulated deficit of $1.1 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;
- decisions of the Centers for Medicare & Medicaid Services, or CMS, with respect to Medicare Part D eligibility of Auryxia;
- 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. We did not begin to market Fexeric in the EU by September 23, 2018, therefore, we believe the EC will likely revoke its approval of Fexeric. We are working with Panion & BF Biotech, Inc., or Panion, the licensor of our rights to ferric citrate to formulate a regulatory and commercial plan for Fexeric in Europe. See the Risk Factor entitled “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” below for additional information about our arrangements with Panion. There can be no assurances that we will successfully work with Panion with respect to the European commercialization of Fexeric or that the EC will still not 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 differ from those approved by the FDA or other applicable regulatory agencies. Such unapproved, or “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 manufacturer communications regarding unapproved uses of an approved drug. Companies are not permitted to promote drugs for unapproved 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 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, potentially 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:

32

- government and health administration authorities;
- 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.

CMS recently communicated to Medicare Part D sponsors that Auryxia is considered by CMS a Part D drug when it is used for its FDA-approved indication for the control of serum phosphorus levels. CMS also indicated that it does not consider use of Auryxia covered under Part D when it is used solely for the treatment of iron deficiency anemia in patients with chronic kidney disease not on dialysis, which is Auryxia's other FDA-approved indication. CMS expects Part D sponsors to utilize a prior authorization, or PA, or other process, to ensure that Auryxia is being used for a Part D covered indication. We expect Part D sponsors will implement a PA for Auryxia no later than January 2019. We have interacted with CMS and Part D sponsors further on this matter. Although we believe that the vast majority of the Part D prescriptions written for Auryxia today are for the treatment of hyperphosphatemia and therefore will continue to be covered by Part D plans in the future, CMS' decision with respect to Part D coverage for Auryxia could have an adverse effect on our business and results of operations.

Likewise, current and future legislative or regulatory efforts to control or reduce healthcare costs or reform government healthcare programs, such as efforts to repeal or replace 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;

33

- 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 we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We participate in and have certain price reporting obligations to the Medicaid Drug Rebate program, several state Medicaid supplemental rebate programs and other governmental pricing programs, and we have obligations to report average sales price under the Medicare program. Under the Medicaid Drug Rebate program, we are required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by us on a monthly and quarterly basis to CMS, the federal agency that administers the Medicaid Drug Rebate program. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug which, in general, represents the lowest price available from the manufacturer to any entity in the United States in any pricing structure, calculated to include all sales and associated rebates, discounts and other price concessions. Our failure to comply with these price reporting and rebate payment obligations could negatively impact our financial results.

PPACA made significant changes to the Medicaid Drug Rebate program, such as expanding rebate liability from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well and changing the definition of average manufacturer price. The PPACA also increased the minimum Medicaid rebate; changed the calculation of the rebate for certain innovator products that qualify as line extensions of existing drugs; and capped the total rebate amount at 100% of the average manufacturer price. Finally, the PPACA requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government. Congress could enact additional legislation that further increases Medicaid drug rebates or other costs and charges associated with participating in the Medicaid Drug Rebate program. CMS issued a final regulation, which became effective on April 1, 2016, to implement the changes to the Medicaid Drug Rebate program under the PPACA. The issuance of the final regulation, as well as any other regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate program, has increased and will continue to increase our costs and the complexity of compliance, has been and will continue to be time-consuming to implement, and could have a material adverse effect on our results of operations, particularly if CMS challenges the approach we take in our implementation of the final regulation.

Federal law requires that any company that participates in the Medicaid Drug Rebate program also participate in the Public Health Service's 340B program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The PPACA expanded the list of covered entities to include certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, but exempts "orphan drugs" from the ceiling price requirements for these covered entities. The 340B ceiling price is calculated using a statutory formula based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate program, and in general, products subject to Medicaid rebate liability are also subject to the 340B ceiling price calculation and discount requirement. Any additional future changes to the definition of average manufacturer price and the Medicaid rebate amount under the PPACA or otherwise could affect our 340B ceiling price calculations and negatively impact our results of operations.

