

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

██████████ Individually and On  
Behalf of All Others Similarly Situated,

Plaintiff,

v.

KERYX BIOPHARMACEUTICALS,  
INC., GREGORY P. MADISON, and  
SCOTT A. HOLMES,

Defendants.

Case No.:

**CLASS ACTION COMPLAINT FOR  
VIOLATIONS OF THE FEDERAL  
SECURITIES LAWS**

**JURY TRIAL DEMANDED**

Plaintiff [REDACTED] (“Plaintiff”), by and through his attorneys, alleges the following upon information and belief, except as to those allegations concerning Plaintiff, which are alleged upon personal knowledge. Plaintiff’s information and belief is based upon, among other things, his counsel’s investigation, which includes without limitation: (a) review and analysis of regulatory filings made by Keryx Biopharmaceuticals, Inc. (“Keryx” or the “Company”), with the United States (“U.S.”) Securities and Exchange Commission (“SEC”); (b) review and analysis of press releases and media reports issued by and disseminated by Keryx; and (c) review of other publicly available information concerning Keryx.

### **NATURE OF THE ACTION AND OVERVIEW**

1. This is a class action on behalf of persons and entities that acquired Keryx securities between February 25, 2016, and August 1, 2016, inclusive (the “Class Period”), against the Defendants,<sup>1</sup> seeking to pursue remedies under the Securities Exchange Act of 1934 (the “Exchange Act”).

2. Keryx is a biopharmaceutical company focused on marketing therapies for patients with renal disease. The Company’s product, Auryxia (ferric citrate), also known as Riona in Japan and Fexeric in Europe, is an oral, absorbable iron-based compound, that received marketing approval from the U.S. Food and Drug Administration (“FDA”) in September 2014 for the control of serum phosphorus levels in patients with chronic kidney disease (“CKD”) on dialysis.

3. On August 1, 2016, Keryx announced that it had determined that a supply interruption of Auryxia was going to occur due to a production-related issue in converting active pharmaceutical ingredient (“API”) to finished drug product at its contract manufacturer. The

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<sup>1</sup> “Defendants” refers collectively to Keryx, Gregory P. Madison, and Scott A. Holmes.

Company also disclosed that this issue has resulted in variable production yields of finished drug product, and that as a result, the Company had exhausted its reserve of finished drug product. Finally, the Company stated that it expects to restore adequate supply of Auryxia and make Auryxia available to patients during the fourth quarter of 2016.

4. On this news, Keryx's stock price fell \$2.64 per share, or 35.8%, to close at \$4.72 per share on August 1, 2016, on unusually heavy trading volume.

5. Throughout the Class Period, Defendants made materially false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose: (1) that the Company was experiencing production-related difficulties in converting API to finished drug product; (2) that the issue was resulting in decreased production yields of finished drug product; (3) that, as a result, the Company would, and did exhaust its reserve of finished drug product; and (4) that, as a result of the foregoing, Defendants' statements about Keryx's business, operations, and prospects, were false and misleading and/or lacked a reasonable basis.

6. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

#### **JURISDICTION AND VENUE**

7. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

8. This Court has jurisdiction over the subject matter of this action pursuant to 28

U.S.C. § 1331 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

9. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)). Substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this Judicial District. Many of the acts charged herein, including the dissemination of materially false and/or misleading information, occurred in substantial part in this Judicial District. In addition, Keryx maintains offices within this Judicial District.

10. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the United States mail, interstate telephone communications, and the facilities of a national securities exchange.

### **PARTIES**

11. Plaintiff [REDACTED] as set forth in the accompanying certification, incorporated by reference herein, purchased Keryx common stock during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

12. Defendant Keryx is a Delaware corporation with its principal executive offices located at One Marina Park Drive, 12th Floor, Boston, Massachusetts 02210. Keryx's common stock trades on the NASDAQ Stock Market ("NASDAQ") under the symbol "KERX."

