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

FORM 10-Q

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

For the quarterly period ended September 30, 2017

OR

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

For the transition period from _____ to _____

Commission File Number 000-30929

KERYX BIOPHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

One Marina Park Drive, 12th Floor
Boston, Massachusetts 02210
(Address including zip code of principal executive offices)

(617) 466-3500
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files): Yes ☒ 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	☒	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 ☒

There were 119,223,490 shares of the registrant's common stock, $0.001 par value, outstanding as of October 31, 2017.

KERYX BIOPHARMACEUTICALS, INC.
FORM 10-Q
FOR THE QUARTER ENDED SEPTEMBER 30, 2017

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SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

Certain matters discussed in this report, including matters discussed under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations," may constitute forward-looking statements for purposes of the Securities Act of 1933, as amended, or the Securities Act, and the Securities Exchange Act of 1934, as amended, or the Exchange Act, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from the future results, performance or achievements expressed or implied by such forward-looking statements. The words "anticipate," "believe," "estimate," "may," "expect," "will," "project" and similar expressions are generally intended to identify forward-looking statements. Our actual results may differ materially from the results anticipated in these forward-looking statements due to a variety of factors, including, without limitation, those discussed under the caption "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2016, as well as under the 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 Auryxia for the treatment of iron deficiency anemia in adults with chronic kidney disease, not on dialysis in the United States;
- expectations regarding our ability to identify a commercial partner(s) to launch Fexeric® (ferric citrate coordination complex) in the European market;
- expectations for generating revenue, positive cash flow or becoming profitable on a sustained basis;
- expectations for our mix of business between private commercial payers and government-sponsored plans;
- estimates of the sufficiency of our existing cash and cash equivalents to finance our operating requirements;
- expected losses;
- expectations for future capital requirements;
- expectations for increases or decreases in expenses;
- expectations for pre-clinical and clinical development and regulatory progress, including manufacturing, commercialization and reimbursement (including market acceptance) of ferric citrate or any other products that we may acquire or in-license;
- expectations for incurring capital expenditures to expand our development and manufacturing capabilities;
- expectations regarding our ability to successfully market Riona® through our Japanese partner, Japan Tobacco, Inc. and its subsidiary Torii Pharmaceutical Co., Ltd.;
- expectations of the scope of patent protection with respect to Auryxia, Fexeric and Riona;
- expectations or ability to enter into marketing and other partnership agreements; and
- expectations or ability to enter into product acquisition and in-licensing transactions.

The forward-looking statements contained in this report reflect our views and assumptions only as of the date that this report is signed. Except as required by law, we assume no responsibility for updating any forward-looking statements.

In addition, with respect to all of our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Keryx Biopharmaceuticals, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share amounts)
(unaudited)

	September 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 113,999	$ 111,810
Inventory	26,010	12,681
Accounts receivable, net	9,198	5,236
Other current assets	15,571	3,170
Total current assets	164,778	132,897
Property, plant and equipment, net	4,698	4,211
Goodwill	3,208	3,208
Other assets, net	1,138	1,111
Total assets	$ 173,822	$ 141,427
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable and accrued expenses	$ 36,538	$ 21,190
Deferred lease incentive, current portion	244	244
Other current liabilities	138	117
Total current liabilities	36,920	21,551
Convertible senior notes	125,000	125,000
Deferred lease incentive, net of current portion	1,078	1,262
Deferred tax liability	930	870
Other liabilities	932	1,040
Total liabilities	164,860	149,723
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value per share (5,000,000 shares authorized, no shares issued and outstanding)	—	—
Common stock, $0.001 par value per share (230,000,000 and 180,000,000 shares authorized, 119,224,738 and 105,921,052 shares issued, 119,144,790 and 105,841,104 shares outstanding at September 30, 2017 and December 31, 2016, respectively)	119	106
Additional paid-in capital	977,309	827,053
Treasury stock, at cost, 79,948 shares	(357)	(357)
Accumulated deficit	(968,109)	(835,098)
Total stockholders' equity (deficit)	8,962	(8,296)
Total liabilities and stockholders' equity (deficit)	$ 173,822	$ 141,427

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

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

	Three months ended September 30,		Nine months ended September 30,	
	2017	2016	2017	2016
Revenues:				
Net U.S. Auryxia product sales	$ 13,597	$ 5,050	$ 38,218	$ 18,945
License revenue	1,399	1,287	3,741	3,505
Total revenues	14,996	6,337	41,959	22,450
Costs and expenses:				
Cost of goods sold	5,856	18,196	14,508	24,365
License expense	838	772	2,244	2,103
Research and development	9,275	8,674	25,051	23,320
Selling, general and administrative	22,746	20,521	70,835	61,518
Total costs and expenses	38,715	48,163	112,638	111,306
Operating loss	(23,719)	(41,826)	(70,679)	(88,856)
Other income (expense):				
Amortization of debt discount	—	—	(62,965)	(34,226)
Other income (expense), net	241	150	693	(4,169)
Total other income (expense)	241	150	(62,272)	(38,395)
Loss before income taxes	(23,478)	(41,676)	(132,951)	(127,251)
Income taxes	20	20	60	60
Net loss	$ (23,498)	$ (41,696)	$ (133,011)	$ (127,311)
Basic and diluted net loss per common share	$ (0.20)	$ (0.39)	$ (1.18)	$ (1.20)
Weighted average shares used in computing basic and diluted net loss per common share	118,992,825	105,924,106	112,928,551	105,805,669

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,	
	2017	**2016**
Cash flows from operating activities		
Net loss	$ (133,011)	$ (127,311)
Adjustments to reconcile loss to cash flows used in operating activities:		
Stock-based compensation expense	10,707	10,563
Amortization of debt discount	62,965	34,226
Change in fair value of derivative liability	(225)	4,718
Depreciation and amortization	689	776
Loss on disposal of fixed assets	—	54
Amortization of deferred lease incentive	(184)	(183)
Write-down of inventory to net realizable value	1,671	16,352
Cash received from landlord	—	637
Deferred income taxes	60	60
Changes in operating assets and liabilities:		
Other current assets	(12,382)	(563)
Accounts receivable, net	(3,962)	3,656
Inventory	(11,845)	(2,148)
Other assets	(27)	—
Other current liabilities	21	(355)
Accounts payable and accrued expenses	12,318	(3,313)
Deferred revenue	—	(3,526)
Other liabilities	(108)	105
Net cash used in operating activities	(73,313)	(66,252)
Cash flows from investing activities		
Purchases of property, plant and equipment	(1,176)	(2,064)
Net cash used in investing activities	(1,176)	(2,064)
Cash flows from financing activities		
Proceeds from issuance of common stock, net of commission	75,722	—
Payments for common stock issuance costs	(102)	—
Proceeds from exercise of stock options	1,058	198
Net cash provided by financing activities	76,678	198
Net increase (decrease) in cash and cash equivalents	2,189	(68,118)
Cash and cash equivalents at beginning of the period	111,810	200,290
Cash and cash equivalents at end of the period	$ 113,999	$ 132,172
Non-cash financing activities:		
Reclassification of derivative liability to equity	$ 62,735	$ 51,404

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

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; the medication was originally approved in September 2014 for the control of serum phosphorus levels in patients with chronic kidney disease, or CKD, on dialysis. The FDA approved Auryxia tablets for an additional indication in November 2017 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. 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®. Our vision of building a multi-product kidney care company includes expansion of our product portfolio with other medicines that can help patients with kidney disease.

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

Basis of Presentation

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

Principles of Consolidation

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

Use of Estimates

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

Revenue Recognition

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

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

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

(in thousands)	Three months ended September 30, 2017	Percent of gross Auryxia product sales	Three months ended September 30, 2016	Percent of gross Auryxia product sales
Gross Auryxia product sales	$ 30,620		$ 8,711	
Less provision for product sales allowances and accruals:				
Trade allowances	2,894	9%	750	9%
Rebates, chargebacks and discounts	13,251	43%	2,787	32%
Product returns	592	3%	—	—
Other incentives[1]	286	1%	124	1%
Total	17,023	56%	3,661	42%
Net U.S. Auryxia product sales	$ 13,597		$ 5,050	

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

(in thousands)	Nine months ended September 30, 2017	Percent of gross Auryxia product sales	Nine months ended September 30, 2016	Percent of gross Auryxia product sales
Gross Auryxia product sales	$ 74,603		$ 29,896	
Less provision for product sales allowances and accruals				
Trade allowances	7,122	10%	3,451	12%
Rebates, chargebacks and discounts	27,365	37%	7,008	23%
Product returns	870	1%	—	—
Other incentives[1]	1,028	1%	492	2%
Total	36,385	49%	10,951	37%
Net U.S. Auryxia product sales	$ 38,218		$ 18,945	

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

Reclassifications

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

Basic and Diluted Net Loss Per Common Share

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

The 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, 2017	September 30, 2016
Options to purchase common stock	12,135	8,823
Shares issuable upon conversion of convertible senior notes	33,422	33,422
	45,557	42,245

Concentrations of Credit Risk

We do not have significant off-balance-sheet risk or credit risk concentrations. We primarily maintain our cash and cash equivalents in deposit accounts and institutional money market funds. As of September 30, 2017, approximately $25.9 million of our total $114 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, 2017 and December 31, 2016 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, 2017 and December 31, 2016.

	September 30, 2017	December 31, 2016
McKesson Corporation	24%	31%
Fresenius Medical Care Rx	23%	22%
AmerisourceBergen Drug Corporation	21%	23%
Cardinal Health, Inc.	18%	11%
DaVita Rx	9%	10%

New Accounting Pronouncements

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

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

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

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

NOTE 3 – FAIR VALUE MEASUREMENTS

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

	Financial assets at fair value as of September 30, 2017			Financial assets at fair value as of December 31, 2016		
(in thousands)	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Assets:						
Cash equivalents[1]	$ 25,911	$ —	$ —	$ 107,084	$ —	$ —
Total assets	$ 25,911	$ —	$ —	$ 107,084	$ —	$ —

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

Debt

In October 2015, we issued $125 million in Convertible Senior Notes, due 2020, or the Notes, in a private financing to funds managed by Baupost Group Securities, L.L.C., or Baupost. As of September 30, 2017 and December 31, 2016, the fair value of the Notes was $237 million and $196 million, respectively, which differs from their carrying value. The fair value of the Notes is influenced by our stock price and stock price volatility. See Note 9 – *Debt* for additional information on our debt obligations.

NOTE 4 – INVENTORY

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

(in thousands)	September 30, 2017	December 31, 2016
Raw materials	$ 520	$ 418
Work in process	22,330	11,430
Finished goods	3,160	833
Total inventory	$ 26,010	$ 12,681

NOTE 5 – STOCKHOLDERS' EQUITY (DEFICIT)

Change in Stockholders' Equity (Deficit)

Total stockholders' equity was $9.0 million at September 30, 2017, which is an increase of $17.3 million during the nine months ended September 30, 2017 as compared to stockholders' deficit at December 31, 2016 of $8.3 million. This increase was primarily attributable to the proceeds from the issuance of common stock of $75.7 million, the reclassification of the derivative liability related to the Notes to equity of $62.7 million and $10.7 million related to stock-based compensation expense, partially offset by our net loss of approximately $133.0 million.

NOTE 6 – STOCK-BASED COMPENSATION EXPENSE

Equity Incentive Plans

As of September 30, 2017, a total of 1,966,235 shares were available for the issuance of stock options or other stock-based awards under our stock option and incentive plans.

Stock Options

The following table summarizes stock option activity for the nine months ended September 30, 2017:

	Number of shares	Weighted average exercise price
Outstanding at December 31, 2016	8,677,998	$ 7.28
Granted	4,581,750	5.46
Exercised	(328,575)	3.28
Forfeited or Expired	(796,533)	7.27
Outstanding at September 30, 2017	12,134,640	$ 6.70
Vested and expected to vest at September 30, 2017	7,227,274	$ 7.64
Exercisable at September 30, 2017	4,056,699	$ 9.17

Upon the exercise of stock options, we issue new shares of our common stock. As of September 30, 2017, 4,338,750 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, 2017:

	Number of shares	Weighted average grant date fair value
Outstanding at December 31, 2016	1,524,884	$ 7.07
Granted	1,171,575	5.73
Vested	(513,236)	6.01
Forfeited	(133,638)	5.56
Outstanding at September 30, 2017	2,049,585	$ 6.67

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

Stock-Based Compensation Expense

We incurred $3.4 million and $3.7 million of stock-based compensation expense related to equity incentive grants during the three months ended September 30, 2017 and 2016, respectively, and $10.7 million and $10.6 million during the nine months ended September 30, 2017 and 2016, respectively. The following table reflects stock-based compensation expense for the three and nine months ended September 30, 2017 and 2016:

(in thousands)	Three months ended September 30, 2017	Three months ended September 30, 2016	Nine months ended September 30, 2017	Nine months ended September 30, 2016
Cost of goods sold	$ 37	$ 39	$ 125	$ 53
Research and development	468	558	1,529	2,143
Selling, general and administrative	2,867	3,120	9,053	8,367
Total stock-based compensation expense	$ 3,372	$ 3,717	$ 10,707	$ 10,563

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

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

The weighted average grant date fair value of stock options granted during the three months ended September 30, 2017 and 2016 was $5.14 and $5.94 per share, respectively, and during the nine months ended September 30, 2017 and 2016 was $3.91 and $4.54 per share, respectively. We used historical information to estimate forfeitures of stock options. As of September 30, 2017, there was $10.7 million and $6.3 million of total unrecognized compensation cost related to non-vested stock options and restricted stock, respectively, which is expected to be recognized over weighted-average periods of 1.7 years and 1.6 years, respectively. These amounts do not include 4,338,750 unvested options and 435,000 shares of unvested restricted stock as of September 30, 2017 which are performance-based and vest upon achievement of certain corporate milestones. Stock-based compensation for these awards will be measured and recorded if and when it is probable that the milestone will be achieved.

NOTE 7 – LICENSE AGREEMENTS

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

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

In January 2014, JT and Torii received manufacturing and marketing approval of ferric citrate from the Japanese Ministry of Health, Labour and Welfare. Ferric citrate launched in May 2014 and is marketed in Japan by Torii under the brand name Riona and is indicated as an oral treatment for the improvement of hyperphosphatemia in patients with CKD. Under the terms of the Revised Agreement, we receive royalty payments based on a tiered double-digit percentage of net sales of Riona in Japan escalating up to the mid-teens and may also receive up to an additional $55.0 million upon the achievement of certain annual net sales milestones. In accordance with our revenue recognition policy, royalty revenues are recognized in the quarter that JT and Torii provide their written report and related information to us regarding sales of Riona, which generally will be one quarter following the quarter in which the underlying sales by JT and Torii occurred. For the three months ended September 30, 2017 and 2016, we recorded $1.4 million and $1.3 million, respectively, in license revenue related to royalties earned on net sales of Riona in Japan. For the nine months ended September 30, 2017 and 2016, we recorded $3.7 million and $3.5 million, respectively, in license revenue related to royalties earned on net sales of Riona in Japan. We record the associated mid-single digit percentage of net sales royalty expense due Panion, the licensor of ferric citrate, in the same period as the royalty revenue from JT and Torii is recorded. For each of the three months ended September 30, 2017 and 2016, we recorded $0.8 million 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, 2017 and 2016, we recorded $2.2 million and $2.1 million, respectively, in license expense related to royalties due to the licensor of ferric citrate relating to sales of Riona in Japan.

NOTE 8 – ACCOUNTS PAYABLE AND ACCRUED EXPENSES

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

(in thousands)	September 30, 2017	December 31, 2016
Accounts payable	$ 6,799	$ 2,225
Accrued compensation and related liabilities	6,377	8,190
Accrued professional, license, and other fees and expenses	8,106	6,159
Accrued commercial rebates, fees and product returns	15,256	4,616
Total accounts payable and accrued expenses	$ 36,538	$ 21,190

NOTE 9 – DEBT

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

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

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

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

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

We determined the expected life of the debt was equal to the period through July 1, 2016, as this represented the earliest point at which a portion of the Notes was initially contingently convertible into cash. Accordingly, for the nine months ended September 30, 2016, approximately $34.2 million of interest expense was recognized related to the Notes, all of which was attributable to the amortization of the debt discount.

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

In accordance with accounting guidance for debt modifications and exchanges, we assessed the terms of the First Supplement and determined that it resulted in a modification. During the three months ended June 30, 2017, we separated the conversion option from the debt instrument and accounted for it separately as a derivative liability, due to the Notes being contingently convertible to cash at the option of Baupost per the terms of the First Supplement. We allocated the proceeds between the debt component and the embedded conversion option (the derivative) by performing a valuation of the derivative as of

the date of the First Supplement, which was determined based on the difference between the fair value of the Notes with the conversion option and the fair value of the Notes without the conversion option. The fair value of the derivative liability was recognized as a debt discount and the carrying amount of the convertible senior notes represented the difference between the principal amount of the Notes and the fair value of the derivative liability on the date of the First Supplement. The excess of the principal amount of the debt component over its carrying amount, or debt discount, was amortized to interest expense using the effective interest method over the expected life of the debt. We determined the expected life of the debt was equal to the period through June 8, 2017, as this represented the point at which the Notes was contingently convertible into cash.

In the nine months ended September 30, 2017 and 2016, $63.0 million and $34.2 million, respectively, of interest expense was recognized related to the Notes. As of September 30, 2017 and December 31, 2016, the balance of the Notes and the carrying value of the Notes was $125 million, and the fair value of the Notes was $237 million and $196 million, respectively.

NOTE 10 – 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)	2017	2016	2017	2016
Interest income	$ 240	$ 169	$ 475	$ 556
Other income (expense)	1	(19)	(7)	(7)
Fair value adjustment to derivative liability	—	—	225	(4,718)
	$ 241	$ 150	$ 693	$ (4,169)

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

NOTE 11 – COMMITMENTS AND CONTINGENCIES

Commitments

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

Contingencies

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

Four purported class action lawsuits have been filed against us and certain of our current and former officers (Gregory P. Madison, Scott A. Holmes, Ron Bentsur, and James Oliviero). Three of these actions were filed in the U.S. District Court for the Southern District of New York, captioned respectively Terrell Jackson v. Keryx Biopharmaceuticals, Inc., et al., No. 1:16-cv-06131, filed on August 2, 2016, Richard J. Erickson v. Keryx Biopharmaceuticals, Inc., et al. No. 1:16-cv-06218, filed on August 4, 2016, and Richard King v. Keryx Biopharmaceuticals, Inc., et al., No. 1:16-cv-06233, filed on August 5, 2016. The Jackson complaint purports to be brought on behalf of stockholders who purchased our common stock between February 25, 2016 and August 1, 2016, the Erickson complaint purports to be brought on behalf of stockholders who purchased our common stock between March 2, 2016 and July 29, 2016, and the King complaint purports to be brought on behalf of stockholders who purchased our common stock between February 25, 2016 and July 29, 2016. On August 26, 2016, the fourth complaint, captioned Tim Karth v. Keryx Biopharmaceuticals, Inc., et al., No. 1:16-cv-11745, was filed in the U.S. District Court for the District of Massachusetts, which complaint was subsequently amended. The Karth complaint purports to be brought on behalf of stockholders who purchased our common stock between May 8, 2013 and August 1, 2016. The Jackson, Erickson and King matters were transferred to the U.S. District Court for the District of Massachusetts on April 5, 2017. Each complaint generally alleges that we and certain of our current and former officers violated Sections 10(b) and/or 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder by making allegedly false and/or misleading statements concerning us and our business operations and future prospects in light of the August 1, 2016 announcement of an interruption in our supply of Auryxia. Two stockholder derivative complaints were also filed on December 16, 2016 against us and certain of our current and former officers (Gregory P. Madison, Scott A. Holmes, Ron Bentsur and James Oliviero), certain of our current directors (Kevin J. Cameron, Daniel P. Regan, Steven C. Gilman, Michael Rogers and John P. Butler) and our former directors (Michael P. Tarnok, Joseph Feczko, Jack Kaye and Wyche Fowler, Jr.), in the Superior Court of Massachusetts, one captioned Venkat Vara Prasad Malledi v. Keryx Biopharmaceuticals, Inc., et al., No. 16-3865 and one captioned James Anderson v. Keryx Biopharmaceuticals, Inc., et al., No. 16-3866. Each of these two complaints generally allege that the individual defendants breached their fiduciary duties owed to us, unjustly enriched themselves by their actions, abused their control positions with us, mismanaged us and wasted corporate assets since July 31, 2013 in light of our August 1, 2016 announcement by us of an interruption in the supply of the our product Auryxia. On June 27, 2017, the Superior Court granted the parties' motion to consolidate and stay the derivative litigations. All of the complaints seek unspecified damages, interest, attorneys' fees, and other costs. We deny any allegations of wrongdoing and intend to vigorously defend against these lawsuits. There is no assurance, however, that we or the other defendants will be successful in our defense of either of these lawsuits or that insurance will be available or adequate to fund any settlement or judgment or the litigation costs of these actions. Moreover, we are unable to predict the outcome or reasonably estimate a range of possible losses at this time. A resolution of these lawsuits adverse to us or the other defendants, however, could have a material effect on our financial position and results of operations in the period in which the particular lawsuit is resolved.