As required under the PPACA, the Health Resources and Services Administration, or HRSA, has updated the agreement that manufacturers must sign to participate in the 340B program to obligate a manufacturer to offer the 340B price to covered entities if the manufacturer makes the drug available to any other purchaser at any price and to report to the government the ceiling prices for its drugs. The PPACA also obligates the Secretary of the Department of Health and Human Services, or HHS, to create regulations and processes to improve the integrity of the 340B program. On January 5, 2017, HRSA issued a final regulation regarding the calculation of the 340B ceiling price and

the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities. The effective date of the regulation has been delayed until July 1, 2019. Implementation of this final rule and the issuance of any other final regulations and guidance could affect our obligations under the 340B program in ways we cannot anticipate. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in an inpatient setting.

Federal law also requires that a company that participates in the Medicaid Drug Rebate program report average sales price information each quarter to CMS for certain categories of drugs that are paid under the Medicare Part B program. Manufacturers calculate the average sales price based on a statutorily defined formula as well as regulations and interpretations of the statute by CMS. CMS uses these submissions to determine payment rates for drugs under Medicare Part B. Statutory or regulatory changes or CMS guidance could affect the average sales price calculations for our products and the resulting Medicare payment rate, and could negatively impact our results of operations.
Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies and the courts. In the case of our Medicaid pricing data, if we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for up to three years after those data originally were due. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate program and could result in an overage or underage in our rebate liability for past quarters. Price recalculations also may affect the ceiling price at which we are required to offer our products under the 340B program.
Civil monetary penalties can be applied if we are found to have knowingly submitted any false price information to the government, if we are found to have made a misrepresentation in the reporting of our average sales price, or if we fail to submit the required price data on a timely basis. Such conduct also could be grounds for CMS to terminate our Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs. We cannot assure you that our submissions will not be found by CMS to be incomplete or incorrect.
In order to be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, we participate in the U.S. Department of Veterans Affairs, or VA, Federal Supply Schedule, or FSS, pricing program. As part of this program, we are obligated to make our products available for procurement on an FSS contract under which we must comply with standard government terms and conditions and charge a price that is no higher than the statutory Federal Ceiling Price, or FCP, to four federal agencies (VA, U.S. Department of Defense, or DOD, Public Health Service, and U.S. Coast Guard). The FCP is based on the Non-Federal Average Manufacturer Price, or Non-FAMP, which we calculate and report to the VA on a quarterly and annual basis. Pursuant to applicable law, knowing provision of false information in connection with a Non-FAMP filing can subject a manufacturer to civil monetary penalties. These obligations also contain extensive disclosure and certification requirements.
We also participate in the Tricare Retail Pharmacy program, under which we pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare Retail Pharmacy network to Tricare beneficiaries. The rebates are calculated as the difference between the annual Non-FAMP and FCP. We are required to list our covered products on a Tricare Agreement in order for these products to be eligible for DOD formulary inclusion. If we overcharge the government in connection with our FSS contract or Tricare Agreement, whether due to a misstated FCP or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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 know of 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. On October 31, 2018, or the Lupin Notice Date, we received a Paragraph IV certification notice letter, or the Lupin Notice Letter, regarding an ANDA submitted to the FDA by Lupin Atlantis Holdings SA, or Lupin, requesting approval to market, sell and use a generic version of Auryxia (ferric citrate) tablets (210 mg iron per tablet). In the Lupin Notice Letter, Lupin alleges that U.S. Patents nos. 5,753,706; 7,767,851; 8,093,423; 8,299,298; 8,338,642; 8,609,896; 8,754,257; 8,754,258; 8,846,976; 8,901,349; 9,050,316; 9,328,133; 9,387,191; and 9,757,416, which cover the approved drug substance, drug product and/or methods of using Auryxia, are invalid, unenforceable and/or will not be infringed by Lupin’s manufacture, use or sale of the product described in its ANDA. On November 6, 2018, or the Teva Notice Date, we received a Paragraph IV certification notice letter, or the Teva Notice Letter, regarding an ANDA submitted to the FDA by Teva Pharmaceuticals USA, Inc., or Teva, requesting approval to market, use or sell a generic version of Auryxia (ferric citrate) tablets (210 mg iron per tablet). In the Teva Notice Letter, Teva alleges that the patents (which are the same patents as those referenced in the Lupin Notice Letter, other than U.S. Patent no. 5,753,706), are invalid, unenforceable and/or will not be infringed by Teva’s manufacture, use or sale of the product described in its ANDA. We refer to the Lupin Notice Letter and the Teva Notice Letter collectively as the Notice Letters, the Lupin Notice Date and Teva Notice Date collectively as the Notice Dates, and the patents referenced in the Notice Letters collectively as the Patents. We are currently reviewing the Notice Letters and intend to vigorously enforce our intellectual property rights relating to Auryxia. By statute, we have 45 days from receipt of each Notice Letter to initiate a patent infringement lawsuit against Lupin and Teva, respectively and as applicable. Such lawsuits would automatically preclude the FDA from approving Lupin’s and Teva's ANDA until the earlier of 30 months from the applicable Notice Date or entry of a district court decision finding the Patents referenced in the applicable Notice Letter invalid, unenforceable or not infringed. The composition and use of Auryxia are currently claimed by 14 issued patents that are listed in the FDA’s Orange Book. The introduction of a generic version of Auryxia by Lupin, Teva or another party or a ruling that the Patents, or other of our patents, are invalid, unenforceable or will not be infringed by a generic version of Auryxia could have a material