13. Defendant Gregory P. Madison ("Madison") was, at all relevant times, the Chief Executive Officer ("CEO") and a Director of Keryx.

14. Defendant Scott A. Holmes ("Holmes") was, at all relevant times, Chief Financial Officer ("CFO") of Keryx.

15. Defendants Madison and Holmes are collectively referred to hereinafter as the “Individual Defendants.” The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of Keryx’s reports to the SEC, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*, the market. Each defendant was provided with copies of the Company’s reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, each of these defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein, as those statements were each “group-published” information, the result of the collective actions of the Individual Defendants.

## **SUBSTANTIVE ALLEGATIONS**

### **Background**

16. Keryx is a biopharmaceutical company focused on marketing therapies for patients with renal disease. The Company’s product, Auryxia (ferric citrate), also known as Riona in Japan and Fexeric in Europe, is an oral, absorbable iron-based compound, that received marketing approval from the FDA in September 2014 for the control of serum phosphorus levels in patients with CKD on dialysis.

### **Materially False and Misleading Statements Issued During the Class Period**

17. The Class Period begins on February 25, 2016. On that day, Keryx issued a press release entitled, “Keryx Biopharmaceuticals Announces Fourth Quarter and Year-End 2015

Financial Results.” Therein, the Company, in relevant part, stated:

**BOSTON, MA**, February 25, 2016 – Keryx Biopharmaceuticals, Inc. (Nasdaq: KERX), a biopharmaceutical company focused on bringing innovative medicines to market for people with renal disease, today announced its financial results for the fourth quarter and year ended December 31, 2015. The company also reviewed its commercialization progress with Auryxia™ (ferric citrate), upcoming milestones and selected 2016 financial guidance.

“As we enter 2016, the fundamentals of Auryxia are solid, and we plan to build on that foundation to advance our launch in the U.S.,” said Greg Madison, chief executive officer of Keryx. “Importantly, the data readout expected in early second quarter from the ferric citrate phase 3 label expansion trial will be an important marker of our efforts to help people with pre-dialysis chronic kidney disease. Specifically, we believe that ferric citrate – which, through its novel mechanism of action, delivers iron orally through the body’s natural absorption process – could be the first FDA-approved oral medicine to treat iron deficiency anemia (IDA) in this patient population.”

## **FOURTH QUARTER 2015 AND RECENT BUSINESS HIGHLIGHTS**

### **Auryxia (ferric citrate) Commercialization**

- Auryxia net U.S. product sales for the fourth quarter of 2015 were \$4.8 million, based on approximately 7,850 prescriptions, an increase of 46 percent from the third quarter. For the full year 2015, Auryxia net U.S. product sales were \$10.1 million, representing greater than 18,000 prescriptions.
- Cumulative target physicians who have written a prescription for Auryxia increased more than 25 percent from the third quarter of 2015.
- Keryx completed its sales force expansion and now will have 95 sales representatives calling on target prescribers. The expansion enables increased reach and frequency of contact with physicians, dieticians and the entire dialysis care team.

### **Product Expansion Opportunities**

#### *Pivotal Phase 3 Trial Aimed at Increasing the Number of Adults Eligible for Treatment with Ferric Citrate*

- The 24-week pivotal phase 3 trial evaluating ferric citrate for the treatment of IDA in patients with stages 3-5 CKD completed in January, as planned. Early in the second quarter of 2016, Keryx expects to announce topline safety and efficacy results. If the results are successful, Keryx intends to submit a regulatory application for approval to the U.S. FDA in the third quarter of 2016, and submit the data for presentation at a fourth quarter 2016 medical conference.

*Potential Geographic Expansion*

- Keryx is seeking potential partners to make Fexeric<sup>®</sup> (ferric citrate) available to patients in Europe.