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

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

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

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; the medication was originally approved in September 2014 for the control of serum phosphorus levels in patients with chronic kidney disease, or CKD, on dialysis. The FDA approved Auryxia tablets for an additional indication in November 2017 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. 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. 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.

RECENT DEVELOPMENTS

On November 6, 2017, the FDA approved Auryxia for the treatment of iron deficiency anemia in adults with CKD, not on dialysis. The approval of Auryxia for a second indication significantly increases the number of patients in the United States that can benefit from Auryxia. Upon receipt of this approval, we made Auryxia available to these patients and we plan to leverage our existing U.S. commercial infrastructure to sell Auryxia in this indication.

OUR STRATEGY

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

Maximize Auryxia's Potential

We developed and subsequently launched Auryxia in the United States in late December 2014. Auryxia is approved by the FDA for two indications. It is a non-calcium, non-chewable, orally-administered phosphate binder for patients with CKD on dialysis; Auryxia is also approved for treatment of iron deficiency anemia in adults with CKD, not on dialysis. Auryxia is the first FDA-approved oral iron medication to treat iron deficiency anemia in CKD patients, not on dialysis. Auryxia is being marketed in the United States to nephrologists and renal care teams through our specialty salesforce and commercial infrastructure. In the United States, there are approximately 450,000 adult patients with CKD requiring dialysis (referred to as End Stage Renal Disease, or ESRD), including approximately 350,000 adults currently taking a phosphate binder. We estimate that in the United States, approximately 1.7 million adults under the care of a nephrologist 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. There is significant literature that correlates anemia with increased risk of heart disease and death. Our field-based organization is aligned to 95 territories calling on target nephrologists and their associated dialysis centers. We believe strong fundamentals are in place to 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 several clinical-drug candidates and commercial medicines to in-license or acquire to add to our portfolio and provide us with new commercial opportunities. We will seek to add assets that leverage the infrastructure we have built to support our foundational medicine, Auryxia, including our clinical development and commercial teams. We believe these efforts have the potential to provide additional revenues to us in the future.

Manage Growth and Talent

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

Financial Performance Overview

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

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

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

Our license expense consists of royalties due to the licensor of Auryxia related to our license agreement with JT and Torii. License expense is recognized in the same period as the license revenue is recorded.

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

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

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

Even though our trials demonstrated that Auryxia is effective in the control of serum phosphorus levels in patients with CKD on dialysis and treating iron deficiency anemia in certain patients in the non-dialysis setting, 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.

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.

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

NEW ACCOUNTING PRONOUNCEMENTS

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

RESULTS OF OPERATIONS

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

Net U.S. Auryxia Product Sales. For the three months ended September 30, 2017, we recognized $13.6 million in product sales of Auryxia, net of allowances, discounts, incentives, rebates and chargebacks, as compared with $5.1 million for the three months ended September 30, 2016.

(in thousands)	Three months ended September 30, 2017	Percent of gross Auryxia product sales	Three months ended September 30, 2016	Percent of gross Auryxia product sales
Gross Auryxia product sales	$ 30,620		$ 8,711	
Less provision for product sales allowances and accruals				
Trade allowances	2,894	9%	750	9%
Rebates, chargebacks and discounts	13,251	43%	2,787	32%
Product returns	592	3%	—	—
Other incentives[1]	286	1%	124	1%
Total	17,023	56%	3,661	42%
Net U.S. Auryxia product sales	$ 13,597		$ 5,050	

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

Gross Auryxia product sales increased for the three months ended September 30, 2017 as compared to the same period in 2016 primarily as a result of an increase in patient prescriptions and related units sold, partially offset by a higher gross-to-net adjustment. Provisions for product sales allowances and accruals as a percentage of gross Auryxia product sales for the three months ended September 30, 2017 as compared to the same period in 2016 increased primarily as a result of a higher percentage of sales through government (Medicare Part D) contracts that generally receive a larger rebate. Our gross-to-net adjustments may increase depending on our mix of business between Medicare Part D and commercial payers as well as the portion of our business coming from the use of Auryxia as a treatment for hyperphosphatemia as compared to the portion of our business coming from the use of Auryxia as a treatment for iron deficiency anemia.

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

License Revenue. For the three months ended September 30, 2017 and 2016, we recognized $1.4 million and $1.3 million, respectively, in license revenue on royalty payments from sales of Riona in Japan.

Cost of Goods Sold. For the three months ended September 30, 2017, we recognized $5.9 million in cost of goods sold, as compared to $18.2 million for the three months ended September 30, 2016. This decrease was primarily due to a decrease of $12.7 million in inventory write-offs in the 2017 period as compared to the 2016 period, partially offset by additional units sold in the 2017 period as compared to the 2016 period.

License Expense. For each of the three months ended September 30, 2017 and 2016, we recognized $0.8 million in license expense related to royalties due to the licensor of Auryxia relating to sales of Riona in Japan.

Research and Development Expenses. Research and development expenses increased by $0.6 million to $9.3 million for the three months ended September 30, 2017, as compared to $8.7 million for the three months ended September 30, 2016. The increase in research and development expenses was primarily due to an increase in process development-related manufacturing costs as we seek to increase our manufacturing capabilities, as well as clinical trial costs related to the treatment of iron deficiency anemia patients. We expect our research and development expenses will increase for the remainder of 2017 as compared to the three months ended September 30, 2017, due to continued process development-related manufacturing costs, as well as our investments in investigator sponsored research and other clinical trial costs.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased by $2.2 million to $22.7 million for the three months ended September 30, 2017, as compared to $20.5 million for the three months ended September 30, 2016. The increase was primarily due to an increase in personnel costs attributable to the continued commercialization of Auryxia, as well as costs associated with preparing for the approval and launch of Auryxia for the treatment of iron deficiency anemia in adults with CKD, not on dialysis. We expect our selling, general and administrative costs

to increase slightly for the remainder of 2017 as compared to the three months ended September 30, 2017, due to costs associated with supporting the launch of Auryxia for the treatment of iron deficiency anemia.

Other income (expense). Other income (expense) for each of the three months ended September 30, 2017 and September 30, 2016 was $0.2 million in income.

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

Nine months ended September 30, 2017 and September 30, 2016

Net U.S. Auryxia Product Sales. For the nine months ended September 30, 2017, we recognized $38.2 million in product sales of Auryxia, net of allowances, discounts, incentives, rebates and chargebacks, as compared with $18.9 million for the nine months ended September 30, 2016.

(in thousands)	Nine months ended September 30, 2017	Percent of gross Auryxia product sales	Nine months ended September 30, 2016	Percent of gross Auryxia product sales
Gross Auryxia product sales	$ 74,603		$ 29,896	
Less provision for product sales allowances and accruals				
Trade allowances	7,122	10%	3,451	12%
Rebates, chargebacks and discounts	27,365	37%	7,008	23%
Product returns	870	1%	—	—
Other incentives[1]	1,028	1%	492	2%
Total	36,385	49%	10,951	37%
Net U.S. Auryxia product sales	$ 38,218		$ 18,945	

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

Gross Auryxia product sales increased for the nine months ended September 30, 2017 as compared to the same period in 2016 primarily as a result of an increase in patient prescriptions and related units sold, partially offset by a higher gross-to-net adjustment. Provisions for product sales allowances and accruals as a percentage of gross Auryxia product sales for the nine months ended September 30, 2017 as compared to the same period in 2016 increased primarily as a result of a higher percentage of sales through government (Medicare Part D) contracts that generally receive a larger rebate.

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

License Revenue. For the nine months ended September 30, 2017, we recognized $3.7 million in license revenue on royalty payments from sales of Riona in Japan as compared to $3.5 million for the nine months ended September 30, 2016. This increase was due to increased sales by JT and Torii of Riona in Japan.

Cost of Goods Sold. For the nine months ended September 30, 2017, we recognized $14.5 million in cost of goods sold, as compared to $24.4 million for the nine months ended September 30, 2016. This decrease was primarily due to a decrease of $14.7 million in inventory write-offs in the 2017 period as compared to the 2016 period, partially offset by additional units sold during the 2017 period as compared to the 2016 period.

License Expense. For the nine months ended September 30, 2017, we recognized $2.2 million in license expense related to royalties due to the licensor of Auryxia relating to sales of Riona in Japan as compared to $2.1 million for the nine months ended September 30, 2016. This increase was due to an increase in sales of Riona in Japan during the 2017 period.

Research and Development Expenses. Research and development expenses increased by $1.8 million to $25.1 million for the nine months ended September 30, 2017, as compared to $23.3 million for the nine months ended September 30, 2016. The increase in research and development expenses was primarily due to an increase in process development-related manufacturing

costs as we seek to increase our manufacturing capabilities, as well as an increase in filing fees in the first quarter of 2017 related to our submission of the supplemental new drug application to the FDA for Auryxia.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased by $9.3 million to $70.8 million for the nine months ended September 30, 2017, as compared to $61.5 million for the nine months ended September 30, 2016. The increase was primarily due to an increase in personnel costs attributable to the continued commercialization of Auryxia and costs associated with preparing for the approval and launch of Auryxia for the treatment of iron deficiency anemia in adults with CKD, not on dialysis.

Other income (expense). Other income (expense) for the nine months ended September 30, 2017 was $62.3 million in expense as compared to $38.4 million in expense for the nine months ended September 30, 2016. The increase was primarily due to an increase in the amortization of the debt discount of $29.0 million offset by a change in the fair value adjustment to the derivative liability related to our convertible senior notes of $5.0 million.

Income Taxes. For each of the nine months ended September 30, 2017 and 2016, we recognized $60,000 in income tax expense related to the recording of a deferred tax liability associated with capitalized goodwill, an indefinite-lived intangible asset that is being amortized for tax purposes.

LIQUIDITY AND CAPITAL RESOURCES

Our major sources of cash have been proceeds from various public and private offerings of our common stock, the issuance of convertible senior notes, from the upfront and milestone payments from our agreement with JT and Torii, sales of Auryxia, option and warrant exercises, interest income, and miscellaneous payments from our other prior licensing activities. The commercial launch of our product, Auryxia, occurred in late December 2014 and we began to recognize revenue from the sales of Auryxia in 2015. On November 6, 2017, the FDA approved Auryxia for the treatment of iron deficiency anemia in adults with CKD, not on dialysis, expanding the number of patients which can benefit from Auryxia. Even if we successfully commercialize Auryxia, including in the non-dialysis setting, we may not become profitable. Our ability to achieve profitability depends on a number of factors, including our ability to complete our development efforts, obtain any additional regulatory approvals which we may seek for our drug, successfully complete any post-approval regulatory obligations and successfully manufacture and commercialize our drug alone or in partnership. We may continue to incur substantial operating losses even after we begin to generate meaningful revenues from Auryxia.

In November 2016, we filed a registration statement on Form S-3 (No. 333-214513), which the Securities and Exchange Commission, or SEC, declared effective on December 6, 2016, which registered the issuance from time to time of up to $250 million of our securities. At that time, we also entered into a Controlled Equity Offering℠ Sales Agreement, or the Sales Agreement, with Cantor Fitzgerald & Co., as sales agent, or Cantor Fitzgerald, pursuant to which we were initially able to offer and sell, from time to time, through Cantor Fitzgerald, shares of our common stock having an aggregate offering price of up to $75.0 million. During the six months ended June 30, 2017, we sold 11,574,320 shares under the Sales Agreement for aggregate net proceeds of $73.1 million. The sales during the six months ended June 30, 2017 amounted to the initial $75.0 million issuable pursuant to the Sales Agreement. 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 three months ended September 30, 2017, we sold 362,854 shares under the Sales Agreement for aggregate net proceeds of $2.6 million. The initial $75.0 million of common stock issued pursuant to the Sales Agreement and the additional $75.0 million of common stock is included as part of the $250 million registered on the registration statement referred to above.

In October 2015, we completed the sale of $125 million of Convertible Senior Notes due 2020, or the Notes, to funds managed by The Baupost Group, L.L.C, or Baupost. See Note 9 – *Debt* for a description of the Notes. We also entered into a Registration Rights Agreement with the purchasers of the Notes, or the Registration Rights Agreement, pursuant to which we agreed to (i) file a registration statement with the SEC covering the resale of the Notes and the underlying common stock which the Notes are convertible into upon the written request of Baupost, and (ii) use commercially reasonable efforts, subject to receipt of necessary information from all the purchasers of the Notes, to cause the SEC to declare such resale registration statement effective. Further, the Registration Rights Agreement permits Baupost to demand from time to time that we file a shelf Registration Statement pursuant to Rule 415 of the Securities Act from which any number of shelf takedowns may be conducted upon written request from Baupost. In addition, the Registration Rights Agreement provides Baupost certain piggyback registration rights.

As of September 30, 2017, we had $114 million in cash and cash equivalents, as compared to $112 million in cash and cash equivalents at December 31, 2016, representing an increase of $2.0 million. The increase in cash and cash equivalents was primarily due to net proceeds from sales of our common stock under the Sales Agreement as discussed above, partially offset by cash used to fund operations.

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

Net cash used in operating activities for the nine months ended September 30, 2017 was $73.3 million as compared to $66.3 million net cash used in operating activities for the same period in 2016. This increase in net cash used in operating activities was primarily related to an increase in net loss after non-cash adjustments, as well as increases in prepaid manufacturing costs and purchases of inventory.

Net cash used in investing activities for the nine months ended September 30, 2017 was $1.2 million as compared to $2.1 million net cash used in investing activities for the same period in 2016. The net cash used in investing activities for the nine months ended September 30, 2017 and 2016 relates to purchases of property, plant and equipment in connection with certain leasehold improvements.

Net cash provided by financing activities for the nine months ended September 30, 2017 was $76.7 million as compared to $0.2 million for the same period in 2016. Net cash provided by financing activities for the nine months ended September 30, 2017 is attributable to the net proceeds from the issuance

of common stock under the Sales Agreement.

OBLIGATIONS AND COMMITMENTS

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

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

Leases

In April 2015, we signed a lease agreement for approximately 27,300 square feet in Boston, Massachusetts, for a 94-month term that commenced on May 1, 2015. In order to make the space usable for our operations, substantial improvements were made. Our landlord agreed to pay for up to approximately $1.9 million of the improvements, and we bore all additional costs that were incurred. As such, we have determined that we are the owner of the improvements and account for tenant improvements paid by our landlord as a lease incentive. On May 1, 2015, in accordance with 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, 2017, we have paid an aggregate of $11.6 million of milestone payments to Panion, including the $2.0 million paid upon European marketing approval in 2015. In addition, Panion is eligible to receive royalty payments based on a mid-single digit percentage of net sales of Auryxia in the United States and of Riona in Japan. We record royalties on net sales of Auryxia in cost of goods sold and royalties on net sales of Riona in license expense.

OFF-BALANCE SHEET ARRANGEMENTS

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

INTEREST RATE RISK

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

EQUITY PRICE RISK

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

ITEM 4. CONTROLS AND PROCEDURES

EVALUATION OF DISCLOSURE CONTROLS AND PROCEDURES

As of September 30, 2017, management carried out, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our disclosure controls and procedures are designed to provide reasonable assurance that information we are required to disclose in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in applicable rules and forms. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of September 30, 2017, our disclosure controls and procedures were effective.

CHANGES IN INTERNAL CONTROLS OVER FINANCIAL REPORTING

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

LIMITATIONS ON EFFECTIVENESS OF CONTROLS

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal controls over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only

reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our company have been detected.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

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

Risks related to our business and industry

We 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 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, 2017, we had an accumulated deficit of $968.1 million. 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, Auryxia. 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 U.S. Food and Drug Administration, or 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 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 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 recent interruption in its supply;
- the size of the treatable patient population;
- our ability to both secure and maintain adequate reimbursement for, and optimize patient access to Auryxia by providing third-party payers with a strong value proposition and the benefits of Auryxia to patients;
- our mix of business between private commercial payers and government-sponsored plans;
- the occurrence of any side effects, adverse reactions or misuse, or any unfavorable publicity in these areas, associated with Auryxia;
- our ability to obtain and maintain strong intellectual property protection for Auryxia; and

- the development or commercialization of competing products.

Our revenues from the commercialization of Auryxia are subject to these and other factors, and therefore may be unpredictable from quarter-to-quarter. 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 expand our marketing organization and hire additional sales representatives, 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, however, we are seeking potential partners to commercialize Fexeric in the EU. We cannot assure you that we will be able to find a commercialization partner in the EU or that we will be able to agree to acceptable terms with any partner to launch and commercialize Fexeric in the EU. If we do not begin to market Fexeric in the EU by September 23, 2018, the EC may withdraw its approval of Fexeric.

The commercial success of Fexeric is subject to the same 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, and therefore we may never reach or maintain profitability 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 we may decide to conduct a product recall;
- 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, we expect 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 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 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 practices, or cGMPs, and other regulatory requirements, including requirements from federal, state and local environmental and safety 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 FDA inspection. 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 intend to 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 two suppliers with three approved sites for the supply of Auryxia drug product. We are currently utilizing one of these suppliers at its two approved sites to manufacture Auryxia drug product, are working with this supplier to have a third site approved and are conducting additional development work at the other supplier. If any of our suppliers were to limit or terminate production, or otherwise fail to meet the quality or delivery requirements needed to supply Auryxia at adequate levels, we could experience losses of revenue, which could materially and adversely impact our results of operations.

Our third-party manufacturers may not perform as required under the terms of our supply agreement or quality agreement, 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 governmental 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 studies, which could significantly delay our ability to receive regulatory approvals for our drug. Additionally, changes in the analytical specifications required by the FDA or other regulatory authority, such as United States Pharmacopeial Convention standards, from time to time, could delay our ability to receive 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 recent 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 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. 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.

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

Physicians are permitted to prescribe drug products for uses that are not described in the product's labeling and that differ from those approved by the FDA or other applicable regulatory agencies. Such "off-label" uses are common across medical specialties. Although the FDA and other regulatory agencies do not regulate a physician's choice of treatments, the FDA and other regulatory agencies do restrict communications on the subject of off-label use. Companies are not permitted to promote drugs for off-label uses or promote drugs using marketing claims that are not otherwise consistent with the FDA-approved labeling, including comparative or superiority claims that are not consistent with the FDA-approved labeling or supported by substantial evidence. Accordingly, we may not promote Auryxia in the United States for use in any indications other than for the control of serum phosphorus levels in patients with CKD on dialysis and for the treatment of iron deficiency anemia in adults with CKD, not on dialysis, and all promotional claims must be consistent with the FDA-approved labeling for Auryxia. The FDA and other regulatory and enforcement authorities actively enforce laws and regulations prohibiting promotion of off-

label uses and the promotion of products for which marketing approval has not been obtained as well as the false advertising or misleading promotion of drugs. A company that is found to have improperly promoted off-label uses or to have otherwise engaged in false or misleading promotion of drugs will be subject to significant liability, including civil and administrative remedies as well as criminal sanctions.

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

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

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

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

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

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

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

- federal healthcare program anti-kickback laws, which prohibit, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent, and which may apply to entities like us which provide coding and billing advice to customers;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to

healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

- the Federal Food, Drug, and Cosmetic Act, or FDCA, which among other things, strictly regulates drug product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples;
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts;
- the federal Foreign Corrupt Practices Act which prohibits corporations and individuals from paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity; and
- the federal Physician Payments Sunshine Act, which was passed as part of the Patient Protection and Affordable Care Act of 2010, and similar state laws in certain states, that require pharmaceutical and medical device companies to monitor and report certain payments and transfers of value made to physicians and teaching hospitals.

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

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

If our competitors develop and market products that are less expensive, have a reduced pill burden, 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), or Genzyme, 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. 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. In addition, a generic

formulation of PhosLo® manufactured by Roxane Laboratories, Inc. was launched in the United States in October 2008. In addition, upon the expiration of its core patents, generic formulations of Fosrenol may be launched. These generic formulations could have a further material effect on the pricing of phosphate binders.