adverse effect on our business, results of operations and financial condition.

Auryxia is also competing in the United States with other FDA-approved treatments for iron deficiency anemia, such as Venofer® (iron sucrose) and Injectafer® (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 September 30, 2018, we had 189 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 employment agreements and retention bonus award agreements with 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.

38

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.

39

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. For example, following announcement of our proposed strategic combination with Akebia Therapeutics, Inc., or Akebia, Panion notified us in writing that Panion would terminate the license agreement on November 21, 2018 if we did not cure the breach alleged by Panion, specifically, that we failed to use commercially reasonable best efforts to commercialize Auryxia outside the United States. We disagreed with Panion's claims, and the parties entered discussions to resolve this dispute. On October 24, 2018, we entered into a letter agreement with Panion and Akebia, or the Panion Letter Agreement, pursuant to which Panion agreed to rescind any and all prior termination threats or notices relating to the license agreement and waived its rights to terminate the license agreement based on any breach by us of our obligation to use commercially reasonable efforts to commercialize Auryxia outside the United States until the parties execute an amendment to the license agreement in accordance with the terms of the Panion Letter Agreement following consummation of the merger with Akebia. These terms of the amendment to the license agreement include establishing a joint steering committee consisting of Panion and Akebia representatives to oversee the development and commercialization of Fexeric in Europe and providing Panion with an exclusive license under patents we own covering the rights to make, use, sell, offer for sale and import ferric citrate in certain countries in the Asia-Pacific region. The parties will agree on a regulatory plan for Fexeric in Europe within four months after execution of the Panion Letter Agreement. The parties will also agree on a commercialization plan for Fexeric in Europe following execution of the amendment to the license agreement. The amendment to the license agreement will include alternatives in the event a commercialization plan is not agreed upon, such as payment of an annual license maintenance fee to Panion or the return of European intellectual property rights to Panion. In addition, under the terms of the Panion Letter Agreement, Panion has agreed that we will have the right, but not the obligation, to conduct any litigation against any infringer of patent rights under the license agreement on the terms agreed upon in the Panion Letter Agreement. We made a $500,000 payment to Panion in connection with the execution of the Panion Letter Agreement. In the event that our merger with Akebia is not consummated, we and Panion are obligated to fulfill the terms of the Panion Letter Agreement, including negotiating in good faith an amendment to the license agreement. Even though we entered into the Panion Letter Agreement, there are no assurances that we will successfully negotiate with Panion and Akebia with respect to the regulatory and commercial plans for Fexeric in Europe, that an amendment to the license agreement will be entered into or that Panion will not allege other breaches to the license agreement or otherwise attempt to terminate the license agreement in the future.

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.

40

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
- 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 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 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.

Other legislative changes have been proposed and adopted since the PPACA was enacted. For example, on January 2, 2013, former President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Certain legislative changes to and regulatory changes under the PPACA have occurred in the 115th United States Congress and under the Trump Administration. For example, on December 22, 2017, President Trump signed the U.S. Tax Cuts and Jobs Act of 2017, which among other things, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Additional legislative changes to and regulatory changes under the PPACA remain possible. We expect that other state and federal healthcare reform measures will be adopted in the future, any of which could reduce the number of patients with coverage or limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

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.

