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

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**FORM 8-K**

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**CURRENT REPORT  
Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934**

**Date of report (Date of earliest event reported): November 8, 2018**

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**Keryx Biopharmaceuticals, Inc.**

(Exact Name of Registrant as Specified in Charter)

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**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**000-30929**  
(Commission  
File Number)

**13-4087132**  
(IRS Employer  
Identification No.)

**One Marina Park Drive, 12<sup>th</sup> Floor**  
**Boston, Massachusetts 02210**  
(Address of Principal Executive Offices)

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

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act.
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act.
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act.
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act.

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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.

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**Item 2.02. Results of Operations and Financial Condition.**

On November 8, 2018, Keryx Biopharmaceuticals, Inc. (“Keryx”) issued a press release announcing its results of operations for the third quarter ended September 30, 2018. A copy of such press release is being furnished as Exhibit 99.1 to this report and is incorporated herein by reference.

The information set forth in Exhibit 99.1 shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

**Item 9.01. Financial Statements And Exhibits.**

(d) Exhibits.

The following exhibit is furnished herewith:

99.1 [Press release issued by Keryx Biopharmaceuticals, Inc., dated November 8, 2018.](#)

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**SIGNATURE**

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 hereunto duly authorized.

Date: November 8, 2018

**Keryx Biopharmaceuticals, Inc.**  
(Registrant)

By: /s/ Scott A. Holmes  
Scott A. Holmes  
Chief Financial Officer



### **Keryx Biopharmaceuticals Announces Third Quarter 2018 Financial Results**

- Third quarter 2018 total revenues of \$28.0 million including net U.S. Auryxia® (ferric citrate) product sales of \$26.6 million, a 96 percent increase compared to the third quarter of 2017
- Approximately 47,500 Auryxia Prescriptions were written in the third quarter of 2018, nearly double the number reported in the third quarter of 2017
- Merger with Akebia Therapeutics on track to close by year end, subject to stockholder approval and the satisfaction of other closing conditions

**BOSTON, MA**, November 8, 2018 – Keryx Biopharmaceuticals, Inc. (Nasdaq: KERX), a biopharmaceutical company focused on bringing innovative medicines to people with kidney disease, today announced its financial results for the third quarter ended September 30, 2018. The company also reviewed its commercial progress with Auryxia and provided a general business update.

“We continued to see significant growth year-over-year in the number of prescriptions written and the revenue generated by Auryxia,” said Jodie Morrison, interim chief executive officer of Keryx Biopharmaceuticals. “We are continuing to make progress on consummating our merger with Akebia and have scheduled a stockholder meeting to approve the transaction for December 11, 2018. We are excited about the potential strategic, financial and operational benefits of this transaction and are aiming, subject to stockholder approval and satisfaction of other customary conditions, to close the transaction by the end of the year.”

#### **Business Highlights**

- Net U.S. Auryxia product sales were \$26.6 million in the third quarter of 2018, as compared to \$13.6 million in the same quarter in 2017, representing growth of 96 percent.
- Approximately 47,500 Auryxia prescriptions were reported in the third quarter of 2018, representing 9.4 million Auryxia tablets. This compares to approximately 25,200 prescriptions and 5.4 million Auryxia tablets in the third quarter of 2017.
- Auryxia market share for the third quarter of 2018 was 6.4 percent, compared to 3.5 percent in the third quarter of 2017.
- The breadth of physicians prescribing Auryxia continued to expand in the third quarter of 2018 compared to the same period in 2017, with approximately 6,500 prescribers in the 2018 quarter, nearly 2,000 more than the third quarter of 2017.
- The depth of Auryxia prescribing also increased significantly in the third quarter of 2018, with a 28 percent increase in the average number of prescriptions per prescriber as compared to the third quarter of 2017.
- As expected, there was a shift in channel mix for Auryxia during the third quarter of 2018, with 61 percent of prescriptions coming through IMS reporting channels and 39 percent coming through specialty pharmacies (including Fresenius Rx and Davita Rx); the shift in mix is due the closing of Davita’s specialty pharmacy business, which occurred in September 2018.
- The gross-to-net adjustment for Auryxia for the third quarter of 2018 was 50 percent. This is consistent with year-to-date 2018 gross-to-net adjustment of 50 percent.