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.

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.

If we lose our key personnel or are unable to attract and retain additional personnel, our operations could be disrupted and our business could be harmed.

As of September 30, 2017 we had 206 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.

Greg Madison has been our Chief Executive Officer since April 30, 2015. Previously, Mr. Madison was appointed to our Board of Directors in March 2015. Mr. Madison joined Keryx in February 2014 as Executive Vice President and Chief Operating Officer to transition Keryx from a development stage organization into a fully-integrated commercial entity, and bring to Keryx a wealth of relevant expertise in both the phosphate binder and iron deficiency anemia markets.

Brian Adams joined Keryx in April 2014 as General Counsel and was additionally appointed as our Corporate Secretary in March 2015.

In April 2015, we appointed John F. Neylan, M.D., as our Senior Vice President and Chief Medical Officer.

In July 2015, we appointed Scott Holmes as our Senior Vice President and Chief Financial Officer. In January 2017, we appointed Christine Carberry as our Chief Operating Officer.

Although we have employment agreements with Greg Madison, Brian Adams, 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 and we 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.

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 preclinical 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 regulatory approval. Accordingly, we may encounter unforeseen problems and delays in the approval process. Although we engage, from time to time, clinical research organizations, or CROs, with experience in conducting regulatory trials, errors in the conduct, monitoring, data capture and analysis, and/or auditing could potentially invalidate the results.

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

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

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

In the course of product development, we engage CROs and other vendors to conduct and manage clinical studies and to assist us in guiding our products through the FDA review and approval process. 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, as well as the commercialization of 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 we make 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 effect acquisitions to obtain additional businesses, products, technologies, capabilities and personnel. If we make one or more significant acquisitions 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, the ownership interests of our stockholders will be diluted.

Acquisitions 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 acquisition 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 reimportation of drugs into the United States from other countries (where they are then sold at a lower price), and the amount of reimbursement available from governmental agencies or other third-party payers. For example, drug manufacturers are required to have a national rebate agreement with the Department of Health and Human Services, or HHS, in order to obtain state Medicaid coverage, which requires manufacturers to pay a rebate on drugs dispensed to Medicaid patients. On January 27, 2012, the Centers for Medicare and Medicaid Services, or CMS, issued a proposed regulation covering the calculation of Average Manufacturer Price, or AMP, which is the key variable in the calculation of these rebates.

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

For example, in July 2010, CMS released its final rule to implement a bundled prospective payment system for end-stage renal disease facilities as required by the Medicare Improvements for Patients and Providers Act, or MIPPA. The final rule

delayed the inclusion of oral medications without intravenous equivalents, such as phosphate binders, in the bundle until January 1, 2014; however, on January 3, 2013, the United States Congress passed legislation known as the American Taxpayer Relief Act of 2012, which, among other things, delayed by two years the implementation of oral-only end-stage renal disease related drugs, including phosphate binders, in the bundled 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 internal systems to ensure compliance with this law will require 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 expanded our insurance coverage to include 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 currently expect that our existing capital resources, future anticipated cash flows from product sales and the funds from future financings will be sufficient to execute our current business objectives. The actual amount of cash that we will need to operate our business is subject to many factors, including, but not limited to, the timing and expenditures associated with commercial activities related to Auryxia and the timing and magnitude of cash received from product sales, the timing and expenditures associated with the build-up of inventory and capacity expansion, and the timing, design and conduct of any further clinical trials for Auryxia. As a result of these factors, we will need to seek additional financing to provide the cash necessary to execute our current operations, including beyond commercializing Auryxia, and to develop and commercialize any drugs or drug candidates we may in-license or acquire.

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 recent interruption in its supply;
- the timing, design and conduct of, and results from, clinical trials that we may conduct;
- the timing of expenses associated with manufacturing and product development of Auryxia and those proprietary drug candidates that may be in-licensed, partnered or acquired;
- the timing of the in-licensing, partnering and acquisition of new product opportunities;
- the timing and expenditures associated with commercial activities related to launching Fexeric in Europe, either by us or through a commercialization partner;
- the progress of the development efforts of parties with whom we have entered, or may enter, into research and development agreements;
- our ability to achieve our milestones under our licensing arrangement;
- the timing and expenses associated with capital expenditures to expand our manufacturing capabilities;
- the timing and expenses associated with building our own commercial infrastructure to manufacture, market and sell our drug and those that may be in-licensed, partnered or acquired; and
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights, defending against post-grant proceedings initiated by third parties attempting to limit or cancel our intellectual property rights in the United States and elsewhere, such as U.S. inter partes review proceedings and/or European oppositions, or defending against claims of infringement initiated by third parties in respect of their intellectual property rights.

If our cash is insufficient to meet our future operating requirements, we will have to raise additional funds. If we are unable to obtain additional funds on terms favorable to us, or at all, we may be required to cease or reduce our operating

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

Risks related to our intellectual property and third-party contracts

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

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

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

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. No consistent policy regarding the breadth of claims allowed in 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, are still being interpreted and those laws 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 our patents at the European Patent Office. We currently have two issued European patents involved in such post-grant opposition proceedings.

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 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 exclusivity, or NCE, or new formulation exclusivity, to provide market exclusivity for a drug candidate.

In the United States, the FDA has the authority to grant additional data 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 data protection as well as to the term of a relevant patent, to the extent these protections have not already expired.

The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of a new drug application, or NDA, for a 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. 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 application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing 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. Five-year and three-year exclusivity will not delay the submission or tentative approval of a full ANDA; however, an applicant submitting a full ANDA would be required to conduct sufficient studies to demonstrate that their generic product is bioequivalent to Auryxia.

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, 2017, Baupost beneficially owns approximately 22% of our issued and outstanding common stock. If Baupost converts all of the convertible notes it holds into shares of our common stock, Baupost would beneficially

own approximately 39% of our issued and outstanding common stock. Baupost, through its equity interests, may have significant influence over matters submitted to our stockholders for approval and other corporate actions, such as:

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

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

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

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

In November 2016, we filed a registration statement on Form S-3 (No. 333-214513), which the 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. During the six months ended June 30, 2017, we sold 11,574,320 shares under the Sales Agreement for aggregate net proceeds of $73.1 million. The sales during the six months ended June 30, 2017 amounted to the initial $75.0 million issuable pursuant to the Sales Agreement. 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 three months ended September 30, 2017, we sold 362,854 shares under the Sales Agreement for aggregate net proceeds of $2.6 million. The initial $75.0 million of common stock issued pursuant to the Sales Agreement and the additional $75.0 million of common stock issuable pursuant to the Sales Agreement are included as part of the $250 million registered on the registration statement referred to above.

In October 2015, we raised $125 million through the private placement of Convertible Senior Notes, due 2020, with funds managed by Baupost. The zero-coupon notes will mature in October 2020 unless converted into shares of our common stock in accordance with their terms prior to such date. Keryx does not have the right to redeem the notes prior to maturity. The conversion price of the notes is equal to the $3.74 per share closing price of our common stock on the day prior to the issuance of the Notes in October, 2015, subject to certain adjustments under the terms of the notes.

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 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 or capital commitments 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. Our amended and restated bylaws prohibit our stockholders from acting by written consent and eliminate the right of stockholders to call a special meeting of stockholders, which could make it more difficult for stockholders to effect certain corporate actions. Any of these provisions could also have the effect of delaying or preventing a change in control.

ITEM 6. EXHIBITS

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

Exhibit Number	Exhibit Description
10.1!	Amended and Restated Sub-License Agreement, dated June 8, 2009, as amended by the First Amendment thereto, dated June 12, 2013, by and between Keryx Biopharmaceuticals, Inc., Japan Tobacco, Inc. and Torii Pharmaceutical Co., Ltd.
10.2!	Product Agreement, dated August 29, 2017, by and between Keryx Biopharmaceuticals, Inc. and Patheon Inc. (an affiliate of Patheon Manufacturing Services LLC) related to the Master Manufacturing Services Agreement by and between Keryx Biopharmaceuticals, Inc. and Patheon Manufacturing Services LLC and certain of its affiliates dated November 12, 2016.
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated November 6, 2017.
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 6, 2017.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated November 6, 2017.
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated November 6, 2017.
101	Interactive data files pursuant to Rule 405 of Regulation S-T: (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statements of Cash Flows, and (iv) the Notes to Condensed Consolidated Financial Statements.

! Confidential treatment has been granted or is being sought with respect to the omitted portions of this exhibit.

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 7, 2017

By: /s/ Scott A. Holmes

Scott A. Holmes
Chief Financial Officer
Principal Financial and Accounting Officer

AMENDED AND RESTATED SUBLICENSE AGREEMENT

THIS AMENDED AND RESTATED SUBLICENSE AGREEMENT (the "Agreement"), effective this 8th day of June, 2009 (the "Effective Date"), by and between KERYX BIOPHARMACEUTICALS, INC., with offices at 750 Lexington Avenue, 20th Floor, New York, NY 10022, U.S.A. ("Keryx" or "Sublicensor") and JAPAN TOBACCO INC., with offices at JT Building, 2-1, Toranomon 2-Chome, Minato-ku, Tokyo 105-8422, Japan ("JT") and TORII PHARMACEUTICAL CO., LTD., with offices at Torii Nihonbashi Bldg., 4-1, Nihonbashi-Honcho 3-chome, Chuo-ku, Tokyo 103-8439, Japan ("TORII") (JT and TORII collectively referred to herein as "Sublicensee");

WHEREAS, Sublicensor acquired an exclusive license under the Patent Rights and Know-How to sublicense, develop, have developed, make, have made, use, have used, offer to sell, sell, have sold, import and export the Product in the Sublicense Territory for all Indications (all capitalized terms as hereinafter defined) pursuant to (i) a License Agreement, dated as of November 7, 2005, which was amended and restated as of March 14, 2008, and further amended on November 14, 2008 (as amended, the "Panion License Agreement") by and between Sublicensor and Panion & BF Biotech, Inc. ("Panion") which, in turn, is based upon a Patent License Agreement, dated July 20, 2001 as amended pursuant to Amendment No. 1 thereto dated as of August 29, 2005 (the "Hsu License Agreement") between Dr. Chen Hsing Hsu ("Dr. Hsu") and Panion and (ii) an Exclusive License Agreement, dated as of November 7, 2005 (the "GloboAsia License Agreement") by and between Panion and GloboAsia, LLC ("GloboAsia");

WHEREAS, effective as of September 26, 2007 Sublicensor and Sublicensee entered into a Sublicense Agreement under which Sublicensee obtained an exclusive sublicense to the Compound and Product for all Indications in the Sublicense Territory;

WHEREAS, Sublicensee has received delivery of two Consent Documents and paid to Sublicensor initial license fee payments totaling $20,000,000;

WHEREAS, Sublicensee has initiated the first Phase II clinical trial in the Sublicense Territory and paid to Sublicensor the applicable milestone payment of three million dollars ($3,000,000);

WHEREAS, Sublicensor and Sublicensee now wish to amend and restate the Sublicense Agreement in its entirety on the terms and conditions set forth herein in order to reflect certain of the amended and restated terms in the Panion License Agreement; and

WHEREAS, Sublicensor has the authority and is willing to grant such a sublicense to Sublicensee and Sublicensee is willing to accept such sublicense from Sublicensor, under the terms and conditions set forth in this Agreement.

NOW THEREFORE, in consideration of the mutual promises and covenants set forth herein and other good and valuable consideration, the receipt of which is hereby acknowledged, the parties hereto agree as follows:

ARTICLE 1. DEFINITIONS

As used in this Agreement, the following terms, whether used in the singular or the plural, shall have the following meanings:

1.1 "Affiliate" means any corporation or non-corporate business entity, which controls, is controlled by, or is under common control with a party to this Agreement. A corporation or non-corporate business entity shall be regarded as in control of another corporation if it owns or directly or indirectly controls at least fifty-one percent (51%) of the voting stock of the other corporation, or (i) in the absence of the ownership of at least fifty-one percent (51%) of the voting stock of a corporation, or (ii) in the case of a non-corporate business entity, if it possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of the corporation or non-corporate business entity, as applicable. Notwithstanding the foregoing, the Government of Japan and other entities controlled by the Government of Japan (other than through Japan Tobacco Inc.) are not considered Affiliates of Sublicensee.

1.2 "Combination Product" means a Product containing one or more therapeutically active ingredients in addition to the Compound.

1.3 "Compound" means ferric citrate: $FeC_6H_5O_7 \cdot xH_2O$

1.4 Intentionally omitted.

1.5 Intentionally omitted.

1.6 "Follow-on Product" means products, other than the Product, which contain ferric ion as an active pharmaceutical ingredient for use, either alone, or in combination with one or more therapeutically active ingredients.

1.7 "Improvements" means any and all improvements, materials, technical data and information whether patented or unpatented, including but not limited to any changes to, or new therapeutic applications for, the Compound, the Product or in the Sublicensor Know-How or Sublicensee Know-How including, but not limited to any analogues, or derivatives of the Compound, and changes in the manufacturing process for the Compound or the Product which are conceived or reduced to practice during the term of this Agreement.

1.8 "Indication" means any therapeutic application for a Product that is covered by the Patent Rights.

1.9 "Initiation" means the administration of the first dose to the first patient in a clinical trial.

1.10 "Net Sales" with respect to any Product means the gross sales (i.e. gross invoice prices) of such Product billed by Sublicensee and its sublicensees, if any, to Third Party customers on all sales of a Product, and exclusive of inter-company transfer or sales, less the reasonable and customary deductions from such gross sales, including:

(a) actual credited allowances to such Third Party customers for spoiled, damaged, outdated and returned Product and for retroactive price reductions,

(b) the amounts of trade, cash discounts and rebates, to the extent such discounts and rebates were not deducted by Sublicensee at the time of invoice in order to arrive at the gross invoice prices,

(c) all transportation, handling charges and freight insurance, sales taxes, excise taxes, use taxes or import/export duties paid, and

(d) all other reasonable and customary allowances and adjustments actually credited to customers whether during the specific royalty period or not.

In the event that the Product(s) is sold as part of a Combination Product, the Net Sales of the Product(s), for the purposes of determining royalty payments, shall be determined by multiplying the Net Sales of Combination Product (as defined in the standard Net Sales definition) by the fraction, A / (A+B) where A is the weighted average sale price of the Product(s) when sold separately in finished form (as defined below), and B is the weighted average sale price of the other product(s) sold in the Sublicense Territory separately in finished form.

In the event that the weighted average sale price of the Product(s) can be determined but the weighted average sale price of the other product(s) in the Sublicense Territory cannot be determined, Net Sales for purposes of determining royalty payments shall be calculated by multiplying the Net Sales of the Combination Product by the fraction A / C where A is the weighted average sale price of the Product(s) when sold separately in finished form and C is the weighted average selling price of the Combination Product.

In the event that the weighted average sale price of the other product(s) in the Sublicense Territory can be determined but the weighted average sale price of the Product cannot be determined, Net Sales for purposes of determining royalty payments shall be calculated by multiplying the Net Sales of the Combination Product by the following formula: 1 – (B/C) where B is the weighted average sale price of the other product(s) when sold separately in finished form and C is the weighted average selling price of the Combination Product.

In the event that the weighted sale price of both the Product(s) and the other product(s) in the Combination Product in the Sublicense Territory cannot be determined, the Parties will attempt to agree on an appropriate weighted average sale price of both the Product(s) and the other product(s) in the Combination Product, and lacking such agreement the Net Sales of the Product(s) shall be deemed equal to fifty percent (50%) of the Net Sales of the Combination Product.

By way of example, the parties assume a Combination product "C" consisting of the Product "A" and the other product "B." When the weighted average sale prices in the Sublicense Territory of A, B and C are 50, 40 and 90, respectively, the parties agree that the fraction to be used for Net Sales calculation for determining royalty payments shall become as follows:

i) in case the "50" and "40" are known, 50/(50+40), i.e., 5/9;
ii) in case the "40" is unknown but "90" is known, 50/90, i.e., 5/9;
iii) in case the "50" is unknown but "90" is known, 1-40/90, i.e., 5/9; and
iv) in case none of those is known, 1/2 unless otherwise agreed between the parties.

The weighted average sale price for a Product, other product(s), or Combination Product shall be calculated once each calendar year and such price shall be used during all applicable royalty reporting periods for the entire calendar year. When determining the

weighted average sale price of a Product, other product(s), or Combination Product, the weighted average sale price shall be calculated by dividing the sales dollars (translated into U.S. Dollars) by the daily dose units of active ingredient sold during the twelve (12) months (or the number of months sold in a partial calendar year) for the respective Product(s), other product(s), or Combination Product. In the initial calendar year, a forecasted weighted average sale price will be used for Product(s), other product(s), or Combination Product. Any over or under payment due to a difference between forecasted and actual weighted average sale prices will be paid or credited in the first royalty payment of the following calendar year.

The Parties acknowledge that the foregoing determination for Net Sales of Combination Products may not be the same as the determination for Net Sales of Combination Products to be agreed upon between Sublicensor and Panion in accordance with the Panion License Agreement. Sublicensor agrees to use its commercially reasonable efforts to obtain Panion's agreement to adopt the terms of this Section 1.10 to calculate Net Sales of Combination Products and will keep Sublicensee informed of ongoing negotiations concerning the provisions for Combination Products with Panion. In the event Sublicensor and Panion agree upon a different determination, Sublicensor shall immediately seek Sublicensee's consent to amend this Section 1.10 to match such determination, which consent shall not be unreasonably withheld or delayed.

The sale of a Product solely for the research or clinical testing of such Product shall be excluded from the computation of Net Sales of such Product, provided that Sublicensee's sale of the Product was at cost, and such Product was used for research or clinical testing.

1.11 "Patent Rights" means the patents and patent applications set forth in **Exhibit 1**, all other patents and patent applications that are directed to the Compound or its manufacture or use and in which Sublicensor holds rights, including, without limitation, those patents and patent applications that are directed to Sublicensor's interest in Improvements, and any and all patents in which Sublicensor holds rights and that may issue from any of the foregoing patent applications, including any and all divisions, continuations, continuations-in-part, extensions, substitutions, renewals, registrations, supplementary protection certificates, revalidations, reissues or additions of or to any of the aforesaid patents and patent applications, and any additional patents or patent applications to which Sublicensor acquires rights, including rights to license, during the term of this Agreement which pertain in any way to the Compound or the Product or their manufacture or use.

1.12 "Product" means any pharmaceutical products that contain the Compound as a therapeutically active ingredient either alone or in combination with other active ingredients in any formulation or presentation.

1.13 "Proprietary Information" means all information, including without limitation all Sublicensee Know-How, Sublicensor Know-How, Sublicensee Development Data, Sublicensor Development Data and all other scientific, clinical, regulatory, marketing, financial and commercial information or data, whether communicated in writing, orally or electronically which is provided by one party to the other party in connection with this Agreement.

1.14 "Registration" in relation to any Product means such approvals by a Regulatory Authority in a country or community or association of countries as may be legally required before such Product may be commercialized in such country or community or association of countries.

1.15 "Regulatory Authority" means the Ministry of Health, Labor and Welfare of Japan (hereinafter referred to as the "MHLW") and any other applicable regulatory authority in the Sublicense Territory involved in granting regulatory approval for the Product.

1.16 "Sublicense Territory" means Japan.

1.17 "Sublicensee Development Data" means and includes all data relating to the Compound or the Product and all chemistry, manufacturing and control data relating to the development and manufacture of the Compound or the Product, results of pre-clinical and clinical studies and all other documentation containing or embodying any pre-clinical, clinical, chemistry, manufacturing and control data relating to any application for Registrations for a Product, including, but not limited to, documents submitted to the Regulatory Authority, which is generated or acquired by Sublicensee during the term of this Agreement.

1.18 "Sublicensee Know-How" means all information and materials, including but not limited to, discoveries, processes, instructions, formulas, data, inventions, know-how and trade secrets, patentable or otherwise, which arise out of the development, manufacture and commercialization by Sublicensee of the Compound or the Product, including, without limitation, Sublicensee Development Data and all biological, chemical, pharmacological, toxicological, pharmaceutical, physical, analytical, clinical, safety,

manufacturing and quality control data and information related thereto, and all applications, registrations, licenses authorizations, documents, approvals and correspondence relating to the Compound or the Product, including without limitation, correspondence submitted to Regulatory Authorities, and all information and data contained in Registrations. Sublicensee Know-How shall also include Sublicensee's interest in Improvements.