**Fourth Quarter and Year Ended December 31, 2015 Financial Results**

“In the fourth quarter of 2015, we strengthened our financial position through a re-alignment of our cost structure and an infusion of capital, which we expect will take the Auryxia franchise to cash flow positive,” said Scott Holmes, chief financial officer of Keryx. “For 2016, we expect prescription volume to increase between 20 percent and 35 percent on a sequential quarter basis, ramping as we realize the full impact of our expanded sales force. As we progress through 2016, we are committed to maintaining fiscal discipline, while advancing our business and supporting the continued growth of Auryxia.”

At December 31, 2015, the company had cash and cash equivalents of \$200.3 million.

**Total revenues** for the quarter ended December 31, 2015 were approximately \$5.8 million, compared to \$0.6 million during the same period in 2014. Total revenues for the quarter consisted of Auryxia net U.S. product sales of \$4.8 million, and license revenue of \$1.0 million associated with royalties received on ferric citrate net sales from Keryx’s Japanese partner. For the year ended 2015, total revenues were \$13.7 million, including \$10.1 million of Auryxia net U.S. product sales.

**Cost of goods sold** for the quarter ended December 31, 2015 was \$1.1 million. Cost of goods sold for the full year 2015 was \$4.5 million, which included \$2.6 million related to manufacturing charges incurred as a result of not fully utilizing planned production at certain of the company’s third party manufacturers as reported in the third quarter.

**Research and development expenses** for the quarter ended December 31, 2015 were \$8.0 million compared to \$5.8 million during the same period in 2014. The increase was primarily due to an increase in costs associated with our medical affairs efforts in support of Auryxia. For the full year 2015, total research and development expenses were \$36.7 million compared to \$51.5 million in 2014.

**Selling, general and administrative expenses** for the quarter ended December 31, 2015 were \$21.6 million, as compared to \$34.1 million during the same period in 2014. The decrease was related to a \$10.5 million decrease in non-cash stock-based compensation expense compared to the prior period, primarily related to expense recognized in connection with the first commercial sale of Auryxia in 2014. For the full year 2015, total selling, general and administrative expenses were \$81.4 million compared to \$70.1 million in 2014.

**Net loss** for the fourth quarter ended December 31, 2015 was \$37.8 million, or

\$0.36 per share, compared to a net loss of \$40.3 million, or \$0.44 per share, for the comparable quarter in 2014. For the full year 2015, net loss was \$123.1 million or \$1.19 per share compared to a net loss of \$111.5 million, or \$1.23 per share in 2014.

### **2016 Financial Guidance**

*This section contains forward-looking guidance about the financial outlook for Keryx Biopharmaceuticals*

**Auryxia net U.S. product sales:** Keryx expects full year 2016 Auryxia net U.S. product sales to be in the range of \$31 to \$34 million. The company expects sales to ramp throughout the year, as it realizes the full impact of its expanded sales force.

**Cash operating expenses:** Keryx reiterated its cash operating expenses in 2016 will be in the range of \$87 million to \$92 million. Cash operating expense guidance excludes cost of goods sold, license expenses, and other non-cash expenses.\*

18. On February 26, 2016, Keryx filed its Annual Report with the SEC on Form 10-K for the fiscal year ended December 31, 2015. The Company's Form 10-K was signed by Defendant Madison, and reaffirmed the Company's statements regarding its financial results and Auryxia made in the press release on February 25, 2016.

19. On April 28, 2016, Keryx issued a press release entitled, "Keryx Biopharmaceuticals Announces First Quarter 2016 Financial Results." Therein, the Company, in relevant part, stated:

**BOSTON, MA**, April 28, 2016 – Keryx Biopharmaceuticals, Inc. (Nasdaq: KERX), a biopharmaceutical company focused on bringing innovative medicines to people with renal disease, today announced its financial results for the first quarter ended March 31, 2016.

"In March, our recently expanded and fully trained field team began calling on physicians, dietitians and the entire dialysis care team to enhance awareness of Auryxia and drive increased adoption," said Greg Madison, chief executive officer of Keryx Biopharmaceuticals. "Through the expansion of our field team, we are able to increase the reach and frequency of contact with the treating community, and I am confident that with their efforts we will continue to increase uptake of Auryxia in people with chronic kidney disease (CKD) on dialysis."