### Akebia Merger Update

- On June 28, 2018, Keryx announced that it had entered a definitive merger agreement with Akebia Therapeutics, Inc. that is expected to close by the end of 2018, subject to stockholder approvals and satisfaction of customary closing conditions.
- If the merger is consummated, Keryx stockholders would continue to participate in the growth of Auryxia and gain access to an innovative Phase 3 product candidate with the potential to compete in a complementary multi-billion-dollar market, upon successful completion of its development program. The combined company would have substantial financial resources, an integrated platform for the development and launch of renal drugs and be led by a seasoned executive with decades of experience in the renal field.
- The definitive proxy materials were filed with the Securities and Exchange Commission (SEC) on October 30, 2018 and the companies' respective stockholder meetings are scheduled for December 11, 2018 for stockholders of record as of October 22, 2018.
- The Keryx Board continues to unanimously support the merger and recommends that stockholders vote **FOR** the merger proposals at the upcoming stockholders' meeting.

Given the pending merger with Akebia, Keryx will not be holding a conference call to discuss third quarter 2018 results.

### Third Quarter Ended September 30, 2018 Financial Results

"I'm pleased to be reporting another solid quarter of Auryxia performance, having nearly doubled revenue over the same period a year ago, driven primarily by increases in volume," said Scott Holmes, senior vice president and chief financial officer of Keryx Biopharmaceuticals. "We believe the proposed merger with Akebia will put us in a strong position financially, with Akebia's significant cash position today and Auryxia's growing revenues contributing to the financial strength of the combined company in the future."

**Total revenues** for the quarter ended September 30, 2018 were \$28.0 million, compared with \$15.0 million during the same period in 2017. Total revenues for the third quarter of 2018 include \$26.6 million in net U.S. Auryxia product sales, as compared to \$13.6 million in the third quarter of 2017. Total revenues for the third quarter of 2018 also include \$1.4 million in license revenue, as compared to \$1.4 million during the same period in 2017.

**Cost of goods sold** for the quarter ended September 30, 2018 were \$7.5 million, compared with \$5.9 million during the same period in 2017.

**Selling, general and administrative expenses** for the quarter ended September 30, 2018 were \$26.5 million, as compared to \$22.7 million during the same period in 2017. Selling, general and administrative expenses for the quarter ended September 30, 2018 included \$3.4 million in non-cash stock compensation expense, as compared to \$2.9 million during the third quarter of 2017.

**Research and development expenses** for the quarter ended September 30, 2018 were \$7.9 million, as compared to \$9.3 million during the same period in 2017. Research and development expenses for the quarter ended September 30, 2018 included \$0.4 million in non-cash stock compensation expense, as compared to \$0.5 million during the same period in 2017.

**Net loss** for the quarter ended September 30, 2018 was \$17.0 million, or \$0.14 per share, as compared to a net loss of \$23.5 million, or \$0.20 per share, for the same period in 2017. Net loss for the quarter ended September 30, 2018 included \$2.2 million in non-cash interest expense related to the amortization of a discount recognized in connection with the modification of the convertible senior notes.

**Cash and cash equivalents** as of September 30, 2018 totaled \$41.1 million.



## About Auryxia® (ferric citrate) tablets

Auryxia (ferric citrate) was approved by the U.S. Food and Drug Administration (FDA) on September 5, 2014 for the control of serum phosphorus levels in patients with chronic kidney disease on dialysis and approved by the FDA on November 6, 2017 for the treatment of iron deficiency anemia in patients with chronic kidney disease not on dialysis. Auryxia tablets were designed to contain 210 mg of ferric iron, equivalent to 1 gram of ferric citrate, and offers convenient mealtime dosing. The starting dose of Auryxia for the treatment of hyperphosphatemia for patients on dialysis is six tablets per day (two per meal) and for the treatment of iron deficiency anemia in patients not on dialysis is three tablets per day (one per meal). For more information about Auryxia and the U.S. full prescribing information, please visit [www.Auryxia.com](http://www.Auryxia.com).

## IMPORTANT U.S. SAFETY INFORMATION FOR AURYXIA® (ferric citrate)

### CONTRAINDICATION

AURYXIA® (ferric citrate) is contraindicated in patients with iron overload syndromes, e.g., hemochromatosis.