1.19 "Sublicensor Development Data" means and includes all data to which Sublicensor has rights relating to the Compound or the Product and all chemistry, manufacturing and control data relating to the development and manufacture of the Compound or the Product, results of pre-clinical and clinical studies and all other documentation containing or embodying any pre-clinical, clinical, chemistry, manufacturing and control data relating to any application for Registrations for the Product, including, but not limited to, documents submitted to the regulatory authorities outside the Sublicense Territory, whether such Sublicensor Development Data is in existence as of the Effective Date or is generated or acquired by Sublicensor during the term of this Agreement.

1.20 "Sublicensor Know-How" means all information and materials to which Sublicensor has rights, including but not limited to, discoveries, processes, formulas, instructions, data, inventions, know-how and trade secrets, patentable or otherwise, in each case, which as of September 26, 2007 and during the term of this Agreement are necessary or useful to Sublicensee in connection with the development, registration, manufacture, marketing, use or sale of a Product. Sublicensor Know-How shall also include without limitation, Sublicensor Development Data and all biological, chemical, pharmacological, toxicological, pharmaceutical, physical, analytical, clinical, safety, manufacturing and quality control data and information related thereto, and all applications, registrations, licenses, authorizations, documents, approvals and correspondence relating to a Compound or a Product. Sublicensor Know-How shall also include Sublicensor's interest in Improvements.

1.21 "Third Party" means any entity other than Sublicensor or Sublicensee or their respective Affiliates.

1.22 "Valid Claim" means a claim of an issued and unexpired patent included within the Patent Rights which has not been held unenforceable or invalid in the applicable jurisdiction by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been admitted to be invalid or unenforceable through dedication, disclaimer or otherwise.

ARTICLE 2. REPRESENTATIONS AND WARRANTIES

2.1 Mutual. Each party represents and warrants to the other party that it has the full right and authority to enter into this Agreement, and that, to the best of its knowledge, there are no prior agreements, commitments or other obstacles which could prevent it from carrying out all of its obligations hereunder.

2.2 Sublicensor. Sublicensor represents to Sublicensee that as of the date hereof:

(a) it is the exclusive licensee in the Sublicense Territory of the entire right, title and interest in and to the Patent Rights, and to the best of its knowledge, there are no charges, encumbrances, licenses, options, restrictions, liens, rights of others, disputes, proceedings or claims relating to, affecting, or limiting its rights or the rights of Sublicensee under this Agreement other than those included in provisions of the Panion License Agreement, the Hsu License Agreement and the GloboAsia License Agreement that have been previously disclosed to Sublicensee;

(b) it has the right, to enter into this Agreement and to grant the sublicense granted herein, and there is nothing in any Third Party agreement Sublicensor has directly or indirectly entered into as of the Effective Date, which in any way, will limit the ability of Sublicensor to perform any and all of the obligations undertaken by Sublicensor hereunder other than the provisions of the Panion License Agreement, the Hsu License Agreement and the GloboAsia License Agreement that have been previously disclosed to Sublicensee;

(c) there is no claim, pending or threatened, of infringement, interference or invalidity regarding any part or all of the Patent Rights and their use as contemplated in this Agreement, and it has no present knowledge from which it can be inferred that the Patent Rights are invalid or that their exercise would infringe the patent rights of any Third Party;

(d) it is a party to the Panion License Agreement, under which it acquired an exclusive license under the Patent Rights and Licensor Know-How (as defined in the Panion License Agreement) to sublicense, develop, have developed, make, have made,

use, have used, offer to sell, sell, have sold and import and export the Product in the Sublicense Territory for all Indications and that the Panion License Agreement remains valid and in effect and has not been amended nor has any provision thereof been waived and to its knowledge the Hsu License Agreement and GloboAsia License Agreement remain valid and in effect and have not been amended;

(e) there are no other patents owned or licensed by Sublicensor or its Affiliates, other than the Patent Rights, that would impair Sublicensee's ability to exercise its rights under this Sublicense Agreement and, to its knowledge, there are no other patents owned or licensed by Third Parties that would impair Sublicensee's ability to exercise its rights under this Sublicense Agreement;

(f) it will not enter into any agreement after the Effective Date which will limit its ability to perform any and all of the obligations undertaken by Sublicensor hereunder;

(g) neither this Agreement, nor, to its knowledge, any document or piece of Sublicensor Development Data, Sublicensor Know-How or Patent Rights contains any untrue statement of a material fact or omits to state a material fact necessary in order to make the statements contained herein or therein misleading; and

(h) to its knowledge, the Patent Rights, including, but not limited to, U.S. Patent No. 5,753,706 are valid and free from any lien or encumbrances.

2.3 Sublicensee. Sublicensee represents to Sublicensor that as of the date hereof:

(a) it has the right to enter into this Agreement and to its knowledge, there is nothing in any Third Party agreement Sublicensee has entered into as of the Effective Date, which in any way, will limit the ability of Sublicensee to perform any and all of the obligations undertaken by Sublicensee hereunder, and

(b) neither this Agreement, nor, to its knowledge, any document provided to Sublicensor in connection with the Agreement as of the Effective Date contains any untrue statement of a material fact or omits to state a material fact necessary in order to make the statements contained herein or therein misleading; and

(c) it will not enter into any agreement after the Effective Date which will limit its ability to perform any and all of the obligations undertaken by Sublicensee hereunder.

ARTICLE 3. LICENSE GRANT AND GOVERNANCE

3.1 Grant. Subject to the terms and conditions of this Agreement, Sublicensor hereby grants to Sublicensee an exclusive sublicense, with the right to further sublicense to its Affiliates, to develop, have developed, make, have made, use, have used, offer to sell, sell, have sold, and import and export the Product or the Compound in the Sublicense Territory and to make, manufacture, have made and have manufactured outside the Sublicense Territory under the Sublicensor Know-How, and the Patent Rights for all Indications.

3.2 Sublicensing. Sublicensee shall be entitled to sublicense to Third Parties the right to manufacture the Product or the Compound, provided such Third Party manufacturers are permitted to sell only to Sublicensee or their Affiliates. Except as expressly permitted under Sections 3.1 and 3.2, Sublicensee may not grant further sublicenses under this Agreement without the written consent of Sublicensor, which consent shall not be unreasonably withheld or delayed. For the avoidance of doubt, Sublicensor and Sublicensee agree that this Section does not apply to Third Party distributors and that Sublicensee may contract with Third Party distributors without the written consent of Sublicensor.

3.3 Retained Rights. The grant of licenses under Section 3.1 shall not preclude Sublicensor from utilizing the Patent Rights and Sublicensor Know-How, and any Improvements related thereto, for the purpose of carrying out development and commercialization activities relating to the Product in connection with Sublicensor's rights outside of the Sublicense Territory, provided, however, that Sublicensor shall not sell and shall cause its Affiliates and its sublicensees not to sell Compound or Product to customers outside the Sublicense Territory which Sublicensor, its Affiliate or its sublicensee knows, or has reason to know, plan to resell for use in the Sublicense Territory. In addition, Sublicensor will not conduct clinical trials of the Compound or Product in the Sublicense Territory except upon the prior written consent of Sublicensee.

3.4 Sublicense Territory. Other than as permitted by this Article 3, Sublicensee shall not develop, manufacture, sell, use, offer for sale or import any Product or Compound outside of the Sublicense Territory, without the prior written consent of Sublicensor, which Sublicensor may grant or withhold in its sole discretion. Sublicensee shall not sell and shall cause its Affiliates and its sublicensees not to sell Compound or Product to customers in the Sublicense Territory which Sublicensee, its Affiliate or its sublicensee knows, or has reason to know, plan to resell for use outside the Sublicense Territory.

3.5 Territories without Patent Protection. Nothing in this Agreement precludes Sublicensee from developing, manufacturing, selling, using, offering for sale or importing Product in territories where Patent Rights do not exist or have already expired in their entirety. Notwithstanding the foregoing, Sublicensee shall not be entitled to use Proprietary Information solely owned by Sublicensor outside of the Sublicense Territory other than to make, manufacture, have made or have manufactured the Product outside the Sublicense Territory for sale within the Sublicense Territory.

3.6 Joint Steering Committee. To coordinate the activities under this Agreement, the parties will form a Joint Steering Committee (the "JSC"). The JSC will meet on a schedule to be determined by parties, but not less than twice yearly, and will be responsible for generally sharing information regarding the activities of the parties and shall include, without limitation, (a) review of non-clinical and toxicology programs to maximize the potential for use in multiple territories, (b) periodic updates on the status of the clinical development program and sharing of pharmacovigilance information, (c) review of marketing plans and sales forecasts and the coordination of activities at international conferences, (d) coordination of marketing activities that have an international component, including medical education and promotion, and (e) determining cost allocation for joint activities.

Sublicensor and Sublicensee shall each appoint one of its members as a JSC co-chair ("JSC Co-Chair"). Sublicensor's JSC Co-Chair shall be chairperson of all the JSC meetings. The JSC Co-Chairs shall be jointly responsible for preparing the meeting agenda, and Sublicensor's JSC Co-Chair shall be responsible for preparing the first draft of the minutes from such meeting. JSC meeting minutes shall be distributed in draft form to the members of the JSC not later than thirty (30) days following each JSC meeting, and shall be deemed accepted and effective unless the other party's JSC Co-Chair has objected to the same in writing within thirty (30) days of its receipt of such minutes. Final minutes of each JSC meeting shall be promptly distributed to the parties. Each party shall bear its own personnel and travel costs and expenses relating to JSC meetings.

As of the Effective Date, the parties agree that participation on, and any duties associated with, the JSC shall be voluntary, and no penalty under this Agreement shall apply for non-participation.

3.7 Joint Development Team. The parties will form a Joint Development Team (the "JDT"). The JDT will meet on a schedule to be determined by the parties but not less than twice yearly and will be responsible for facilitating the exchange of preclinical data, clinical data, information, materials and results between Sublicensor and Sublicensee and for consulting on the regulatory development of Product in the Sublicense Territory, including regulatory filings relating to manufacture of Product for the Sublicense Territory and consultation as to changes in specifications or other changes for Product in the Sublicense Territory.

As of the Effective Date, the parties agree that participation on, and any duties associated with, the JDT shall be voluntary, and no penalty under this Agreement shall apply for non-participation.

3.8 Alliance Managers. Each party shall designate one (1) alliance manager (the "Alliance Manager"). One of the JSC Co-Chairs or JDT Co-Chairs may also serve as the Alliance Manager of the party. The Alliance Managers will manage and oversee operational activities in connection with this Agreement, and will serve as the contact persons concerning on-going operations under this Agreement. The Alliance Managers shall promote effective communication between the parties and coordination of the parties activities and responsibilities in furtherance of the development and commercialization of Product in the Sublicense Territory.

3.9 Committee Decision and Dispute Resolution. Sublicensee shall be solely responsible for making final decisions arising out of the JSC, JDT or such other committee(s) as may be established ("Other Committee(s)"). Notwithstanding the foregoing, in the event that Sublicensor has a commercially reasonable belief that action to be taken by Sublicensee is reasonably likely to have a material adverse impact on its activities, or the activities of its sublicensees, outside the Sublicense Territory, Sublicensor shall notify Sublicensee of such belief. In case Sublicensee disagrees with such belief by Sublicensor, and the JSC, JDT or Other Committee fails to reach unanimous agreement on such a matter and that disagreement cannot be resolved within a period of fifteen (15) business days following the meeting of the JSC, JDT or Other Committee, the matter shall be referred to the Chief Executive Officer of Keryx and to the President of the JT Pharmaceutical Division for discussion and, if not resolved in such manner, shall be subject to Arbitration

pursuant to Article 19.

ARTICLE 4. LICENSE FEE; MILESTONE PAYMENTS

4.1 *Intentionally omitted.*

4.2 Milestone Payments. Sublicensee will pay to Sublicensor non-refundable, one-time milestone payments as follows:

(a) Intentionally omitted.

(b) Within thirty (30) days following Initiation of the first Phase III clinical trial in the Sublicense Territory: five million dollars ($5,000,000);

(c) Within thirty (30) days following filing of a first marketing approval application to MHLW in the Sublicense Territory: seven million dollars ($7,000,000); and

(d) Within thirty (30) days following a first marketing approval by MHLW for a Product in the Sublicense Territory: ten million dollars ($10,000,000).

For the purpose of this Agreement, a Phase II clinical trial shall mean that portion of the Regulatory Authority submission and approval process which provides for the initial trials of Product on a limited number of patients for the purposes of determining dose and evaluating safety and efficacy in the proposed therapeutic indication and a principal purpose of which is to demonstrate a proof of concept, and a Phase III clinical trial shall mean that portion of the Regulatory Authority submission and approval process which provides for the expanded trials of Product on a large number of patients for the purposes of evaluation of the overall benefit-risk relationship and long-term safety of the proposed therapeutic indication.

4.3 Sales Milestone Payments. Sublicensee will pay to Sublicensor the following non-refundable, one-time milestone payments as follows:

(a) Within sixty (60) days following attainment of annual Net Sales in Japan equal to******;

(b) Within sixty (60) days following attainment of annual Net Sales in Japan equal to******;

(c) Within sixty (60) days following attainment of annual Net Sales in Japan equal to******.

For purposes of this Section 4.3, annual Net Sales shall be calculated on a calendar year basis. Nothing herein shall preclude multiple milestone payments from being paid in a given 12-month period if multiple milestones have been reached.

4.4 Limitations. It is understood and agreed that Sublicensee shall pay the milestone payments set forth in Sections 4.2 and 4.3 only with respect to the first Indication for which a Product achieves a particular milestone event, and regardless of the number of Products which achieve a particular milestone event and regardless of the number of times which a particular milestone event is achieved.

4.5 Payment Method. All payments of license fees and milestones under this Article 4 shall be made by wire transfer in the United States currency to a designated bank account of Sublicensor.

ARTICLE 5. ROYALTIES

5.1 Royalties. In consideration of the sublicense rights granted to Sublicensee hereunder, for each Product where the manufacture, use or sale of such Product would but for the license granted hereunder, infringe a Valid Claim, Sublicensee shall pay to Sublicensor a royalty on their respective Net Sales, as follows:

(a) a royalty of ****** of annual Net Sales equal to or less ******;

(b) a royalty of ****** of annual Net Sales between ******;

(c) a royalty of ****** of annual Net Sales in excess of ******.

For purposes of this Section 5.1, royalties shall be calculated based on total Net Sales in any given calendar year. By way of example, if in a given calendar year Net Sales were forty (40) billion Japanese Yen, then the amount of royalty owed for that year would be ****** (calculated as the sum of ****** x ****** plus ****** x ****** plus ****** x ******). Notwithstanding the foregoing, in the event (i) the Panion License Agreement expires before the termination or expiration of this Agreement and Sublicensor is no longer required to pay royalties to Panion under the Panion License Agreement, the applicable royalty percentage to be paid by Sublicensee to Sublicensor under clauses (a), (b) and (c) of this Section 5.1 shall be reduced to ******, ****** and ******, respectively, or (ii) subject to Section 16.3, the Panion License Agreement is terminated before the termination or expiration of this Agreement, the royalties and other amounts to be paid by Sublicensee to Sublicensor shall be reduced by all royalties and other amounts payable directly by Sublicensee to Panion.

5.2 Accrual of Royalties. No royalty shall be payable on a Product made, sold, or used for research or clinical testing purposes or distributed as samples, provided such samples are sold by Sublicensee at cost. No multiple royalty shall be payable because the manufacture, use, or sale of a Product is covered by more than one Valid Claim.

5.3 Royalty Withheld due to Invalid Claims. In the event that all applicable claims of a patent included within the Patent Rights under which Sublicensee is paying a royalty according to Section 5.1 shall be held invalid or unenforceable by a court of competent jurisdiction in the Sublicense Territory, Sublicensee may withhold payments of royalties which would otherwise have been due on Net Sales in the Sublicense Territory by reason of Sections 4.3 and 5.1 until such judgment shall be finally reviewed by an unappealed or unappealable decree of a higher court of competent jurisdiction in the Sublicense Territory. The Sublicensee shall promptly repay Sublicensor any withheld royalty payments upon a final adjudication that the applicable claims of a patent included within the Patent Rights under which Sublicensee is paying a royalty under Section 5.1 are valid and enforceable. For clarification, the aforementioned withheld royalty shall not bear any interest thereon.

5.4 Compulsory Licenses. If Sublicensee is caused to grant a compulsory license to any Third Party with respect to a Product in the Sublicense Territory, then the royalty rate to be paid by Sublicensee on Net Sales due on such Product in that country under Section 5.1 shall be reduced to the rate paid by such Third Party compulsory Sublicensee on such Product.

5.5 Third Party Royalties. Sublicensor shall be responsible for payment of Third Party royalties owed on sales of Product in the Sublicense Territory with respect to any issued patent or patent application that has been published by the applicable patent office anywhere in the world prior to and including the date that is two (2) years after September 26, 2007 that are required to secure Freedom to Operate in the Sublicense Territory. For the purposes of this Agreement, "Freedom to Operate" shall mean such valid patents that, but for a license, would be infringed by the development, manufacture, use or sale of a Product for the Indication. With respect to patents or patent applications that are published by the applicable patent office anywhere in the world more than two (2) years after September 26, 2007 that are required to secure Freedom to Operate in the Sublicense Territory, then (a) if a license to such patent is limited to the Sublicense Territory, then Sublicensor and Sublicensee shall each be responsible for ****** of such license fees and royalty obligations; and (b) if a license to such patent includes countries outside the Sublicense Territory, then Sublicensor shall be responsible for ****** of such license fees and royalty obligations and Sublicensee shall be responsible for ****** of such license fees and royalty obligations. Notwithstanding the foregoing, Sublicensor's obligation to pay Third Party royalties, including, without limitation, royalties owed to Panion, shall not exceed the sales milestone payments and royalties to which Sublicensor is entitled under Sections 4.3 and 5.1 of this Agreement

5.6 Withholding Tax. If any payment due to Sublicensor hereunder is subject to withholding taxes or similar governmental charge ("Withholding Tax") required to be paid or withheld thereon by applicable law in Japan, then Sublicensee shall deduct such Withholding Tax from such payment due Sublicensor hereunder at a rate not to exceed the then-prevailing rate provided for in applicable provisions of the Conventions between the Governments of the United States and Japan for the Avoidance of Double Taxation and the Evasion of Taxes (the "Convention"). Sublicensee shall provide Sublicensor, as soon as possible, a certificate evidencing withholding or payment of any such Withholding Tax by Sublicensee, its Affiliates or its sublicensees for the benefit of Sublicensor. The parties understand as of September 26, 2007 that under the provisions of the current Convention, payments to Sublicensor under this Agreement are not subject to withholding, provided that Sublicensor provide Sublicensee with appropriate certificates of residency as required by Japanese law.

ARTICLE 6. ROYALTY REPORTS AND ACCOUNTING

6.1 Royalty Reports and Currency Conversion. Beginning with the First Commercial Sale by Sublicensee of a Product in the

Sublicense Territory, and continuing thereafter during the term of this Agreement, Sublicensee shall furnish to Sublicensor a written report covering each calendar quarter (the "Reporting Period") showing (a) the calculation of Net Sales of each Product in the Sublicense Territory during the Reporting Period; (b) the royalties, payable in United States Dollars, which shall have accrued hereunder in respect of such sales with a summary computation of such royalties; (c) withholding taxes, if any required by law to be deducted in respect of such sales; and (d) the exchange rates used in determining the amount of United States Dollars payable. Royalty reports shall be submitted to Sublicensor within forty-five (45) days after the close of each Reporting Period. Net Sales and royalties payable shall be expressed in both Japanese Yen and the United States Dollars equivalent, calculated using the simple average of the exchange rate published in the Wall Street Journal on the last day of each month of the Reporting Period. Sublicensee shall furnish to Sublicensor appropriate evidence of payment of, and itemize any tax, credits or specific amount deducted from any royalty payment.

6.2 Royalty Payments and Records. Royalty payments shall be made by wire transfer in United States currency to a designated bank account of Sublicensor in the United States and shall be due forty-five (45) days after the close of each Reporting Period. Payment of royalties in whole or in part may be made in advance of such due date. In case no royalty is due for any given Reporting Period, Sublicensee shall so report to Sublicensor. Sublicensee shall keep accurate records for a period of at least three (3) years in sufficient detail to enable the royalty payable hereunder to be determined and confirmed.