We believe that our existing cash and cash equivalents will be sufficient to fund our current and planned operations into the first quarter of 2019. To fund our operations beyond that time, we will need to either complete the proposed merger with Akebia announced on June 28, 2018, utilize the remaining available capacity, if any, under the asset-based revolving credit facility that we entered in July 2018, and/or raise additional capital through the issuance of common stock or other securities. 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 expenditures associated with commercial activities related to Auryxia, 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 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 our Controlled Equity Offering^{SM} Sales Agreement, or Sales Agreement, with Cantor Fitzgerald & Co., or Cantor Fitzgerald; the issuance of debt, including the asset-based credit facility with Silicon Valley Bank, or SVB; or possible business combinations, such as the proposed merger with Akebia. In addition, although we secured an up to $40.0 million revolving loan facility from SVB in July 2018, the borrowing base we may utilize at any one time under this facility or any other asset-based credit facility, if successfully entered into, may be significantly lower than the total commitment under any 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.

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 and ability of third parties to launch generic competition against Auryxia;
- the timing of the in-licensing, partnering and acquisition of new product opportunities;
- the timing and expenditures associated with commercial activities, if any, related to Fexeric in Europe, other expenses incurred in connection with our Fexeric marketing rights in Europe and our ability to successfully work with Panion with respect to the commercialization of Fexeric 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;

44

- 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 Sales Agreement with 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. Patent number 1 978 807 was determined to be properly patentable by the European Patent Office and has been maintained as granted, though it is still possible for the third-party opponent to appeal this decision.

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.

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.

47

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. Refer to the Risk Factor, “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” above for additional information related to Notice Letters received.

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 September 30, 2018, Baupost beneficially owns approximately 21% of our issued and outstanding common stock. If Baupost converts all of the $164.7 million of Convertible Senior Notes due 2021 issued in May 2018, or the New Notes, into shares of our common stock pursuant to their terms, not including the additional 4.0 million shares that may be issuable under the Notes Conversion Agreement we entered into with Baupost on June 28, 2018 in connection with the proposed merger with Akebia, 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, or the Old Notes, with funds managed by Baupost. The Old 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 New Notes to a fund managed by Baupost in exchange for the Old Notes and an additional $10 million in cash. The zero-coupon New 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 Old Notes initially converts into approximately the same number of shares (33.4 million) into which the Old 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.

Risks related to our strategic merger with Akebia Therapeutics, Inc.

In addition to the risks set forth above, our proposed strategic merger with Akebia present the following additional risks to our business and operations.

Our merger with Akebia is subject to various closing conditions, including governmental approvals, and other uncertainties and there can be no assurances as to whether and when it may be completed.

On June 28, 2018, we entered into an Agreement and Plan of Merger, or the Merger Agreement, with Akebia and Alpha Therapeutics Merger Sub, Inc., or Merger Sub, pursuant to which Merger Sub will merge with and into us, with our company surviving as a wholly-owned subsidiary of Akebia, or the merger. The consummation of the merger is subject to customary closing conditions and a number of the conditions are not within our control, and may prevent, delay or otherwise materially adversely affect the completion of the transaction. These conditions include, among other things, (i) the effectiveness of the registration statement on Form S-4 to be filed with the SEC with respect to the shares of common stock of Akebia to be issued pursuant to the merger, which registration statement was declared effective on October 30, 2018; (ii) the approval of the Merger Agreement by our stockholders; (iii) the approval of the issuance of Akebia common stock in connection with the merger by Akebia's stockholders; (iv) the expiration or termination of the applicable waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, or HSR Clearance, which waiting period was terminated by the U.S. Federal Trade Commission on August 21, 2018; and (v) the absence of any law, regulation or order that has the effect of making the merger illegal or otherwise preventing the consummation of the merger. It is also possible that a change, event, fact, effect or circumstance could occur that could lead to a material adverse effect to us, which may give Akebia the ability to not complete the merger. We cannot predict with certainty whether and when the required closing conditions that have not yet been satisfied will be satisfied or if another uncertainty may arise.

If the merger does not receive, or timely receive, the required stockholder approvals, or if another event occurs delaying or preventing the merger, such delay or failure to complete the merger may cause uncertainty or other negative consequences that may materially and adversely affect our sales, financial performance and operating results, and the price per share for our common stock and perceived acquisition value.

Additionally, if the merger is not completed for any reason, the market price of our common stock may decline. Furthermore, we will be required to pay certain costs relating to the merger, whether or not it is completed, such as

significant fees and expenses relating to legal, accounting and printing services. In addition, we could be subject to litigation related to any failure to complete the merger. If it is not completed, these risks may materially and adversely affect our stock price, operating results and ongoing business.