Mr. Madison continued, "In the first quarter, we announced positive top-line



results from our pivotal Phase 3 study evaluating ferric citrate in people with non-dialysis dependent CKD struggling with iron deficiency anemia (IDA). These results bring us one step closer to treating another important complication of CKD. The rapid, durable and significant responses observed with ferric citrate in the study were a major milestone for Keryx and confirmed the unique attributes of ferric citrate's mechanism of action, which delivers iron orally through the body's natural absorption process. As we look ahead, our top priorities for this year are to increase adoption of Auryxia in the dialysis setting, submit a regulatory application seeking label expansion, and prepare for potential launch in 2017 in the new indication."

## **FIRST QUARTER 2016 BUSINESS HIGHLIGHTS**

### **Auryxia Commercialization**

- Auryxia net U.S. product sales for the first quarter of 2016 were \$5.6 million compared with \$0.4 million in the first quarter of 2015. First quarter 2016 Auryxia product sales resulted from approximately 9,150 prescriptions, which represented 17 percent growth in total prescriptions compared to the fourth quarter of 2015.
- In the first quarter of 2016, cumulative target physicians who have written a prescription for Auryxia increased approximately 25 percent from the fourth quarter of 2015. This reflects continued efforts to increase the breadth of physicians prescribing Auryxia.

### **Potential Label Expansion**

#### *Pivotal Phase 3 Trial Aimed at Increasing the Number of Adults Eligible for Treatment with Ferric Citrate*

- In March, the company announced that its 24-week pivotal Phase 3 trial evaluating ferric citrate for the treatment of iron deficiency anemia in adults with stage 3-5 non-dialysis dependent CKD demonstrated statistically significant differences between ferric citrate- and placebo-treated patients for the primary and all pre-specified secondary endpoints. Specifically, 52 percent (61/117) of patients who received ferric citrate achieved the primary endpoint, which was a 1g/dL or greater rise in hemoglobin at any time point during the 16-week randomized efficacy period, compared with 19 percent (22/115) in the placebo group (p<0.001). Importantly, the vast majority of patients who achieved the primary endpoint (57/61) had a durable response. In terms of safety, during the randomized efficacy period, the majority of adverse events reported were mild to moderate, with the most common being diarrhea. Read the full press release of the top-line Phase 3 results [here](#).

- The company intends to submit an sNDA for approval to the U.S. FDA in the third quarter of 2016.
- Keryx plans to submit detailed Phase 3 results for presentation at the American Society of Nephrology's 2016 Kidney Week taking place November 15 – 20, 2016, and plans to submit data for possible publication in a peer reviewed medical journal.

### **Corporate**

- In April, Keryx announced new appointments and changes to its board of directors.

### **First Quarter Ended March 31, 2016 Financial Results**

“As a result of our continued focus on commercial execution and fiscal discipline, we met or exceeded all of our internal financial goals in the first quarter and, therefore, are progressing nicely toward achieving our previously stated 2016 full year financial objectives,” said Scott Holmes, chief financial officer of Keryx. “The passion and commitment that my colleagues at Keryx bring to work each day both in the field and in our home office will drive us to achieve our goals in 2016 and beyond.”

At March 31, 2016, the company had cash and cash equivalents of \$170.5 million.

**Total revenues** for the quarter ended March 31, 2016 were approximately \$6.8 million, compared with \$1.2 million during the same period in 2015. Total revenues for the quarter consisted of Auryxia net U.S. product sales of \$5.6 million, and license revenue of \$1.2 million associated with royalties received on ferric citrate net sales from Keryx's Japanese partner.

**Cost of goods sold** for the quarter ended March 31, 2016 was \$1.1 million or 19 percent of Auryxia net U.S. product sales, as compared with \$0.1 million or 18 percent during the same period in 2015.