6.3 Right to Audit. Upon written request of Sublicensor, but not more than once in each calendar year, Sublicensee shall permit an independent public accountant, selected by Sublicensor or Panion and acceptable to Sublicensee, which acceptance shall not be unreasonably withheld, to have access during normal business hours to those records of Sublicensee as may be reasonably necessary to verify the accuracy of the royalty reports hereunder in respect of any calendar year ending not more than thirty-six (36) months prior to the date of such request. The report prepared by such independent public accountant, a copy of which promptly shall be provided to Sublicensee, shall disclose only the amount of any underpayment or overpayment of royalties, if any, without disclosure of or reference to supporting documentation. If such independent accountant's report shows any underpayment of royalties, Sublicensee shall remit to Sublicensor the amount of such underpayment within thirty (30) days after Sublicensee's receipt of such report, and if such underpayment exceeds five percent (5%) of the royalty due, Sublicensee shall reimburse Sublicensor for its reasonable out-of-pocket expenses for the audit, upon submission of supporting documentation. Any overpayment of royalties shall be creditable against future royalties payable in subsequent royalty periods, allocated evenly over the next-following two (2) royalty periods. In the event this Agreement is terminated or expires before such overpayment is fully credited, Sublicensor shall pay Sublicensee the portion of such overpayment not credited within one hundred twenty (120) days after the date of such termination or expiration.

6.4 Confidentiality of Records. Sublicensor agrees that all information subject to review under Section 6.3 shall be deemed the Proprietary Information of Sublicensee.

6.5 Late Payment Interest. Royalties and other payments required to be paid by Sublicensee pursuant to this Agreement shall, if overdue, bear interest at the rate equal to two percent (2%) over the prime rate as quoted by Citibank NA and not to exceed ten percent (10%) per annum until paid. The payment of such interest shall not preclude Sublicensor from exercising any other rights it may have because any payment is overdue.

ARTICLE 7. CLINICAL, PRE-CLINICAL, REGULATORY AND COMMERCIAL DEVELOPMENT

7.1 Clinical and Pre-Clinical Development Program. Sublicensee will have sole responsibility for the clinical development of the Product in the Sublicense Territory, and shall be solely responsible for all costs associated therewith. Sublicensee will have final decision-making authority to decide the protocols for all clinical and pre-clinical studies to be conducted by Sublicensee to support the approval of the Product in the Sublicense Territory. Notwithstanding the foregoing, Sublicensee shall consult with Sublicensor regarding protocol design for all clinical and pre-clinical studies. Sublicensee shall use commercially reasonable best efforts (a) to conduct a clinical development program directed to obtaining regulatory approval of the Product in the Sublicense Territory (the "Development Program"), and (b) if, in the opinion of Sublicensee, the results of the Development Program so justify, to diligently seek regulatory and pricing approval for such Product for such Indication. For purposes of this Section, "commercially reasonable best efforts" shall mean efforts and timelines consistent with those used by Sublicensee in its own priority development projects with its own products deemed to have high commercial potential. Preliminary timelines are attached hereto as **Exhibit 2** and shall be subject to

adjustment in consultation with the JDC. Notwithstanding anything herein contained to the contrary, in the event the results of two toxicity studies conducted by Sublicensee, that is, i) A 6-Month Oral (Dietary) Toxicity Study in Rats with a 1-Month Recovery Period and ii) A 42-Week Oral (Dietary) Toxicity Study in Dogs with a 60-Day Recovery Period (collectively, the "Long-Term Toxicity Studies") is sufficient to meet Sublicensor's long-term toxicology needs, as accepted by FDA, Sublicensor shall reimburse JT for one-half (1/2) of the costs of the Long-Term Toxicity Studies or for one-half (1/2) of any portion of the Long-Term Toxicity Studies accepted by FDA as satisfying such toxicology requirements.

7.2 Carcinogenicity Studies. The parties will discuss in good faith potential arrangements for a carcinogenicity study, including, without limitation, potential cost-sharing mechanisms.

7.3 Regulatory Matters.

7.3.1 Assistance by Sublicensor. Sublicensor shall assist Sublicensee as follows:

(a) At any time during the term of this Agreement and as soon as practical, Sublicensor shall make available to Sublicensee all Sublicensor Know-How in the possession of Sublicensor, and shall cooperate with and provide reasonable assistance to Sublicensee in its evaluation of such Sublicensor Know-How. On a continuing basis during the term of this Agreement, Sublicensor shall make available to Sublicensee all additional Sublicensor Know-How generated, acquired or possessed by Sublicensor or any Third Party on behalf of Sublicensor. Sublicensor shall provide Sublicensee with a right of reference to all such Sublicensor Know-How and Sublicensee shall have the right to include such Sublicensor Know-How in any of its applications for Registrations. All such Sublicensor Know-How shall be deemed the Proprietary Information of Sublicensor, and all right, title and interest in and to such Sublicensor Know-How shall remain vested in Sublicensor.

(b) In the event that Sublicensor receives any inquiries or notices from any Regulatory Authority which may affect the development and marketing of a Product in the Sublicense Territory, Sublicensor shall immediately notify Sublicensee. Sublicensor agrees to assist Sublicensee in formulating a response to such inquiries, including being available to meet with the Regulatory Authority at a time and place acceptable to Sublicensor. Sublicensee shall reimburse Sublicensor for its reasonable expenses incurred in rendering such assistance, upon presentation by Sublicensor of an invoice documenting such expenses.

In the event that Sublicensee receives any inquiries or notices from any Regulatory Authority which may affect the development and marketing of a Product in the Sublicense Territory, Sublicensee shall immediately notify Sublicensor. Sublicensor agrees to assist Sublicensee in formulating a response to such inquiries, including being available to meet with the Regulatory Authority at a time and place acceptable to Sublicensee.

7.3.2 Assistance by Sublicensee.

(a) On a continuing basis during the term of this Agreement, Sublicensee shall make available to Sublicensor all Sublicensee Development Data generated by Sublicensee or any Third Party on behalf of Sublicensee. Sublicensee shall provide Sublicensor with a right of reference to all such Sublicensee Development Data and Sublicensor shall have the right to include such Sublicensee Development Data in any of its applications for Registrations outside of the Sublicense Territory. All such Sublicensee Development Data shall be deemed the Proprietary Information of Sublicensee, and all right, title and interest in and to such Sublicensee Development Data shall remain vested in Sublicensee.

(b) In the event that Sublicensee receives any inquiries from any Regulatory Authority which may affect the development and marketing of a Product outside of the Sublicense Territory, Sublicensee shall immediately notify Sublicensor. Sublicensee agrees to assist Sublicensor in formulating a response to such inquiries, including being available to meet with the Regulatory Authority at a time and place acceptable to Sublicensee, if necessary. Sublicensor shall reimburse Sublicensee for its reasonable expenses incurred in rendering such assistance, upon presentation by Sublicensee of an invoice documenting such expenses.

7.3.3 Registrations. Subject to the terms and conditions of this Agreement, each application for Registration shall be filed in the name of Sublicensee or a designated Affiliate or sublicensee. Sublicensee shall own all right, title and interest in and to all applications for Registrations and granted Registrations. Sublicensee shall be responsible for all disclosures and correspondence to and with the Regulatory Authorities, and all disclosures and correspondence with any Regulatory Authority in the Sublicense Territory

involving Sublicensor shall be made through Sublicensee. Sublicensee shall keep Sublicensor advised of the status of all Registrations and any applications for Registration.

7.3.4 Exchange of Safety Information. The Parties shall exchange safety information as per ICH guidelines so that each party can meet their regulatory requirements. The parties agree that a detailed agreement with respect to the exchange of safety data is to be entered into separately. Sublicensor shall, at its own cost and expense, assemble, maintain, deploy and make available to Sublicensee a database on any and all information on all serious adverse events including those collected from its existing and future sublicensees, Sublicensee and Panion.

7.4 Commercial Matters. Subject to the provisions of Section 3.9, Sublicensee shall have sole responsibility for all activities and costs associated with marketing, advertising, promoting and selling the Products in the Sublicense Territory. Sublicensee shall use its commercially reasonable efforts to market and sell the Product in the Sublicense Territory, in order to maximize Net Sales. Without limiting Sublicensee's commercially reasonable efforts obligation under this Section 7.4, Sublicensee shall (a) apply for all required authorizations, including pricing and reimbursement, from Regulatory Authorities in the Sublicense Territory as soon as reasonably and commercially practicable following completion of all appropriate clinical trials; and (b) make the first commercial sale of the Product in the Sublicense Territory as soon as reasonably and commercially practicable following the issuance of the marketing authorizations required for the manufacturing, distribution, marketing, sale and use of the Product in the Sublicense Territory and the completion of NHI (National Health Insurance) price listing.

7.5 Intentionally Omitted.

7.6 Progress Reports. Within thirty (30) days of the close of each calendar quarter, Sublicensee shall provide to Sublicensor a written report of Sublicensee's progress and activities in meeting Sublicensee's obligations under this Article 7 ("Progress Report"). Progress Reports shall be in writing, and shall set forth, in reasonable detail, relevant information including (i) the status of clinical development programs for any Product; (ii) the status of regulatory approvals in the Sublicense Territory concerning Products; (iii) the status of other manufacturing, development and/or commercial activities regarding Products, including, without limitation, names of Third Party distributors; and (iv) any potential new Indications or line extensions. Sublicensee shall promptly supplement or clarify such Progress Reports, upon Sublicensor's reasonable request.

ARTICLE 8. PATENTS AND IMPROVEMENTS

8.1 Patent Prosecution and Maintenance. For the purpose of securing for the benefit to Sublicensee the Patent Rights in the Sublicense Territory, Sublicensor shall maintain the bridge between Panion, Dr. Hsu and GloboAsia and Sublicensee by: (i) promptly passing along to Sublicensee any and all copies of relevant materials received from Panion, Dr. Hsu and GloboAsia with respect to prosecution and maintenance of the Patent Rights in the Sublicense Territory; and (ii) promptly passing along back to Panion, Dr. Hsu and GloboAsia any and all comments, opinions, requests, suggestions and so forth received from Sublicensee. Sublicensor shall also promptly pass along to Sublicensee any relevant rights obtained from Panion, Dr. Hsu or GloboAsia with respect to prosecution and maintenance of Patent Rights in the Sublicense Territory. Notwithstanding the foregoing, Sublicensee may make direct contact with Panion, Dr. Hsu and GloboAsia upon written consent by Keryx, which consent shall not be unreasonably withheld or delayed, and provide to Sublicensor in a timely manner i) summaries of meetings held with Panion, Dr. Hsu or GloboAsia, as the case may be, without the presence of Sublicensor's employees or representatives, and ii) copies of relevant documents exchanged with Panion, Dr. Hsu or GloboAsia, as the case may be, without being copied to Sublicensor. Sublicensor shall obtain from Panion, Dr. Hsu and GloboAsia the authority in the Sublicense Territory for Sublicensee to prosecute or to cause the prosecution of the patent applications that are enumerated in Exhibit 1 of this Agreement, to obtain patents thereon and to maintain patents, including any correction trials and invalidation trials, included in the Patent Rights in effect during the term of this Agreement using outside patent counsel, selected by Sublicensee, that is agreed upon by Sublicensor and Panion, which agreement shall not be unreasonably withheld or delayed by Sublicensor. Sublicensee shall be solely responsible for said prosecution of the patent applications that are enumerated in Exhibit 1 of this Agreement, to obtain patents thereon and to maintain patents, including any correction trials and invalidation trials, included in the Patent Rights in effect during the term of this Agreement using outside patent counsel that is mutually agreed upon by Sublicensor and Sublicensee. Sublicensor and Sublicensee agree as of the Effective Date that Albert Wai-Kit Chan, Esq. is acceptable. Sublicensee shall be solely responsible for all costs and expenses relating to such patent applications and patents. Sublicensor shall make reasonably appropriate arrangements to enable Sublicensee to: (i) obtain registration under the name of Sublicensee in the Sublicense Territory of the exclusive license granted to Sublicensee under Section 3.1 of this Agreement as a "*Senyo Jisshiken*" in accordance

with Article 77 of the Japanese Patent Law within sixty (60) days after issuance or registration of the relevant patents, and (ii) fully secure Sublicensee's right as a primary licensee in the Sublicense Territory until said registration of "*Senyo Jisshiken*." Sublicensee shall keep Sublicensor advised of the status of all patent applications and patents relating to the Patent Rights by providing Sublicensor with copies of such patent applications and patents and copies of all patent office correspondence relating thereto including any office actions received by Sublicensee and responses or other papers filed by Sublicensee. Sublicensee specifically agrees to provide Sublicensor with copies of patent office correspondence in sufficient time for Sublicensor to review and comment on such correspondence and submit to Sublicensee any proposed response thereto. Sublicensee further agrees to provide Sublicensor with sufficient time and opportunity, but in no event less than ten (10) days, to review and comment on all proposed responses to patent office correspondence relating to such patent applications and patents. Sublicensor agrees that all final decisions regarding the preparation and prosecution of such patent applications and patents, reissues, reexaminations, interferences and oppositions relating thereto shall be made by Sublicensee. Notwithstanding the foregoing, in the event of a decision regarding a Significant Event, Sublicensee will provide Sublicensor with notice of such Significant Event and Sublicensor shall have thirty (30) working days in which to assent or refuse to assent to such action, with such assent not to be unreasonably withheld. For purposes of this Section 8.1, "Significant Event" shall mean abandonment of an application, the filing of divisional or continuation applications, or a significant narrowing of the scope of patent application claims. Sublicensee shall have the right in its sole discretion, to discontinue the prosecution of any such patent applications or the maintenance of any such patents, and Sublicensor shall have the right to assume responsibility for the prosecution of such patent applications or the maintenance of such patents at its own expense. If Sublicensee elects not to prosecute, and Sublicensor elects not to assume, any such patent applications or not to maintain any such patents in the Sublicense Territory, Sublicensee's license rights and its obligations under this Agreement, with respect to such patent applications and patents in the Sublicense Territory shall terminate, without affecting its license rights and other obligations to pay with respect to any other patent applications or patents included in the Patent Rights. After the Effective Date of this Agreement, in the event Exhibit 1 of the Panion License Agreement is amended to add additional patents related to the Compound ("Additional Patents"), the parties shall amend Exhibit 1 hereof to add such Additional Patents. Upon the written amendment of Exhibit 1, such additional Patents shall be prosecuted and maintained in accordance with the provisions of this Section 8.1.

8.2 Improvements and Use of Development Data.

(a) Each party shall notify the other party promptly of any sole or joint inventions directed to Improvements under such party's control. As between the parties, Sublicensee shall own all right, title and interest in and to Improvements invented solely by Sublicensee's employees or contractors and Sublicensor shall own all right, title and interest in and to Improvements invented solely by Sublicensor's employees or contractors. Patent applications and patents directed to jointly invented Improvements shall be jointly assigned to and owned by Sublicensee and Sublicensor. Subject to the provisions of Article 12 with respect to Follow-on Products, during the term of this Agreement, i) in the Sublicense Territory, to such extent as granted to Sublicensee under Section 3.1 Sublicensee shall have the liberty to freely practice Improvements, or license to any third party in connection with a sublicense to sell Products, provided that such sublicensees agree to share any Improvements with Sublicensor and Sublicensee, and ii) outside the Sublicense Territory, the Sublicensor shall have the liberty to freely practice Improvements, or license to any third party in connection with a sublicense to sell Products, provided that such sublicensees agree to share any Improvements with Sublicensor and Sublicensee. In the event of a termination of this Agreement by Sublicensor for breach by Sublicensee or by Sublicensee in the absence of a breach by Sublicensor, then Sublicensor's rights under this Section 8.2 related to Improvements shall survive but Sublicensee's rights shall be terminated and Sublicensor shall have a perpetual, exclusive, royalty-free, sublicensable license for the purpose of commercialization of Product to any patented Improvements solely or jointly invented by Sublicensee. If this Agreement is terminated by Sublicensee for breach by Sublicensor, then Sublicensor may continue to have the rights set forth herein to non-patented Improvements outside the Sublicense Territory without any consideration therefor and shall have the option to acquire a license for the use outside the Sublicense Territory of patented Improvements that were solely invented by Sublicensee at a royalty rate of ****** of net sales of the relevant products which, but for the license, would infringe a valid patent owned by Sublicensee. Upon expiration of this Agreement, Sublicensor may continue to have the rights set forth herein to non-patented and jointly-invented Improvements outside the Sublicense Territory without any consideration therefor and shall have the option to acquire an exclusive, except as to Sublicensee, license for the use outside the Sublicense Territory of patented Improvements which were solely invented by Sublicensee at a royalty rate of ****** of net sales of the relevant products which, but for the license, would infringe a valid patent owned by Sublicensee. The formula for calculating net sales for Sublicensor's products under this Section 8.2(a) shall be consistent with the provisions of Section 1.10 of this Agreement.

(b) During the term of this Agreement, for patent applications and patents relating to Improvements invented solely by Sublicensor, the provisions of Section 8.1 shall apply.

(c) Following expiration or termination of this Agreement, Sublicensor shall be solely responsible, at its sole discretion and expense, for preparing, filing, prosecuting and maintaining in such countries where it deems appropriate, patent applications and patents relating to Improvements invented solely by Sublicensor and for conducting interference, re-examination, reissue and opposition proceedings relating to such patent applications and patents.

(d) During the term of this Agreement, Sublicensee shall be responsible, in its sole discretion, for preparing, filing, prosecuting and maintaining in the Sublicense Territory, patent applications and patents relating to Improvements invented solely by Sublicensee or jointly by Sublicensee and Sublicensor. In case of Improvements invented jointly by Sublicensee and Sublicensor, the costs necessary for preparation, filing, prosecution and maintenance of the Improvements shall be equally borne by Sublicensor and Sublicensee. Notwithstanding the foregoing, if Sublicensee elects (after consultation with Sublicensor) not to prosecute, or to discontinue the prosecution of any patent applications concerning joint Improvements, or to discontinue the maintenance of any patents or patent applications concerning joint Improvements, then (i) Sublicensor shall have the right to assume the full responsibility for the prosecution of such patent applications or the maintenance of such patents and patent applications at its own cost and expense, (ii) Sublicensee shall assign its interest in such patents and patent applications to Sublicensor, and (iii) such patents and patent applications shall no longer be subject to this Agreement.

(e) Following expiration or termination of this Agreement, Sublicensee shall be solely responsible, in its sole discretion and expense, for preparing, filing, prosecuting and maintaining in such countries where it deems appropriate, patent applications and patents relating to Improvements invented solely by Sublicensee and for conducting interference, re-examination, reissue and opposition proceedings relating to such patent applications and patents.

(f) Following expiration or termination of this Agreement, the parties shall be jointly responsible for preparing, filing, prosecuting and maintaining in such countries where the parties jointly agree, patent applications and patents relating to Improvements jointly invented by the parties and for conducting interference, re-examination, reissue and opposition proceedings relating to such patent applications and patents. The parties shall jointly bear all costs relating thereto. If one party elects to discontinue the prosecution of any patent applications and patents filed pursuant to this Section 8.2(f), or not to conduct any further activities with respect to such patent applications or patents, the party electing to discontinue any such activities shall assign to the other party all right, title and interest in and to such patents or patent applications. The party electing to continue such activities shall be solely responsible for all costs relating to such activities.

8.3 Trademarks. Sublicensee shall be responsible for obtaining and maintaining a trademark of its choice in the Sublicense Territory at its sole expense. Sublicensee shall own such trademark. Sublicensee shall submit its proposed trademark to the JSC for approval, which approval shall not be unreasonably withheld or delayed.

ARTICLE 9. INFRINGEMENT

9.1 Infringement by a Third Party. In the event that either party becomes aware that a Compound or a Product being made, used or sold by a Third Party infringes the Patent Rights licensed hereunder, such party shall promptly advise the other party of all known facts and circumstances relating thereto. To the extent of their respective ability under Japanese law, Panion (on behalf of itself and Dr. Hsu) and Sublicensor shall have the first and second right, respectively, to enforce at its sole expense the Patent Rights licensed under this Agreement against infringement by Third Parties. Sublicensee shall reasonably cooperate in any such enforcement and, if necessary, join as a party therein, at the expense of Sublicensor. Sublicensor shall have the right to retain ****** of the proceeds of any such enforcement action. Notwithstanding the foregoing, Sublicensee shall have the right to enforce against infringement by Third Parties of the Patent Rights licensed hereunder, in the event that neither Panion (on behalf of itself and Dr. Hsu) nor Sublicensor exercise its right. Sublicensor shall make all necessary arrangements with Panion, Dr. Hsu and GloboAsia for Sublicensee to take actions against infringement by Third Parties of the Patent Rights licensed hereunder.