Further, we and our directors and Akebia could become subject to lawsuits relating to the merger that may be filed. Three putative shareholder class action lawsuits and one additional putative shareholder lawsuit have been filed by our shareholders challenging the disclosures made in connection with the merger. The lawsuits seek to enjoin the merger, to recover damages if the merger is consummated, attorneys' fees, and other relief. Additional lawsuits arising out of the merger may be filed in the future. While we intend to defend against any such actions vigorously, the costs of the defense of such lawsuits and other effects of such litigation could have an adverse effect on our business, financial condition and operating results.

If the Merger Agreement is terminated, we may, under certain circumstances, be obligated to pay a termination fee to Akebia and these costs could require us to use available cash that would have otherwise been available for general corporate purposes.

If the Merger Agreement is terminated, in certain circumstances, we would be required to pay Akebia a termination fee of $22.0 million. If the Merger Agreement is terminated, the termination fee we may be required to pay, if any, under the Merger Agreement may require us to use available cash that would have otherwise been available for general corporate purposes. In addition, the failure to complete the merger may negatively impact our ability to raise additional funds on acceptable terms, or at all. For these and other reasons, a failed merger could materially and adversely affect our business, operating results or financial condition, which in turn would materially and adversely affect our business or financial condition, the price per share of our common stock or our perceived acquisition value.

While the merger is pending, we are subject to business uncertainties and contractual restrictions that could materially adversely affect our operations and the future of our business or result in a loss of employees.

The Merger Agreement includes restrictions on the conduct of our business prior to the completion of the merger, generally requiring us to conduct our business in the ordinary course, consistent with past practice, and subjecting us to a variety of specified limitations absent Akebia's prior written consent. We may find that these and other contractual arrangements in the Merger Agreement may delay or prevent us from or limit our ability to respond effectively to competitive pressures, industry developments and future business opportunities that may arise during such period, even if our management and board of directors think they may be advisable. The pendency of the merger may also divert management's attention and our resources from ongoing business and operations. Our employees and partners may have uncertainties about the effects of the merger. Similarly, current and prospective employees may experience uncertainty about their future roles with us following completion of the merger, which may materially adversely affect our ability to attract and retain key employees. If any of these effects were to occur, it could materially and adversely impact our revenues, earnings and cash flows and other business results and financial condition, as well as the market price of our common stock and our perceived acquisition value, regardless of whether the merger is completed. In addition, whether or not the merger is completed, while it is pending we will continue to incur costs, fees, expenses and charges related to the proposed merger, which may materially and adversely affect our business results and financial condition.

ITEM 5. OTHER INFORMATION

First Supplemental Indenture

On November 8, 2018, we entered into the First Supplemental Indenture, or the First Supplement, to that certain Indenture, or the Indenture, dated as May 9, 2018, between us and The Bank of New York Mellon Trust Company, N.A., as trustee. As required by the terms of the previously-disclosed Notes Conversion Agreement, dated as of June 28, 2018, or the Conversion Agreement, among us, Baupost Group Securities, L.L.C., or Baupost, and, with respect to certain sections only, Akebia Therapeutics, Inc., or Akebia, and in connection with our proposed merger with Akebia, the First Supplement amends the Indenture to facilitate the conversion, immediately prior to the effectiveness of the merger as contemplated by the Conversion Agreement, of our Zero Coupon Convertible Senior Notes due 2021 held by Baupost into shares of our common stock.

The foregoing summary of the First Supplement does not purport to be complete and is qualified in its entirety by reference to the full text of the First Supplement, a copy of which is filed as Exhibit 10.1 to this Quarterly Report on Form 10-Q and is incorporated herein by reference.

Employment Agreement with Jodie Morrison

On November 2, 2018, we entered into an Amendment, effective October 31, 2018, or the Amendment, to our Employment Agreement, or the Employment Agreement, with Jodie Morrison, our Interim Chief Executive Officer, to extend the term of the Employment Agreement to the earlier of the closing of a Change of Control (as defined in the Employment Agreement) or December 31, 2018. The Amendment also provides for, among other things, (i) continued payment to Ms. Morrison of her salary through the term of her employment, (ii) conversion of the prorated bonus contemplated by the Employment Agreement to a full annualized bonus, (iii) a $150,000 cash payment payable as of October 31, 2018 in recognition of the considerable efforts undertaken by Mr. Morrison in her role as Interim Chief Executive Officer, and (iv) a $200,000 cash retention payment to be made on the earlier of December 31, 2018 and the closing of a Change of Control, subject to Ms. Morrison's continued employment with us through such date. As disclosed in the joint proxy statement/prospectus filed by us and Akebia on October 30, 2018, the proposed business combination between us and Akebia pursuant to the Agreement and Plan of Merger, dated June 28, 2018, by and between, inter alia, us and Akebia, as amended, will constitute a Change of Control under the Employment Agreement, including the Amendment.