### WARNINGS AND PRECAUTIONS

- **Iron Overload:** Increases in serum ferritin and transferrin saturation (TSAT) were observed in clinical trials with AURYXIA in patients with chronic kidney disease (CKD) on dialysis treated for hyperphosphatemia, which may lead to excessive elevations in iron stores. Assess iron parameters prior to initiating AURYXIA and monitor while on therapy. Patients receiving concomitant intravenous (IV) iron may require a reduction in dose or discontinuation of IV iron therapy.
- **Risk of Overdosage in Children Due to Accidental Ingestion:** Accidental ingestion and resulting overdose of iron-containing products is a leading cause of fatal poisoning in children under 6 years of age. Advise patients of the risks to children and to keep AURYXIA out of the reach of children.

### ADVERSE REACTIONS

Most common adverse reactions with AURYXIA were:

- Hyperphosphatemia in CKD on Dialysis: Diarrhea (21%), discolored feces (19%), nausea (11%), constipation (8%), vomiting (7%) and cough (6%)
- Iron Deficiency Anemia in CKD Not on Dialysis: Discolored feces (22%), diarrhea (21%), constipation (18%), nausea (10%), abdominal pain (5%) and hyperkalemia (5%)

### SPECIFIC POPULATIONS

- **Pregnancy and Lactation:** There are no available data on AURYXIA use in pregnant women to inform a drug-associated risk of major birth defects and miscarriage. However, an overdose of iron in pregnant women may carry a risk for spontaneous abortion, gestational diabetes and fetal malformation. Data from rat studies have shown the transfer of iron into milk, hence, there is a possibility of infant exposure when AURYXIA is administered to a nursing woman.

To report suspected adverse reactions, contact Keryx Biopharmaceuticals at 1-844-445-3799.

Please [click here](#) to view the Full Prescribing Information for Auryxia.



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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
<b>Revenues:</b>				
Net U.S. Auryxia product sales	\$ 26,590	\$ 13,597	\$ 71,317	\$ 38,218
License revenue	1,446	1,399	4,219	3,741
<b>Total Revenues</b>	<u>28,036</u>	<u>14,996</u>	<u>75,536</u>	<u>41,959</u>
<b>Operating Expenses:</b>				
Cost of goods sold	7,506	5,856	24,535	14,508
License expense	867	838	2,531	2,244
Research and development	7,896	9,275	25,058	25,051
Selling, general and administrative	26,453	22,746	81,001	70,835
<b>Total Operating Expenses</b>	<u>42,722</u>	<u>38,715</u>	<u>133,125</u>	<u>112,638</u>
<b>Operating Loss</b>	(14,686)	(23,719)	(57,589)	(70,679)
<b>Other Income (Expense):</b>				
Other income (expense), net	(2,309)	241	(3,454)	(62,272)
<b>Loss Before Income Taxes</b>	(16,995)	(23,478)	(61,043)	(132,951)
Income tax expense (benefit)	—	20	(634)	60
<b>Net Loss</b>	<u>\$ (16,995)</u>	<u>\$ (23,498)</u>	<u>\$ (60,409)</u>	<u>\$ (133,011)</u>
<b>Net Loss Per Common Share</b>				
Basic and diluted net loss per common share	<u>\$ (0.14)</u>	<u>\$ (0.20)</u>	<u>\$ (0.50)</u>	<u>\$ (1.18)</u>
<b>Shares Used in Computing Net Loss Per Common Share</b>				
Basic and diluted	120,432,827	118,992,825	120,245,049	112,928,551



**Selected Consolidated Balance Sheet Data**  
*(In thousands)*  
*(unaudited)*

	September 30, 2018	December 31, 2017
<b>Assets</b>		
Cash and cash equivalents	\$ 41,146	\$ 93,526
Accounts receivable, net	\$ 14,606	\$ 8,146
Inventory	\$ 58,736	\$ 28,695
Other current assets	\$ 11,924	\$ 11,199
Other assets	\$ 18,318	\$ 9,577
Total assets	\$ 151,784	\$ 158,872
<b>Liabilities and Stockholders' Equity (Deficit)</b>		
Accounts payable and accrued expenses	\$ 56,691	\$ 45,031
Convertible senior notes, net of discount	\$ 132,302	\$ 125,000
Total liabilities	\$ 206,003	\$ 172,967
Stockholders' equity (deficit)	\$ (54,219)	\$ (14,095)