9.2 Infringement by Sublicensee. In the event that it is determined by any court of competent jurisdiction that the import, manufacture, use or sale of any Product or Compound by Sublicensee or its sublicensees in accordance with the terms and conditions of this Agreement infringes, or Sublicensee and Sublicensor reasonably determine and agree that the import, manufacture, use or sale

of such Product or Compound is likely to infringe, a Third Party patent or related intellectual property right in the Sublicense Territory, Sublicensee shall in consultation with Sublicensor use its reasonable best efforts to: (i) procure at Sublicensor's expense a license from such Third Party authorizing Sublicensee to continue to import, manufacture, use or sell such Product or Compound; or (ii) modify such Product or Compound or its manufacture so as to render it non-infringing.

9.3 In the event that neither of the foregoing alternatives is reasonably available or commercially feasible, Sublicensee may at its option (i) either cease the import, manufacture, use and sale of such Product or Compound for so long as and to the extent that such activities are infringing the relevant Third Party patents, in which case the obligation of Sublicensee hereunder to pay royalties shall also cease, or (ii) terminate the rights and licenses granted in the Sublicense Territory in which the infringement of Third Party patents has occurred or is likely to occur, in which case the obligation of Sublicensee hereunder to pay royalties shall also terminate in the Sublicense Territory. With regard to damages caused to Sublicensee by a Third Party patent or related intellectual property right for which Sublicensor would otherwise have been solely responsible for payment of royalties under Section 5.5, Section 14.2 will apply.

ARTICLE 10. MANUFACTURE & SUPPLY

10.1 Supply for Sublicensee's pre-clinical and clinical activities.

10.1.1 Supply. As of September 26, 2007, and until the date on which Sublicensee establishes its own supply of Product, whether through Sublicensee's manufacture or through a Direct Supply Agreement with a Third Party as provided in Section 10.2.3 (such end date of Sublicensor's obligation to supply Product shall be hereinafter referred to as the "Supply End Date"), Sublicensor agrees to supply Sublicensee necessary quantities of Compound, formulated Compound (interim product) (if any) and/or Product for Sublicensee's use in preclinical studies and clinical studies ("Development Supplies") in the Sublicensee Territory. As of the Effective Date, Sublicensor and Sublicensee agree that the Supply End Date has occurred and Sublicensee has established a direct supply contract with a Third Party contractor Sublicensor may obtain Development Supplies from its Third Party contract manufacturers ("Third Party Manufacturers") that are then manufacturing Compound, formulated Compound (interim product) (if any) and/or Product for Sublicensor's or its other licensees' use in its non-clinical studies or clinical trials of the Product outside the Sublicensee Territory. Development Supplies provided to Sublicensee shall be manufactured in the same formulation and to the same specifications as the Compound and/or Product such Third Party Manufacturers are supplying to Sublicensor or its other licensees for use in pre-clinical studies or clinical trials in the United States as of September 26, 2007 or such subsequent date as may be specified by Sublicensee unless Sublicensee agrees otherwise in writing.

10.1.2 Purchase Price. The purchase price Sublicensee shall pay Sublicensor for Development Supplies shall be ****** for such Development Supplies provided to Sublicensee in accordance with this Article 10, ****** incurred by Sublicensor directly in connection with the provision of such Development Supplies (including, e.g., cost of Sublicensor staffing necessary to organize such supplies, insurance and taxes, if any), without mark-up by Sublicensor. Where possible, Sublicensor shall organize production of Development Supplier in a manner to minimize staffing costs which must be transmitted to Sublicensee. Sublicensor further agrees that it will disclose in advance to Sublicensee details of such cost and that such cost shall be subject to Sublicensee's approval, which shall not be unreasonably withheld or delayed. Sublicensor shall submit an invoice to Sublicensee therefor, and Sublicensee shall pay Sublicensor within thirty (30) days of its receipt of each such invoice.

10.1.3 Quantity and Schedule for Delivery of Development Supplies. Sublicensee shall present to Sublicensor in writing, at least quarterly, its requirements for Development Supplies for Sublicensee's pre-clinical and clinical development activities sufficiently in advance of initiating pre-clinical or clinical studies. Sublicensor will evaluate, using commercially reasonable efforts, its capability and the capability of its Third Party Suppliers to supply the Development Supplies to Sublicensee in accordance with the requested quantities and schedule. Thereupon, the Sublicensor will provide to Sublicensee a written commitment schedule to supply the requested Development Supplies to Sublicensee. Sublicensee shall not sell any portion of Development Supplies provided by Sublicensor under this Section 10.1 to any Third Party for any purpose. If there are any additional terms and conditions reasonably necessary for the provision of Development Supplies by Sublicensor or its Affiliates to Sublicensee for pre-clinical and clinical development activities in accordance with the pre-clinical and clinical development plan of Sublicensee and this Section 10.1, the Parties shall discuss and agree upon them as soon as reasonably practicable, consistent with this Section 10.1.

10.1.4 Sublicensor's Further Obligations. For Development Supplies, Sublicensor or its Affiliates shall provide (or cause its Third Party Manufacturer to provide) Sublicensee with the following:

(a) specifications of intermediates, as appropriate, and Compound, and testing methods and certificates of analysis ("COA") for the intermediates, as appropriate, and Compound;

(b) specifications of formulated Compound (interim product) (if any) or Product, and testing methods and COAs for the formulated Compound (interim product) (if any) or Product;

(c) specifications of excipients (if any), packaging materials, and testing methods and COAs for the excipients (if any), packaging materials used for formulated Compound (interim product) (if any) or Product;

(d) certificate of manufacturing ("COM") or certificate of compliance ("COC") for intermediates, as appropriate, and Compound;

(e) COC for formulated Compound (interim product) (if any) and/or Product;

(f) batch records for both intermediates, Compound, formulated Compound (interim product) (if any) and Product; and

(g) TSE certificate of Compound and excipients (including capsule shell).

In connection with Development Supplies provided by Sublicensor or its Affiliates to Sublicensee, one or more separate quality agreements ("Quality Agreement(s)") shall, upon Sublicensee's request, be negotiated in good faith and entered into by the Parties. Any such Quality Agreement(s) shall be subject to and governed by this Article 10 and this Agreement, and shall contain customary terms pertaining to the Parties' obligations with respect to cGMP production, release and/or distribution of Product. The quality departments of Sublicensee and Sublicensor shall collaboratively prepare such Quality Agreement(s) within such time period as reasonably requested by Sublicensee. Sublicensor acknowledges that Sublicensee has a right to conduct or have a Third Party conduct quality tests of Development Supplies to verify that the Development Supplies (including their active ingredients) conform to GLP or GMP (as applicable) standards or other quality standards and is authorized to disclose Sublicensor Know-How to such Third Party to the extent necessary for such purpose.

10.1.5 Delivery. All Development Supplies provided by Sublicensor shall be deemed to be delivered to Sublicensee at the point where Sublicensor delivers such Development Supplies to the carrier selected by Sublicensee (which shall be the Third Party Manufacturer's facility or Sublicensor's location), and the title and risk thereto shall be simultaneously transferred to Sublicensee. Sublicensee shall be responsible for all costs of transportation, freight, insurance, customs and import formalities pertaining to shipment of Development Supplies to Sublicensee.

10.1.6 Specification. Specifications for Development Supplies to be delivered pursuant to this Section 10.1 and (if applicable) the Quality Agreement(s) shall be those approved and utilized by Sublicensor and presented to the JDT. To the extent that Sublicensee desires to obtain Development Supplies that are manufactured in accordance with different specifications, Sublicensee may choose to be solely responsible for securing such Development Supplies (from Sublicensor's Third Party Manufacturer or otherwise). Development Supplies shall be provided to Sublicensee along with a COC, relevant batch records and a COA for each shipment.

The parties shall duly review and discuss all specifications and CMC controls to define the Japanese regulatory requirements for Development Supplies with the goal of ensuring that they are fully-compliant with such requirements for each stage of Pharmaceutical Development ("CMC Requirements"). Once the Parties have agreed on such CMC Requirements, which agreement shall not be unreasonably withheld or delayed, Sublicensor will make reasonable efforts, to the extent possible within existing technical and commercial constraints, to ensure Development Supplies prepared for Sublicensee meet such CMC Requirements. In no event will Sublicensor deliberately prepare Development Supplies which do not meet such requirements or ship such to Sublicensee without Sublicensee's express written consent. In the event Development Supplies prepared for Sublicensee do not meet the CMC Requirements, Sublicensor will notify Sublicensee within two business days of such knowledge and the Parties will jointly review and discuss the appropriate course of action.

10.1.7 Audit of facilities by Sublicensee. At any time during clinical development in the Sublicensee Territory, Sublicensee (or its designee) shall have the right to audit facilities that manufacture any of the Development Supplies as well as storage or testing facilities for them. Sublicensor shall cooperate and cause each Third Party Manufacturer and/or testing facility to cooperate with Sublicensee (or its designee) for such audit.

10.1.8 Audit of facilities by Regulatory Authority. If Regulatory Authority requests an inspection or audit of Sublicensor's or its Third Party Manufacturer's facility and Sublicensee with regard to the intermediates, Compound or Product (including a manufacturing, storage or testing facility for each) anywhere in the world, Sublicensor shall use good faith efforts to cooperate with Sublicensee and Regulatory Authority in fulfilling such request (and, if applicable, shall use good faith efforts to cause its Third Party Manufacturer to cooperate with Regulatory Authority and Sublicensee in fulfilling such requested inspection or audit). Following receipt of the inspection or audit observations of the Regulatory Authority (a copy of which Sublicensor shall promptly provide to Sublicensee), Sublicensor shall use good faith and reasonable efforts to consult with Sublicensee and prepare the response to any such observations, in English.

10.2 Transfer of Manufacturing Technology. The Parties jointly acknowledge that the activities which are the subject of this Section 10.2 are complex, time-consuming, and require good communication to execute successfully in a timely manner. Accordingly, at the time Sublicensee invokes any of these parts, the parties may form a Manufacturing Steering Team to plan and execute the activities. The reasonable commercial efforts of Sublicensor cannot make up for lack of adequate planning, task definition, and advance notice. It is agreed that the Manufacturing Steering Team meetings shall be held quarterly and its activities shall be governed by Section 3.6.

10.2.1 Transfer by Sublicensor. At any time during the Term of the Agreement, upon reasonable request by Sublicensee (through the Alliance Managers), Sublicensor shall provide to Sublicensee copies of written documentation pertaining to manufacturing technologies, but only to the extent that such documentation is necessary for Sublicensee (i) to conduct its pre-clinical and clinical development activities or (ii) to make arrangements for supply of Compound, formulated Compound (interim product) (if any) and/or Product for Sublicensee's use in Phase III clinical trials, and commercialization of Product in the Sublicensee Territory. Manufacturing technologies shall include methods of synthesis, manufacturing, testing, analysis and formulation of intermediates, Compound, formulated Compound (interim product) (if any) or Product, as well as the following items, to the extent controlled by Sublicensor:

(a) Methods for testing compliance with the specifications for intermediates, Compound, and additional test methods for stability studies for the intermediates, Compound;

(b) Test Methods for the specifications for formulated Compound (interim product) (if any) or Product, and additional test methods for stability studies for them;

(c) Manufacturing method (including in-process test methods) of Compound, formulated Compound (interim product) (if any) and finished Product;

(d) Specifications or other information regarding intermediates, Compound, formulated Compound (interim product) (if any) or Product, or starting materials, intermediates, reagents, therefor (which shall be provided to Sublicensee by Sublicensor or its Affiliates or, to the extent practicable, through Third Party Manufactures or Third Party suppliers of such starting materials, intermediates, or reagents); and

(e) any other matters related to manufacturing or storage to be agreed on by the parties.

In addition, Sublicensor or its Affiliates shall, upon Sublicensee's reasonable request, provide up to sixty (60) hours of hands-on training at Sublicensor's or its Third Party Manufacturer's facility by qualified Sublicensor or its Third Party Manufacturers' technicians without charge, and thereafter, upon Sublicensor's agreement to provide additional hours of hands-on training at Sublicensor's or its Third Party Manufacturer's facility, Sublicensor shall provide up to fifty (50) additional hours of such training for which Sublicensee shall pay Sublicensor's qualified technicians at a rate to be agreed, based on industry standard, by the Parties, negotiating in good faith. Upon the request for training, the Parties shall jointly approve a plan for training including timing, objectives, and activities. Sublicensor shall use reasonable commercial efforts to ensure the training is completed in accordance with the objectives and timing formulated by the Parties. Upon Sublicensee's reasonable request, Sublicensor also shall use good faith efforts to facilitate an interaction between Sublicensee and Sublicensor's Third Party Manufacturers or other Third Party suppliers which have supplied or are now supplying starting materials to Sublicensor, its other licensees or its Third Party Manufacturers, to aid Sublicensee in obtaining information regarding intermediates, Compound, formulated Compound (interim product) (if any) or Product or starting materials, intermediates, and reagents therefor.

10.2.2 Quality Agreements with Third Party Suppliers. Sublicensor and Sublicensee acknowledge that, pursuant to the

Japanese Pharmaceutical Affairs Law, certain quality agreements are required to be entered into among Sublicensee and each direct or indirect supplier of intermediates, Compound, formulated Compound (interim product) (if any) and Product (each such agreement, a "Third Party Quality Agreement"), and that such Third Party Quality Agreement is required to enable Sublicensee to directly control quality matters with respect to intermediates, Compound, formulated Compound (interim product) (if any) and Product. The Parties also acknowledge that each such Third Party Quality Agreement shall be filed with Regulatory Authority at the time of the filing of the market approval for finished Product in the Sublicensee Territory. For this purpose, upon request of Sublicensee, Sublicensor shall use good faith efforts to reasonably cooperate with Sublicensee, and to cause each Third Party Manufacturer or supplier to cooperate with Sublicensee, in Sublicensee's efforts to enter into such Third Party Quality Agreements with such Third Party(ies) in a timely manner.

10.2.3 Direct Supply Agreement with Third Party Manufacturers.

(a) At any time during the period when Sublicensor or its Affiliates is providing Development Supplies to Sublicensee, and until Sublicensee has a direct supply contract with Third Party contractors, upon reasonable request by Sublicensee, Sublicensor agrees to use good faith and reasonable efforts to (i) facilitate Sublicensee's efforts to enter into supply agreements with Sublicensor's or its Affiliates' Third Party Manufacturers or other Third Party suppliers of intermediates, Compound, formulated Compound (interim product) (if any) or Product or starting materials, intermediates, or reagents for Development or commercial supply purposes ("Direct Supply Agreements"); and (ii) in connection with such Direct Supply Agreements, cooperate with Sublicensee to provide Sublicensee with reasonable access to pertinent manufacture technologies that are necessary for manufacturing intermediates, Compound, formulated Compound (interim product) (if any) and/or Product, including the information specified in clauses (a) through (g) of Section 10.1.4.

(b) Sublicensor grants Sublicensee and its sublicensees the exclusive right, without any restrictions, to manufacture (and have manufactured) the active pharmaceutical ingredient for purposes of developing and supplying the same solely in the Sublicensee Territory, provided that Sublicensee and its sublicensees shall bear all costs associated with such production. Sublicensee shall pay to Sublicensor a fee (the "Manufacturing Fee") equal to seven and one half percent (7.5%) of the manufacturing and procurement cost of all batches of active pharmaceutical ingredient that are manufactured by or on behalf of Sublicensee or its sublicensees, except for when those manufactured batches are for commercial use by Sublicensee or its sublicensees in which case the Manufacturing Fee shall not apply. Sublicensee shall provide to Sublicensor copies of all invoices for such manufacture and procurement of active pharmaceutical ingredient that are manufactured by or on behalf of Sublicensee or its sublicensees where the Manufacturing Fee applies at the same time that Sublicensee provides its Progress Reports. The parties herby confirm and agree that said seven and one half percent (7.5%) Manufacturing Fee shall be retroactively applied to Development Supplies manufactured by a Third Party Manufacturer for and on behalf of Sublicensee under direct contract between such Third Party Manufacturer and Sublicensee on or after November 14, 2008.

(c) It shall be the responsibility of Sublicensee to ensure that the quality of intermediates, Compound, formulated Compound (interim product) (if any) and/or Product in the Sublicense Territory is in compliance with the standards of the applicable Regulatory Authority.

10.2.4 Accreditation. Sublicensor and Sublicensee acknowledge that, pursuant to the Japanese Pharmaceutical Affairs Law, each foreign manufacturer of medical products with respect to each supplier of intermediates, Compound, formulated Compound (interim product) (if any) and/or Product, including any test or storage facility, for commercial supply is required to be accredited as of the time when Sublicensee files a marketing approval for Product in the Sublicensee Territory. In order to obtain such accreditation, Sublicensor shall use good faith efforts to cooperate reasonably with Sublicensee in causing each Third Party Manufacturer to apply to Regulatory Authority by themselves or having Sublicensee apply on their behalf at least six (6) months prior to Sublicensee's anticipated date for the filing of a marketing approval in Japan.

10.3 Further Discussion. Sublicensor shall, in the event it wishes to be supplied with the Compound and/or the Product from Sublicensee and/or its Third Party Manufacturers, enter into discussion with Sublicensee thereon. In case Sublicensee agrees to supply to Sublicensor said Compound and/or Product, then the Sections 10.1 and 10.2 hereinabove shall apply *mutatis mutandis*.

ARTICLE 11. NON-COMPETITION

11.1 Ferric Ion Products. During the Term of this Agreement, Sublicensee shall not develop, make, have made, use, have

used, offer to sell, sell, have sold, import or export a product containing ferric ion as the sole active pharmaceutical ingredient, other than the Product or a Combination Product, for the treatment of hyperphosphatemia in the Sublicense Territory.

11.2 Other Competing Products. For a period of ****** from first commercial launch of a Product in the Sublicense Territory, Sublicensee shall not offer to sell, sell, or have sold a product, other than the Product or a Combination Product, for the treatment of hyperphosphatemia in the Sublicense Territory. Nothing in this Section 11.2 shall prevent Sublicensee from engaging in research and development activities for such a product in anticipation of marketing and selling after expiration of the ****** period. Further, nothing in this Section 11.2 shall relieve Sublicensee of their obligations under Article 7 to diligently advance the development and commercialization of Products in the Sublicense Territory.

ARTICLE 12. FOLLOW-ON PRODUCTS

12.1 Follow-on Products. For a period of ****** from September 26, 2007, Sublicensee will have a right of first negotiation to any Follow-on Products which Sublicensor develops or otherwise obtains rights to as follows: (i) Following completion of the first Phase II clinical study of such Follow-on Product, Sublicensor shall describe the Follow-on Product in writing in reasonable detail, and such description shall be protected as Proprietary Information under this Agreement (a "Confidential Disclosure"); (ii) Sublicensor shall provide the Confidential Disclosure to Sublicensee; and (iii) during the period commencing upon Sublicensee's receipt of the Confidential Disclosure and expiring ****** days thereafter (the "Discussion Period"), the parties shall discuss in good faith a license and commercialization agreement with respect to the Follow-on Product in the Sublicense Territory. If the parties do not reach agreement during the Discussion Period, then the Right of First Negotiation shall expire, and Sublicensor shall be free to exploit the Follow-on Product on its own, or to market the Follow-on Product to others, on terms no less favorable to Sublicensor than the final terms offered by Sublicensor. In the event Sublicensor receives an offer from any Third Party to license or commercialize the Follow-on Products (an "Outside Offer"), Sublicensor shall promptly so notify to Sublicensee before accepting or rejecting such Third Party offer.

12.2 ther Compounds in the Field of Nephrology. For a period of ****** from September 26, 2007, in the event that Sublicensor (a) acquires, licenses, obtains licenses, or develops a compound for use in the field of nephrology; and (b) is considering a development and/or marketing partner or licensee in the Sublicense Territory, then Sublicensor and Sublicensee shall meet (before or at substantially the same time as Sublicensor meets with other potential partners) to discuss in good faith the possibility of collaborating in connection with such compound in the Sublicense Territory.

ARTICLE 13. PRICING

13.1 Pricing. Sublicensee shall be solely responsible for establishing the price for Products in the Sublicense Territory.