The foregoing summary of the Amendment does not purport to be complete and is qualified in its entirety by reference to the full text of the Amendment, a copy of which is filed as Exhibit 10.2 to this Quarterly Report on Form 10-Q and is incorporated herein by reference.

Notice Regarding Abbreviated New Drug Application

On October 31, 2018, or the Lupin Notice Date, we received a Paragraph IV certification notice letter, or the Lupin Notice Letter, regarding an ANDA submitted to the FDA by Lupin Atlantis Holdings SA, or Lupin, requesting approval to market, sell and use a generic version of Auryxia (ferric citrate) tablets (210 mg iron per tablet). In the Lupin Notice Letter, Lupin alleges that U.S. Patents nos. 5,753,706; 7,767,851; 8,093,423; 8,299,298; 8,338,642; 8,609,896; 8,754,257; 8,754,258; 8,846,976; 8,901,349; 9,050,316; 9,328,133; 9,387,191; and 9,757,416, which cover the approved drug substance, drug product and/or methods of using Auryxia, are invalid, unenforceable and/or will not be infringed by Lupin's manufacture, use or sale of the product described in its ANDA. On November 6, 2018, or the Teva Notice Date, we received a Paragraph IV certification notice letter, or the Teva Notice Letter, regarding an ANDA submitted to the FDA by Teva Pharmaceuticals USA, Inc., or Teva, requesting approval to market, use or sell a generic version of Auryxia (ferric citrate) tablets (210 mg iron per tablet). In the Teva Notice Letter, Teva alleges that the patents (which are the same patents as those referenced in the Lupin Notice Letter, other than U.S. Patent no. 5,753,706), are invalid, unenforceable and/or will not be infringed by Teva's manufacture, use or sale of the product described in its ANDA. We refer to the Lupin Notice Letter and the Teva Notice Letter collectively as the Notice Letters, the Lupin Notice Date and Teva Notice Date collectively as the Notice Dates, and the patents referenced in the Notice Letters collectively as the Patents. We are currently reviewing the Notice Letters and intend to vigorously enforce our intellectual property rights relating to Auryxia. By statute, we have 45 days from receipt of each Notice Letter to initiate a patent infringement lawsuit against Lupin and Teva, respectively and as applicable. Such lawsuits

would automatically preclude the FDA from approving Lupin's and Teva's ANDA until the earlier of 30 months from the applicable Notice Date or entry of a district court decision finding the Patents referenced in the applicable Notice Letter invalid, unenforceable or not infringed. The composition and use of Auryxia are currently claimed by 14 issued patents that are listed in the FDA's Orange Book. The introduction of a generic version of Auryxia by Lupin, Teva or another party or a ruling that the Patents, or other of our patents, are invalid, unenforceable or will not be infringed by a generic version of Auryxia could have a material adverse effect on our business, results of operations and financial condition.

ITEM 6. EXHIBITS

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

Exhibit Number	Exhibit Description
2.1	First Amendment to Agreement and Plan of Merger dated October 1, 2018, by and among Akebia Therapeutics, Inc., Alpha Therapeutics Merger Sub Inc. and Keryx Biopharmaceuticals, Inc., filed as Exhibit 2.1 to the Registrant's Current Report on Form 8-K, filed on October 1, 2018 (File No. 000-30929), and incorporated herein by reference.
10.1	First Supplemental Indenture dated November 8, 2018, by and between Keryx Biopharmaceuticals, Inc. and The Bank of New York Mellon Trust Company, N.A. to the Indenture dated as of May 9, 2018.
10.2†	Amendment to Employment Agreement with Jodie Morrison effective as of October 31, 2018.
10.3	Loan and Security Agreement dated July 18, 2018, between Keryx Biopharmaceuticals, Inc. and Silicon Valley Bank, filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on July 20, 2018 (File No. 000-30929), and incorporated herein by reference.
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 November 8, 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 November 8, 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 November 8, 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 November 8, 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.

† 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: November 8, 2018 By: /s/ Scott A. Holmes
Scott A. Holmes
Chief Financial Officer
Principal Financial and Accounting Officer