**About Keryx Biopharmaceuticals, Inc.**

Keryx Biopharmaceuticals, Inc., with headquarters in Boston, Massachusetts, is focused on the development and commercialization of innovative medicines that provide unique and meaningful advantages to people with kidney disease. The Keryx team consists of approximately 200 committed people working with passion to advance the care of people with this complex disease. This dedication has resulted in two FDA-approved indications for Auryxia® (ferric citrate) tablets. For more information about Keryx, please visit [www.keryx.com](http://www.keryx.com).

***Additional Information and Where to Find It***

In connection with the proposed merger, Akebia has filed with the SEC a Registration Statement on Form S-4, which, as amended, includes a final prospectus with respect to the shares of Akebia's common stock to be issued in the proposed merger and a definitive joint proxy statement of Keryx and Akebia with respect to the proposed merger. The Registration Statement was declared effective by the SEC on October 30, 2018 and the definitive joint proxy statement was mailed or otherwise made available to Keryx's and Akebia's respective stockholders on or about October 31, 2018. BEFORE MAKING ANY VOTING DECISION, AKEBIA'S AND KERYX'S RESPECTIVE STOCKHOLDERS ARE URGED TO READ THE JOINT PROXY STATEMENT/PROSPECTUS IN ITS ENTIRETY AND ANY OTHER DOCUMENTS FILED BY EACH OF AKEBIA AND KERYX WITH THE SEC IN CONNECTION WITH THE PROPOSED MERGER OR INCORPORATED BY REFERENCE THEREIN BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION AND THE PARTIES TO THE PROPOSED TRANSACTION. Investors and stockholders will be able to obtain a free copy of the joint proxy statement/prospectus and other documents containing important information about Akebia and Keryx, with the SEC, through the website maintained by the SEC at [www.sec.gov](http://www.sec.gov). Akebia and Keryx make available free of charge at [www.akebia.com](http://www.akebia.com) and [www.keryx.com](http://www.keryx.com), respectively (in the "Investors" section), copies of materials they file with, or furnish to, the SEC.

***Participants in the Solicitation***

Akebia, Keryx and their respective directors, executive officers and certain employees and other persons may be deemed to be participants in the solicitation of proxies from the stockholders of Akebia and Keryx in connection with the proposed merger. Security holders may obtain information regarding the names,



affiliations and interests of Akebia's directors and officers in Akebia's Annual Report on Form 10-K for the fiscal year ended December 31, 2017, which was filed with the SEC on March 12, 2018 and its definitive proxy statement for the 2018 annual meeting of stockholders, which was filed with the SEC on April 30, 2018. Security holders may obtain information regarding the names, affiliations and interests of Keryx's directors and officers in Keryx's Annual Report on Form 10-K for the fiscal year ended December 31, 2017, which was filed with the SEC on February 21, 2018, and the Amendment No. 1 on Form 10-K/A, which was filed with the SEC on April 30, 2018, and its definitive proxy statement for the 2018 annual meeting of stockholders, which was filed with the SEC on May 31, 2018. To the extent the holdings of Akebia's securities by Akebia's directors and executive officers or the holdings of Keryx securities by Keryx's directors and executive officers have changed since the amounts set forth in Akebia's or Keryx's respective proxy statement for its 2018 annual meeting of stockholders, such changes have been or will be reflected on Statements of Change in Ownership on Form 4 filed with the SEC. Additional information regarding the interests of such individuals in the proposed merger are included in the joint proxy statement/prospectus relating to the proposed merger that was filed with the SEC. These documents may be obtained free of charge from the SEC's website at [www.sec.gov](http://www.sec.gov), Akebia's website at [www.akebia.com](http://www.akebia.com) and Keryx's website at [www.keryx.com](http://www.keryx.com).

This document does not constitute a solicitation of proxy, an offer to purchase or a solicitation of an offer to sell any securities.