13.2 Unexpected Events. The parties acknowledge that the economic provisions of this Agreement may be affected by unexpected decisions made by pricing authorities in the Sublicense Territory. In the event that unexpected decisions by the pricing authority causes Sublicensee to have difficulties in continuing development of or marketing Product from economic or commercial point of view such as, (a) a determination by the NHI to set the price for Product in the Sublicense Territory by reference to Caltan (calcium carbonate); or (b) the authority forces drastic price cuts for Phosphate Binders; or (c) the authority applies flat-sum reimbursement to the treatment of dialysis including Phosphate Binders, then the parties agree to meet in good faith to discuss and to determine appropriate adjustments to this Agreement to address the unexpected events, including consideration of any future milestone and royalty obligations contained in Articles 4 and 5. In the event that, after due discussion and consideration under this Section 13.2, Sublicensee determines that it is no longer economically viable to commercialize the Product, then such a decision not to, or to cease, commercialization shall be considered a termination by Sublicensee for purposes of this Agreement and the provisions of Article 16 shall apply

ARTICLE 14. INDEMNIFICATION

14.1 Indemnification by Sublicensee. Sublicensee agrees to indemnify and hold Sublicensor, its directors, officers, employees and agents harmless from and against any liabilities or damages or expenses in connection therewith (including reasonable attorneys' fees and costs and other expenses of litigation) (collectively "Claims") resulting from (i) any willful misrepresentation of a material fact or breach of warranty by Sublicensee under this Agreement; (ii) any Claim by Third Parties (other than Claims related to Third Party

patent or other intellectual property rights in the Sublicense Territory or Claims that are the subject of indemnification by Sublicensor under Section 14.2) arising out of the exercise of Sublicensee's rights under this Agreement or the failure of Sublicensee to perform the activities described in Section 3.1 in compliance with all applicable laws, rules and regulations, applicable product specifications and handling and storage protocols, common practices in the pharmaceutical industry, or requirements of this Agreement, the Clinical Supply Agreement or Commercial Supply Agreement; (iii) Sublicensee's gross negligence or willful misconduct (or that of its Affiliates, sublicensees, third-party contractors or distributors); and (iv) the enforcement by Sublicensor of its indemnification rights against Sublicensee under clause (ii) of this Section 14.1.

14.2 Indemnification by Sublicensor. Sublicensor hereby agrees to indemnify and hold Sublicensee and its officers, directors, employees and agents harmless from and against any liabilities or damages or expenses in connection therewith (including reasonable attorneys' fees and costs and other expenses of litigation) resulting from (i) any willful misrepresentation of a material fact or breach of warranty by Sublicensor under this Agreement; (ii) manufacture of Compound by Sublicensor or its Affiliate(s) or its Third Party contractor(s), for Sublicensee's development activities not in compliance with the agreed specifications therefor; (iii) the development, testing, manufacture, commercialization, use, handling or distribution by or on behalf of Sublicensor or Sublicensor's other sublicensee(s) of the Compound or Product outside the Sublicense Territory, including the administration of Compound or Product to humans and any product liability Claim arising therefrom (other than a Claim that is the subject of indemnification by Sublicensee under Section 14.1(i) or (iii)); (iv) any Claim arising from the Inherent Nature of the Product; (v) Sublicensor's gross negligence or willful misconduct (or that of its Affiliates, sublicensees, third-party contractors or distributors); and (vi) the enforcement by Sublicensee of its indemnification rights under this Section 14.2. For purposes of this Article 14, the term "Inherent Nature of the Product" means bodily injury caused solely by a design defect in the molecular or chemical structure of the Compound and not caused in whole or in part by other factors, including, without limitation, manufacture, testing, warning, advertising, sale, marketing, packaging, alteration or modification, labeling, instructions or promotion of the Product, whether that claim is based in tort, contract, fraud or any other theory.

14.3 Unknown Source Product Liability. Notwithstanding the foregoing, Sublicensor and Sublicensee shall equally share all losses arising from Unknown Source Product Liability in the Sublicense Territory. As used in this Section 14.3, "Unknown Source Product Liability" shall mean any portion of any Third Party claim for product liability that does not arise from: (i) Sublicensee's failure to perform the activities described in Section 3.1 in compliance with all applicable laws, rules and regulations, applicable product specifications and handling and storage protocols, common practices in the pharmaceutical industry, or requirements of this Agreement, the Clinical Supply Agreement or Commercial Supply Agreement; (ii) Sublicensee's gross negligence, or willful misconduct (or that of its Affiliates, sublicensees, third-party contractors or distributors); or (iii) the Inherent Nature of the Product

14.4 Indemnification Procedures. Each indemnified party shall promptly notify the indemnifying party in writing of any action, claim or liability in respect of which the indemnified party intends to claim indemnification from the indemnifying party. The indemnified party shall permit the indemnifying party, at its discretion, to settle any such action, claim or liability, and agrees to the complete control of such defense or settlement by the indemnifying party, provided however, that such settlement does not adversely affect the rights of the indemnified party hereunder or impose any obligations on the indemnified party in addition to those set forth herein in order for it to exercise such rights. No such action, claim or liability shall be settled by the indemnified party without the prior written consent of the indemnifying party, which consent shall not be unreasonably withheld or delayed, and the indemnifying party shall not be responsible for any legal fees or other costs incurred by the indemnified party other than as provided herein. The indemnified party and its directors, officers, employees and agents shall cooperate fully with the indemnifying party and its legal representatives in the investigation and defense of any action, claim or liability covered by this indemnification, and shall have the right, but not the obligation, to be represented by counsel of their own selection and at their own expense.

14.5 Limitation of Liability. Notwithstanding anything to the contrary herein, (i) neither party shall be liable to the other party for any indirect, incidental or consequential damages arising out of any terms or conditions in this Agreement or with respect to the performance hereof; and (ii) Sublicensor's obligation to indemnify Sublicensee for claims arising from the Inherent Nature of the Product pursuant to Section 14.2(iv) and Unknown Source Product Liability pursuant to Section 14.3 shall not exceed the aggregate sum of ******.

14.6 Survival of Representations and Warranties. The representations and warranties contained in this Agreement shall survive the expiration or termination of this Agreement and shall remain in full force and effect.

ARTICLE 15. CONFIDENTIALITY

15.1 Treatment of Proprietary Information. Except as otherwise provided in this Article 15, during the term of this Agreement and for a period of five (5) years following expiration or termination thereof, a party (the "Receiving Party") will retain in confidence and use only for purposes of this Agreement Proprietary Information supplied by or on behalf of the other party (the "Disclosing Party"). For purposes of this Article 15, all such Proprietary Information which a Receiving Party is obligated to retain in confidence shall be disclosed in written form and marked "Confidential" or with similar designation, or if originally disclosed visually or orally, reduced to such written form within thirty (30) days of such original disclosure.

15.2 Right to Disclose. To the extent it is reasonably necessary or appropriate to fulfill its obligations or exercise its rights under this Agreement or any rights which survive termination or expiration hereof, a Receiving Party may disclose Proprietary Information to its Affiliates, Sublicensees, consultants, agents, outside contractors and clinical investigators (collectively the "Representatives") on condition that such Representatives agree (i) to keep the Proprietary Information confidential for at least the same time periods and to the same extent as such party is required to keep the Proprietary Information confidential and (ii) to use the Proprietary Information only for such purposes as the Receiving Party is entitled to use the Proprietary Information. Each party warrants that each of its Representatives to whom any Proprietary Information is disclosed shall previously have been informed of the confidential nature of the Proprietary Information and shall have agreed to be bound by the terms and conditions of confidentiality as set forth in this Agreement. The Receiving Party shall ensure that the Proprietary Information provided by the Disclosing Party shall not be used or disclosed by such Representatives except as permitted by this Agreement. The Receiving Party shall stand responsible for any breach by its Representatives of the confidentiality provisions set forth in this Agreement.

15.3 Release From Restrictions. The obligation not to disclose Proprietary Information shall not apply to any part of such Proprietary Information which:

(i) is or becomes patented, published or otherwise part of the public domain other than by the unauthorized acts of the Receiving Party or its Affiliates or Sublicensees in contravention of this Agreement; or

(ii) is disclosed to the Receiving Party by a Third Party which did not obtain such Proprietary Information directly or indirectly from the Disclosing Party; or

(iii) prior to disclosure under this Agreement, was already in the possession of the Receiving Party as evidenced by its written records, provided such Proprietary Information was not obtained, directly or indirectly, from the Disclosing Party; or

(iv) is developed by the Receiving Party independent of Proprietary Information received from the Disclosing Party as evidenced by its written records.

15.4 Public Domain. For the purpose of this Agreement, specific information disclosed as part of the Proprietary Information shall not be deemed to be in the public domain or in the prior possession of the Receiving Party merely because it is embraced by more general information in the public domain or by more general information in the prior possession of the Receiving Party.

15.5 Ownership of Proprietary Information. Except as otherwise agreed to hereunder, all Proprietary Information disclosed by the Disclosing Party shall remain the property of the Disclosing Party. In cases where return of Proprietary Information is requested according to Article 16 hereunder, upon the written request of the Disclosing Party (i) all tangible Proprietary Information provided by the Disclosing Party (including, but not limited to all copies thereof) except for Proprietary Information consisting of analyses, studies and other documents prepared by or for the benefit of the Receiving Party shall be promptly returned to the Disclosing Party, and (ii) all portions of such analyses, studies and other documents not prepared by or for the benefit of the Receiving Party (including all copies thereof and all unused samples of materials provided by the Disclosing Party) which are within the definition of Proprietary Information shall be destroyed, and the Receiving Party shall certify such destruction in writing to the Disclosing Party. Notwithstanding the foregoing, the Receiving Party may retain one copy of the Proprietary Information of the Disclosing Party in its legal department for the sole purpose of determining its obligations hereunder.

15.6 Legal Disclosure. The Receiving Party may disclose the Proprietary Information of the Disclosing Party to the extent reasonably necessary in prosecuting or defending litigation, complying with applicable laws, governmental regulations or court order, or otherwise submitting required information to tax or other governmental authorities. If the Receiving Party intends to so disclose any

such Proprietary Information, the Receiving Party shall provide the Disclosing Party prompt prior notice of such fact so that the Disclosing Party may seek to obtain a protective order or other appropriate remedy concerning any disclosure of such Proprietary Information. The Receiving Party will reasonably cooperate with the Disclosing Party in connection with the Disclosing Party's efforts to obtain any such order or other remedy. If any such order or other remedy does not fully preclude the disclosure of such Proprietary Information, the Receiving Party will make such disclosure only to the extent that such disclosure is legally required and will use its reasonable efforts to have confidential treatment accorded to the disclosed Proprietary Information.

15.7 No Title. Except as otherwise expressly set forth in this Agreement, nothing herein shall be construed as giving the Receiving Party any right, title and interest in and to the Proprietary Information of the Disclosing Party.

15.8 Permitted Disclosures.

15.8.1 Disclosure by Sublicensee. Notwithstanding the foregoing, subject to review and comment by Sublicensor, Sublicensee may disclose Sublicensor Proprietary Information to the extent such disclosure is reasonably necessary for (a) the development of the Compound or the Product, (b) the filing of applications for Registration, (c) the commercialization of the Compound or the Product, or (d) the filing or prosecution of a patent applications and patents relating to Improvements invented solely by Sublicensee or jointly by Sublicensee and Sublicensor.

15.8.2 Disclosure by Sublicensor. Notwithstanding the foregoing, subject to review and comment by Sublicensee, Sublicensor may disclose Sublicensee Proprietary Information to the extent such disclosure is reasonably necessary for the filing or prosecution of patent applications and patents relating to Improvements invented solely by Sublicensor.

15.9 Publications. Neither Party shall submit or present any written or oral publication, any manuscript, abstract or other communication which includes data or other information related to the Compound or the Products or the Proprietary Information of the other Party without first obtaining the prior written consent of the other Party.

ARTICLE 16. TERM AND TERMINATION

16.1 Term. Unless terminated sooner as provided herein, this Agreement will expire on the last day to expire of the licensed Patent Rights containing a Valid Claim that, but for the license granted by Sublicensor to Sublicensee hereunder, would be directly infringed by the use or usage of Products as permitted in this Agreement, including any period of regulatory exclusivity or patent term extension. Upon expiration or termination of this Agreement, the rights and obligation of the parties shall cease, except as follows:

(i) following expiration, Sublicensee shall have a fully paid non-exclusive license under Sublicensor Know-How to make, have made, use, have used, offer to sell, sell and import the Product in the Sublicensee Territory;

(ii) upon expiration or termination by either party for any reason, the rights and obligations under Articles 2, 6, 10, 14, 15, 16, 19 and 26 and the applicable provisions of Section 8. 2;

(iii) expiration or termination of this Agreement shall not relieve either party of any obligations which accrued to that party prior to such expiration or termination for any reason;

(iv) any cause of action or remedy for breach shall survive the expiration or termination of this Agreement.

16.2 Termination by Sublicensee.

16.2.1 Termination Without Cause. Sublicensee may terminate this Agreement without cause at any time upon at least sixty (60) days prior written notice to Sublicensor if termination occurs prior to the receipt of marketing authorization for the Product in the Sublicense Territory and upon at least six (6) months prior written notice to Sublicensor if termination occurs following receipt of marketing authorization for the Product in the Sublicense Territory.

16.2.2 Termination for Breach. Sublicensee may terminate this Agreement upon or after the breach of any material provision of this Agreement by Sublicensor if such breach is not cured within sixty (60) days after Sublicensee gives Sublicensor written notice thereof.

16.2.3 Termination for Insolvency. Sublicensee may terminate this Agreement in its entirety for cause upon at least

sixty (60) days prior written notice to Sublicensor upon or after the bankruptcy, insolvency, dissolution or winding up of Sublicensor other than for the purpose of reconstruction or amalgamation.

16.3 Termination by Sublicensor. Sublicensor may terminate this Agreement in its entirety for cause at any time upon at least sixty (60) days prior written notice to Sublicensee upon the occurrence of any of the following:

(a) upon or after the breach of any material provision of this Agreement by Sublicensee if such breach is not cured within such sixty (60) day period; or

(b) upon or after the bankruptcy, insolvency, dissolution or winding up of Sublicensee other than for the purpose of reconstruction or amalgamation.

For the avoidance of doubt, a failure to make a payment otherwise owed under Article 4 or Article 5 that remains uncured for at least sixty (60) days following written notice shall be deemed a material breach. Furthermore, Sublicensor agrees that it will not voluntarily terminate the Panion License Agreement (or allow such agreement to be terminated by Panion), unless Sublicensor maintains its license for the Sublicense Territory on terms and conditions no less favorable to Sublicensee as in this Agreement or makes arrangements for Sublicensee be granted a direct license from Panion with terms and conditions no less favorable to Sublicensee as in this Agreement.

16.4 Rights Following Termination.

16.4.1 In the event of termination of this Agreement by Sublicensor pursuant to Section 16.3 or by Sublicensee pursuant to Section 16.2.1, Sublicensee will promptly transfer and hand over to Sublicensor all Sublicensor Development Data, and Sublicensor Know-How provided to Sublicensee hereunder (subject to the provisions of Section 8.2 with respect to Improvements). Each party will return to the other party all copies of the Proprietary Information supplied by one party to the other party hereunder, except that one copy of such Proprietary Information may be retained by each party for archival purposes only. Sublicensee will grant Sublicensor access to all Sublicensee Know-How and shall promptly take all steps necessary to transfer all right, title and interest in any Registration, marketing authorizations or other regulatory approvals to Sublicensor. Sublicensor shall have the right to use and/or disclose to a Third Party all such Sublicensee Development Data and Sublicensee Know-How in connection with Sublicensor's effort to market Products in the Sublicense Territory or to license to such Third Party the right to manufacture and sell a Product in the Sublicense Territory.

16.4.2 Upon expiration of this Agreement or termination of this Agreement pursuant to Sections 16.2.2 and 16.2.3, Sublicensee shall retain the right to use any Proprietary Information in the Sublicense Territory without any additional payment to Sublicensor.

16.5 Disposition of Product. Upon termination of this Agreement by Sublicensor, Sublicensee shall provide Sublicensor a written inventory of all Product (in the form of raw material, work-in-progress and finished goods) in its and its sublicensees' possession, and shall have the right to dispose of such Product within six (6) months thereafter, subject to fulfillment of the royalty obligations relating thereto.

16.6 Change of Control. The rights granted to Sublicensee hereunder (including rights to be supplied under Article 10 hereunder) will survive any change in Sublicensor's current management or ownership, or business as presently conducted.

16.7 Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by Sublicensor are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that Sublicensee, as sublicensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against Sublicensor under the U.S. Bankruptcy Code that is not dismissed within sixty (60) days of the first date of filing, Sublicensor hereby grants to Sublicensee, subject to Sublicensee's obligations under Section 365(n), a right of access and to obtain possession of and to benefit from each of the following embodiments to the extent related to Sublicensee's exercise of its license rights to the Compounds and Products in the Sublicense Territory in accordance with this Agreement: (i) copies of (or complete access to, as appropriate) Sublicensor Development Data necessary or reasonably useful for Sublicensee to manufacture, develop and/or commercialize the Compound and/or Product in the Sublicense

Territory; and (ii) any other embodiments of such intellectual property in Sublicensor's possession and control, which, if not already in Sublicensee's possession, shall be promptly delivered to Sublicensee (a) upon Sublicensee's reasonable written request therefor, unless Sublicensor elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under clause (a), following the rejection of this Agreement by Sublicensor upon Sublicensee's reasonable written request therefor. Recognizing that the embodiments described above may be useful or necessary to Sublicensor in connection with its continued operation of its business, and that a Third Party may also have a right of access to such embodiment under Section 365(n) of the Bankruptcy Code or applicable non-bankruptcy law, where there is a fixed or limited quantity of any tangible item of such embodiment described above, Sublicensee shall be entitled to a pro rata portion thereof.

ARTICLE 17. ASSIGNMENT

This Agreement may not be assigned or otherwise transferred by either party without the written consent of the other party except that either party without such consent but with a prompt notification in writing to the other party may assign or sell the license (i) in connection with the transfer or sale of all or substantially all of its business assets to a Third Party, or (ii) in the event of its merger or consolidation with another company, or (iii) to an Affiliate. Any purported assignment in violation of this clause shall be null and void. Any permitted assignee shall assume all the obligations of its assignor under this Agreement. No assignment shall relieve either party of its responsibility for the performance of any obligation that such party has accrued hereunder as of the date of assignment.

ARTICLE 18. PATENT MARKINGS

Sublicensee agrees to mark all Products made, used or sold under the terms of this Agreement, or their containers, in accordance with applicable patent marking laws.

ARTICLE 19. ARBITRATION

In the event any dispute or difference of any kind whatsoever shall arise between the parties in connection with or arising out of this Agreement or the carrying out of its obligations, except as provided in Section 3.9, it shall first be brought to negotiation between the parties and in case no agreement is reached within a period of sixty (60) days from the day on which such dispute or difference was brought to the attention of the other party, it shall then be referred to arbitration. The arbitration shall be conducted in London, United Kingdom in English and in accordance with the arbitration rules of International Chamber of Commerce. The parties shall request the arbitrators to render award within eighteen (18) months. The award shall be final, binding and enforceable upon the parties.

ARTICLE 20. PATENT TERM EXTENSION

Sublicensee agrees, as exclusive Sublicensee, to apply for and to exercise due diligence in obtaining an extension of the term of any patent included within the Patent Rights under the applicable laws in the Sublicense Territory. Sublicensor agrees to execute such documents and take such additional actions as Sublicensee may reasonably request in connection therewith. Each party shall bear its own expenses in connection with the application for patent term extensions. Sublicensor shall make all necessary arrangements with Panion, Dr. Hsu and GloboAsia for Sublicensee to apply for said patent term extensions.

ARTICLE 21. FORCE MAJEURE

Neither party shall be held liable or responsible to the other party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement, other than an obligation to make a payment, when such failure or delay is caused by or results from fires, floods, embargoes, government regulations, prohibitions or interventions, wars, acts of war, terrorism, insurrections, riots, civil disobedience, strikes, lockouts, acts of God, or any other cause beyond the reasonable control of the affected party.

ARTICLE 22. NEGATION OF AGENCY

Nothing herein contained shall be deemed to create an agency, joint venture, amalgamation, partnership, or similar relationship between Sublicensee and Sublicensor. The relationship between the parties established by this Agreement is that of independent contractors. Neither party shall have the power to bind, obligate, incur any debts or make any commitments for the other party except to the extent, if at all, specifically provided herein.

ARTICLE 23. PUBLICITY

Each party shall give notice to the other party prior to issuing any press release relating to this Agreement within due time to allow for reasonable consideration. The party issuing the press release shall give due consideration and weight to any comments or

concerns raised by the other party. Notwithstanding the foregoing, neither party shall issue a press release announcing the execution of this Agreement outside of a joint press release which has been prepared jointly by the parties.

ARTICLE 24. FILING OF THE AGREEMENT

To the extent, if any, that a party concludes in good faith that it is required to file this Agreement or a notification thereof with any governmental authority, including without limitation the U.S. Securities and Exchange Commission in accordance with applicable laws and regulations, such party may do so, subject to the confidentiality obligations set forth herein, and the other party shall cooperate in such filing or notification and shall execute all documents reasonably required in connection therewith at the, expense of the requesting party. The parties shall promptly inform each other as to the activities or inquiries of any such governmental authority relating to this Agreement, and shall cooperate, in responding to any request for further information therefrom at the expense of the requesting party.

ARTICLE 25. SEVERABILITY

Each party hereby expressly agrees and contracts that it is not the intention of either party to violate any public policy, statutory or common laws, rules, regulations, treaty or decision of any government agency or executive body thereof of any country or community or association of countries. If any word, sentence, paragraph, clause or combination thereof in this Agreement is found by a court or executive body with judicial powers having jurisdiction over this Agreement or any of the parties hereto in a final unappealable or unappealed order to be in violation of any such provisions in any country or community or association of countries, such word, sentence, paragraph, clause or combination thereof shall be inoperative in such country or community or association of countries, and the parties will seek in good faith to amend this Agreement in order to cure such violation; the remainder of this Agreement shall in any event remain binding upon the parties hereto.

ARTICLE 26. NOTICES

Any notices required or permitted to be given hereunder shall be in writing and shall be deemed to have been properly given if delivered in person, or if mailed by registered or certified mail (return receipt requested), postage prepaid, or by recognized courier service, facsimile or e-mail promptly confirmed by first class mail, to the addresses given below or such other addresses as may be designated in writing by the parties from time to time during the term of this Agreement. Any notice sent by facsimile or e-mail shall be effective when sent, and any notice sent by registered or certified mail or recognized courier service shall be effective when mailed.

In the case of Sublicensor:

Keryx Biopharmaceuticals, Inc.
750 Lexington Ave, 20th Floor
New York, NY 10022 U.S.A.
Attn: James Oliviero
Fax: 1-212-531-5970
Email: joliviero@keryx.com

with a copy to:

Keryx Biopharmaceuticals, Inc.
750 Lexington Ave, 20th Floor
New York, NY 10022 U.S.A.
Attn: Kenneth Hoberman
Fax: 1-212-531-5977
Email: khoberman@keryx.com

In the case of Sublicensee:

Japan Tobacco Inc.
JT Building, 2-1, Toranomon 2-Chome
Minato-ku, Tokyo 105-8422, Japan
Attn: Vice President, Pharmaceutical Business Development
Fax: 81-3-5572-1449
Email: takashi.kamiya@jt.com

and

Torii Pharmaceutical Co., Ltd.
Torii Nihonbashi Bldg., 4-1, Nihonbashi-Honcho 3-chome,
Chuo-ku, Tokyo 103-8439, Japan
Attn: General Manager, Business Development Dept.
Fax: 81-3-5203-7334
Email: kiyoshi.sato@torii.co.jp

with a copy to:

Holland& Knight LLP
195 Broadway
New York, NY 10007 U.S.A.
Attn: Neal Beaton, Esq.
Fax: 1-212-341-7103
Email: neal.beaton@hklaw.com

ARTICLE 27. GOVERNING LAW

This Agreement shall be governed by and construed in accordance with the laws of the State of New York, exclusive of choice-of-law rules.

ARTICLE 28. AFFILIATES

Each party may perform its obligations hereunder personally or through one or more Affiliate and shall be responsible for the performance of such obligations, and any liabilities resulting from such performance. Neither party shall permit any of its Affiliates to commit any act (including any act of omission) which such party is prohibited hereunder from committing directly.

ARTICLE 29. ENTIRE AGREEMENT

This Agreement and the Exhibits hereto which are a part hereof, contain the entire understanding of the parties with respect to the subject matter hereof. All express or implied agreements and understanding, either oral or written, heretofore made are expressly merged in and made a part of this Agreement. The parties hereto may not alter, amend, modify, terminate or waive any of the provisions of this Agreement, but only by a written instrument duly executed and delivered by authorized officers of the parties. This agreement may be executed in three (3) counterparts, each of which will be deemed an original, but all of which together will constitute one agreement.

ARTICLE 30. WAIVER

The failure of a party to enforce at any time for any period any of the provisions hereof shall not be construed as a waiver of such provisions or of the right of such party thereafter to enforce each such provision.

ARTICLE 31. CAPTIONS

The captions to the several Articles and Sections hereof are not a part of this Agreement, but are merely guides or labels to assist in location and reading the several Articles and Sections hereof.

IN WITNESS HEREOF, the parties have executed this Agreement as of the date set forth above.

KERYX BIOPHARMACEUTICALS, INC. **JAPAN TOBACCO INC.**

By: /s/ Ron Bentsur By: /s/ Noriaki Okubo
Ron Bentsur Noriaki Okubo
Chief Executive Officer President, Pharmaceutical Business

TORII PHARMACEUTICAL CO., LTD.

By: /s/ Norihiko Matsuo
Norihiko Matsuo
President and Representative Director

List of Exhibits

Exhibit 1: List of Patent and Patent Applications

Exhibit 2: Preliminary Timelines for the Development Program

[Exhibit 1] List of Patent and Patent Applications

Patent Dkt#859 (KWOK *et al.*, 2004)

DOCKET #	MATTER	NOTE
Dkt. #859-PCT-JP	**FERRIC ORGANIC COMPOUNDS, USES THEREOF AND METHODS OF MAKING SAME** Japanese App'l No. 2006-503637, Filed August 18, 2005, National Stage App'l of Int'l App'l No. PCT/US2004/004646, filed February 18, 2004, claiming priority of U.S. Serial No. 60/447,690, filed February 19, 2003 and U.S. Serial No. 60/462,684, filed April 15, 2003 Inventors: David W.K. KWOK and Nikolay Mintchev STOYNOV Applicant: GloboAsia	******

Patent Dkt#859C (CHAN and TOWN., 2006)

DOCKET #	MATTER	NOTE
Dkt. #859-C-PCT-JP	**PHARMACEUTICAL-GRADE FERRIC ORGANIC COMPOUNDS, USES THEREOF AND METHODS OF MAKING SAME** Japanese App'l No. 2008-527177, Filed February 18, 2008, National Stage of Int'l App'l No. PCT/US2006/032385, Filed August 18, 2006 Inventors: Keith CHAN and Winston TOWN Applicant: GBLOBOASIA, LLC	******

Patent Dkt#1092 (HSU, 1997)

DOCKET #	MATTER	NOTE

Dkt. #1092-PCT-JP	**METHOD FOR TREATING RENAL FAILURE** Japanese App'l No. 10-527705, Filed June 15, 1999, now Japanese Patent No. 4173553, issued August 22, 2008, National Stage App'l of Int'l App'l No. PCT/US97/20977, filed November 14, 1997, which is a continuation of U.S. Serial No. 08/794,328, filed February 3, 1997, and U.S. Serial No. 60/032,745, filed December 16, 1996 Applicant: Chen Hsing HSU	******
Dkt. #1092-Z-PCT-JP (Divisional)	Japanese App'l No. 2007-133978, filed May 21, 2007 which is a divisional app'l of Japanese App'l No. 10-527705, Filed June 15, 1999, National Stage App'l of Int'l App'l No. PCT/US97/20977, filed November 14, 1997, which is a continuation of U.S. Serial No. 08/794,328, filed February 3, 1997, and U.S. Serial No. 60/032,745, filed December 16, 1996 Applicant: Chen Hsing HSU	******

Patent Dkt#1148 (CHAN et al., 2007)

DOCKET #	**MATTER**	**NOTE**
Dkt. #1148-A-PCT-JP	**METHOD OF REVERSING, PREVENTING OR STABILIZING SOFT TISSUE CALCIFICATION** Japanese App'l No. 2008-552435, Filed July 30, 2008, National Stage of Int'l App'l No. PCT/US2007/002157, filed January 26, 2007 claiming priority of U.S. Serial 60/763,253, filed January 30, 2006, and Int'l App'l No.PCT/US2006/032385, filed August 18, 2006, Inventors: Keith CHAN, Winston TOWN, Shou Shan CHIANG Applicant: GloboAsia, LLC	******

Patent Dkt#1231 (CHAN & TOWN, 2007)

DOCKET #	**MATTER**	**NOTE**
Dkt. #1231-PCT-JP	**METHOD OF TREATING CHRONIC KIDNEY DISEASE** Japanese Patent Application No. 2008-552431, filed July 30, 2008, National Stage of Int'l App'l No. PCT/US2007/002151, filed January 26, 2007, claiming priority of U.S. Serial No. 60/763,253, filed January 30, 2006, and Int'l App'l No. PCT/US2006/032385, filed August 18, 2006 Inventors: Keith CHAN and Winston TOWN Applicant: GloboAsia, LLC	******

[Exhibit 2] Preliminary Timelines for the Development Program

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FIRST AMENDMENT TO AMENDED AND RESTATED SUBLICENSE AGREEMENT

THIS FIRST AMENDMENT TO AMENDED AND RESTATED SUBLICENSE AGREEMENT (this "Amendment"), effective this 12th day of June, 2013 ("Amendment Effective Date"), is by and between KERYX BIOPHARMACEUTICALS, INC., with offices at 750 Lexington Avenue, 20th Floor, New York, NY 10022, U.S.A. ("Keryx" or "Sublicensor") and JAPAN TOBACCO INC., with offices at JT Building, 2-1, Toranomon 2-Chome, Minato-ku, Tokyo 105-8422, Japan ("JT") and TORII PHARMACEUTICAL CO., LTD., with offices at Torii Nihonbashi Bldg., 4-1, Nihonbashi-Honcho 3-Chome, Chuo-ku, Tokyo 103-8439, Japan ("TORII")(JT and TORII are collectively referred to herein as "Sublicensee");

WHEREAS, Sublicensor and Sublicensee are parties to that certain AMENDED AND RESTATED SUBLICENSE AGREEMENT dated the 8th day of June, 2009 (the "Amended and Restated Agreement"), pursuant to which the Sublicensor granted certain rights and licenses to the Sublicensee; and

WHEREAS, Sublicensor and Sublicensee, in order to avoid potential disputes or confusion regarding certain aspects of the rights and licenses granted pursuant to the Amended and Restated Agreement, desire to amend the Amended and Restated Agreement as set forth in this Amendment.

NOW THEREFORE, in consideration of the foregoing premises and the mutual promises and covenants set forth herein and other good and valuable consideration, the receipt of which is hereby acknowledged, the parties hereto agree as follows:

ARTICLE 32. DEFINITIONS

Capitalized terms used but not defined herein shall have the meaning ascribed to them in the Amended and Restated Agreement.

ARTICLE 33. AMENDMENT

33.1 Amendment of Section 3.1. Section 3.1 of the Amended and Restated Agreement is hereby deleted in its entirety and is replaced by the following text:

> "3.1 Grant. Subject to the terms and conditions of this Agreement, Sublicensor hereby grants to Sublicensee an exclusive sublicense, with the right to further sublicense to its Affiliates, to develop, have developed, make, have made, use, have used, offer to sell, sell, have sold, and import the Product or the Compound in or into the Sublicense Territory and a non-exclusive sublicense to make, manufacture, have made, have manufactured and export the Product or the Compound in or from countries outside of the Sublicense Territory, in each case (that is, in the case of the foregoing exclusive license and the case of the foregoing non-exclusive license) under the Sublicensor Know-How and the Patent Rights for all Indications."

33.2 Amendment of Section 26. Article 26 of the Amended and Restated Agreement is hereby deleted in its entirety and is replaced by the following text:

"Any notices required or permitted to be given hereunder shall be in writing and shall be deemed to have been properly given if delivered in person, or if mailed by registered or certified mail (return receipt requested), postage prepaid, or by recognized courier service, facsimile or e-mail promptly confirmed by first class mail, to the addresses given below or such other addresses as may be designated in writing by the parties from time to time during the term of this Agreement. Any notice sent by facsimile or e-mail shall be effective when sent, and any notice sent by registered or certified mail or recognized courier service shall be effective when mailed.

In the case of Sublicensor:

Keryx Biopharmaceuticals, Inc.
750 Lexington Ave, 20th Floor
New York, NY 10022 U.S.A.
Attn: James Oliviero
Fax: 1-212-531-5970
Email: joliviero@keryx.com

with a copy to:

Keryx Biopharmaceuticals, Inc.
750 Lexington Ave, 20th Floor
New York, NY 10022 U.S.A.
Attn: Ron Bentsur
Fax: 1-212-531-5971
Email: rbentsur@keryx.com

In the case of Sublicensee:

Japan Tobacco Inc.
JT Building, 2-1, Toranomon 2-Chome
Minato-ku, Tokyo 105-8422, Japan
Attn: Vice President, Pharmaceutical Business Development
Fax: 81-3-5572-1449
Email: masanori.sato@jt.com

and

Torii Pharmaceutical Co., Ltd.
Torii Nihonbashi Bldg., 4-1, Nihonbashi-Honcho 3-chome,
Chuo-ku, Tokyo 103-8439, Japan
Attn: Vice President, Business Development Dept.
Fax: 81-3-5203-7334

Email: takashi.kamiya@torii.co.jp

with a copy to:

Holland & Knight LLP
31 West 52nd Street
New York, NY 10019 U.S.A.
Attn: Beaton, Esq.
Fax: 1-212-341-7103
Email: neal.beaton@hklaw.com

ARTICLE 34. CONFIRMATION OF TERMS

34.1 Confirmation of Terms. Except as expressly set forth in this Amendment, the Amended and Restated Agreement shall continue in full force and effect in accordance with its terms.

34.2 Effect of Amendment. This Amendment is entered into by the parties in accordance with Article 29 of the Amended and Restated Agreement, and is part of the Agreement, as the same is amended hereby.

34.3 This Amendment shall be governed by and construed in accordance with the laws of the State of New York, exclusive of choice-of-law rules.

34.4 The Agreement, as amended by this Amendment, constitutes the entire agreement and understanding of the parties and supersedes any prior agreements or understandings relating to the subject matter hereof. In the event of any conflict between the provisions of the Amended and Restated Agreement and this Amendment, the provisions of this Amendment shall govern and control.

34.5 This Amendment may be executed in any number of counterparts, each of which shall be deemed an original and all of which shall constitute one and the same instrument.

[The remainder of this page is intentionally blank.]

IN WITNESS HEREOF, the parties have executed this Amendment as of the Amendment Effective Date set forth above.

KERYX BIOPHARMACEUTICALS, INC.

By: /s/ Ron Bentsur

Name: Ron Bentsur

Title: CEO

JAPAN TOBACCO INC.

By: /s/ Masanori Sato

Name: Masanori Sato

Title: VP, Business Development Pharmaceutical Div.

TORII PHARMACEUT CAL CO., LTD.

By: /s/ Yuji Kagohashi

Name: Yuji Kagohashi

Title: Senior Executive Director, Head of R&D Group

Portions of this Exhibit, indicated by the mark "****," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.**

WHITBY PRODUCT AGREEMENT (Ferric Citrate IR Tablets)

This Product Agreement (this "**Product Agreement**") is issued under the Master Manufacturing Services Agreement dated **September 27, 2016** between Patheon Manufacturing Services LLC and Keryx BioPharmaceuticals, Inc. (the "**Master Agreement**"), and is entered into **August 29, 2017** (the "**Effective Date**"), between Patheon Inc., a Canadian corporation, having a place of business at [***] ("**Patheon**") and Keryx BioPharmaceuticals, Inc., a corporation existing under the laws of Delaware, having a principal place of business at One Marina Park Drive, 12th Floor, Boston, MA 02210 ("**Client**").

The terms and conditions of the Master Agreement are incorporated herein except to the extent this Product Agreement expressly references the specific provision in the Master Agreement to be modified by this Product Agreement. All capitalized terms that are used but not defined in this Product Agreement will have the respective meanings given to them in the Master Agreement.

The Schedules to this Product Agreement are incorporated into and will be construed in accordance with the terms of this Product Agreement.

1. **Product List and Specifications**: (See Schedule A attached hereto)
2. **Minimum Order Quantity, Annual Volume, and Price**: (See Schedule B attached hereto)
3. **Annual Stability Testing and Validation Activities (if applicable)**: (See Schedule C attached hereto)
4. **Active Materials, Active Materials Credit Value, and Maximum Credit Value**: (See Schedule D attached hereto)
5. **Client Supply Chain Inventory Documentation Requirements**: (See Schedule E attached hereto)
6. **Yearly Forecasted Volume:** Not applicable
7. **Territory**: USA, Europe, Canada
8. **Manufacturing Site**: [***]
9. **Governing Law**: New York per the Master Agreement
10. **Inflation Index:** PPI
11. **Currency**: $ USD
12. **Initial Set Exchange Rate**: 1:1.3401 (USD:CAD)
13. **Initial Product Term:** From the Effective Date until December 31, 2024.
14. **Notices**:

    [***]
15. **Other Modifications to the Master Agreement**: None

IN WITNESS WHEREOF, the duly authorized representatives of the parties have executed this Product Agreement as of the Effective Date set forth above.

PATHEON INC.

By: _/s/ Don Liscombe

Name: Don Liscombe

Title: VP and General Manager_____

KERYX BIOPHARMACEUTICALS, INC.

By: /s/ Gregory P. Madison

Name: Gregory P. Madison_____

Title: President & CEO_____

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

SCHEDULE A

PRODUCT LIST AND SPECIFICATIONS

Product List

Auryxia (Ferric Citrate IR Tablets) [***]

Specifications

[***]

SCHEDULE B

MINIMUM ORDER QUANTITY, ANNUAL VOLUME, AND PRICE

[***]

SCHEDULE C

ANNUAL STABILITY TESTING AND VALIDATION ACTIVITIES

Stability Testing

Patheon and Client will agree in writing on any stability testing to be performed by Patheon on the Products. This agreement will specify the commercial and Product stability protocols applicable to the stability testing and the fees payable by Client for this testing.

[***]

SCHEDULE D

ACTIVE MATERIALS

ACTIVE MATERIALS	SUPPLIER
Ferric Citrate	[***]

ACTIVE MATERIALS CREDIT VALUE

The Active Materials Credit Value will be as follows:

PRODUCT	ACTIVE MATERIALS	ACTIVE MATERIALS CREDIT VALUE
Auryxia (Ferric Citrate IR Tablets)	Ferric Citrate	[***]

MAXIMUM CREDIT VALUE

Patheon's liability for Active Materials calculated in accordance with Section 2.2 of the Master Agreement in a Year will not exceed, in the aggregate, the maximum credit value set forth below:

PRODUCT	MAXIMUM CREDIT VALUE
Auryxia (Ferric Citrate IR Tablets)	[***] per Year to Patheon under this Product Agreement.

YIELD TOLERANCE

[***]

SCHEDULE E

Client Supply Chain Inventory Documentation Requirements

[***]

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Exhibit 31.1

CERTIFICATION OF PERIODIC REPORT PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Gregory P. Madison, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Keryx Biopharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2017

/s/ Gregory P. Madison

Gregory P. Madison
Chief Executive Officer
Principal Executive Officer

Exhibit 31.2

CERTIFICATION OF PERIODIC REPORT PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Scott A. Holmes, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Keryx Biopharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2017

/s/ Scott A. Holmes

Scott A. Holmes

Chief Financial Officer

Principal Financial and Accounting Officer

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER OF
KERYX BIOPHARMACEUTICALS, INC.
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of Keryx Biopharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ended September 30, 2017 as filed with the Securities and Exchange Commission (the "Report"), I, Gregory P. Madison, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 7, 2017

/s/ Gregory P. Madison

Gregory P. Madison
Chief Executive Officer
Principal Executive Officer

Exhibit 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER OF
KERYX BIOPHARMACEUTICALS, INC.
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of Keryx Biopharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ended September 30, 2017 as filed with the Securities and Exchange Commission (the "Report"), I, Scott A. Holmes, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 7, 2017

/s/ Scott A. Holmes

Scott A. Holmes
Chief Financial Officer
Principal Financial and Accounting Officer