### ***Forward-Looking Statements***

This document contains forward-looking statements within the meaning of the federal securities law. Such statements are based upon current plans, estimates and expectations that are subject to various risks and uncertainties. The inclusion of forward-looking statements should not be regarded as a representation that such plans, estimates and expectations will be achieved. Words such as "anticipate," "create," "expect," "project," "intend," "believe," "may," "will," "should," "plan," "could," "target," "contemplate," "estimate," "position," "predict," "potential," "opportunity" and words and terms of similar substance used in connection with any discussion of future plans, actions or events identify forward-looking statements. All statements, other than historical facts, including statements regarding the ability of the parties to complete the merger considering the various closing conditions; the consummation of the merger and the potential benefits of the merger, including beliefs about the financial strength of the combined company; and the expected timeline for the merger; are forward looking statements. Important factors that could cause actual results to differ materially from Akebia's and Keryx's plans, estimates or expectations could include, but are not limited to: (i) Akebia or Keryx may be unable to obtain stockholder approval as required for the merger; (ii) conditions to the closing of the merger may not be satisfied; (iii) the merger may involve unexpected costs, liabilities or delays; (iv) the effect of the announcement of the merger on the ability of Akebia or Keryx to retain and hire key personnel and maintain relationships with customers, suppliers and others with whom Akebia or Keryx does business, or on Akebia's or Keryx's operating results and business generally; (v) Akebia's or Keryx's respective businesses may suffer as a result of uncertainty surrounding the merger and disruption of management's attention due to the merger; (vi) the outcome of any legal proceedings related to the merger; (vii) Akebia or Keryx may be adversely affected by other economic, business, and/or competitive factors, including the receipt by Keryx of notice letters on October 31, 2018, and November 6, 2018, regarding abbreviated new drug applications submitted to the FDA requesting approval to market, sell and use a generic version of the Auryxia, (viii) Akebia or Keryx may be adversely affected by other economic, business, and/or competitive factors; (ix) the occurrence of any event, change or other circumstances that could give rise to the termination of the merger agreement; (x) risks that the merger disrupts current plans and operations and the potential difficulties in employee retention as a result of the merger; (xi) the risk that Akebia or Keryx may be unable to obtain governmental and regulatory approvals required for the transaction, or that required governmental and regulatory approvals may delay the transaction or result in the imposition of conditions that could reduce the anticipated benefits from the proposed transaction or cause the parties to abandon the proposed transaction; (xii) risks that the anticipated benefits of the merger or other commercial opportunities may otherwise not be fully realized or may take longer to realize than expected; (xiii) the impact of legislative, regulatory, competitive and technological changes, including the recent changes to reimbursement coverage for Auryxia that could have a material adverse effect on Auryxia sales and profitability; (xiv) expectations for future clinical trials, the timing and potential outcomes of clinical trials and interactions with regulatory authorities; and (xv)



other risks to the consummation of the merger, including the risk that the merger will not be consummated within the expected time period or at all. Additional factors that may affect the future results of Akebia and Keryx are set forth in their respective filings with the SEC, including each of Akebia's and Keryx's most recently filed Annual Report on Form 10-K, subsequent Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, in the definitive joint proxy statement/prospectus filed by Akebia and Keryx and other filings with the SEC, which are available on the SEC's website at [www.sec.gov](http://www.sec.gov). See in particular "Risk Factors" in the joint proxy statement/prospectus, Item 1A of Akebia's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018 under the heading "Risk Factors" and Item 1A of Keryx's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018 under the heading "Risk Factors." The risks and uncertainties described above and in Akebia's most recent Quarterly Report on Form 10-Q and Keryx's most recent Quarterly Report on Form 10-Q are not exclusive and further information concerning Akebia and Keryx and their respective businesses, including factors that potentially could materially affect their respective businesses, financial condition or operating results, may emerge from time to time. Readers are urged to consider these factors carefully in evaluating these forward-looking statements, and not to place undue reliance on any forward-looking statements. Readers should also carefully review the risk factors described in other documents that Akebia and Keryx file from time to time with the SEC. The forward-looking statements in these materials speak only as of the date of these materials. Except as required by law, Akebia and Keryx assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

**Keryx Biopharmaceuticals Contact**

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