**Research and development expenses** for the quarter ended March 31, 2016 were \$7.6 million compared with \$9.6 million during the same period in 2015. The decrease was primarily due to a decrease in costs associated with the company's recently completed Phase 3 clinical trial evaluating ferric citrate for the treatment of IDA in adults with stage 3-5 non-dialysis dependent CKD.

**Selling, general and administrative expenses** for the quarter ended March 31, 2016 were \$20.8 million, as compared with \$18.9 million during the same period in 2015. The increase was primarily related to incremental costs associated with hiring and onboarding of Keryx's expanded field team.

**Net loss** for the first quarter ended March 31, 2016 was \$41.0 million, or \$0.39 per share, compared to a net loss of \$27.7 million, or \$0.28 per share, for the comparable quarter in 2015. The company's net loss for the quarter ended March 31, 2016 includes \$15.7 million in non-cash interest expense related to amortization of the debt discount on its convertible senior notes, as well as a \$2.0 million non-cash charge related to the increase in fair value of the derivative liability that was recorded in connection with the issuance of the convertible senior notes.

**Cash Operating Expenses (a non-GAAP measurement)\***

Total operating expenses (excluding cost of goods sold and license expenses) for the first quarter ended March 31, 2016 were \$28.4 million, which included \$4.5 million in non-cash expenses, thereby making cash operating expenses \$23.9 million for the first quarter. During the same period in 2015, total operating expenses were \$28.5 million, which included \$4.5 million in non-cash expenses, thereby making cash operating expenses \$24.0 million. Non-cash expenses referenced above include stock-based compensation expense, depreciation expense and certain non-cash commercial expenses, such as product samples.

**2016 Financial Guidance**

*This section contains forward-looking guidance about the financial outlook for Keryx Biopharmaceuticals*

Keryx today reiterated the following financial guidance provided in February 2016.

**Auryxia net U.S. product sales:** Keryx expects full year 2016 Auryxia net U.S. product sales to be in the range of \$31 to \$34 million, and expects sales to ramp throughout the year, as it realizes the full impact of its expanded field team.

**Cash operating expenses:** Keryx expects its 2016 cash operating expenses will be in the range of \$87 to \$92 million. Cash operating expense guidance excludes cost of goods sold, license expenses, and other non-cash expenses.\*

20. On the same day, April 28, 2016, Keryx filed its Quarterly Report with the SEC on Form 10-Q for the fiscal quarter ended March 31, 2016. The Company's Form 10-Q was signed by Defendant Holmes, and reaffirmed the Company's statements regarding its financial results and Auryxia made in the press release issued the same day.

21. The above statements contained in ¶¶17-20 were materially false and/or

misleading, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, these statements were false and/or misleading statements and/or failed to disclose: (1) that the Company was experiencing production-related difficulties in converting API to finished drug product; (2) that the issue was resulting in decreased production yields of finished drug product; (3) that, as a result, the Company would, and did exhaust its reserve of finished drug product; and (4) that, as a result of the foregoing, Defendants' statements about Keryx's business, operations, and prospects, were false and misleading and/or lacked a reasonable basis.

### **Disclosures at the End of the Class Period**

22. On August 1, 2016, Keryx disclosed that that an interruption in the supply of Auryxia tablets was imminent due to a production-related issue converting API to finished drug product. More completely, and in relevant part, the Company stated:

**BOSTON, MA**, August 1, 2016 – Keryx Biopharmaceuticals, Inc. (Nasdaq: KERX) today announced that an interruption in the supply of Auryxia<sup>®</sup> (ferric citrate) tablets is imminent due to a production-related issue converting active pharmaceutical ingredient (API) to finished drug product. Keryx expects to make Auryxia available to patients when supply of Auryxia is back to adequate levels, which Keryx anticipates will be during the fourth quarter of 2016.

“We take our responsibility to patients and the treating community very seriously and recognize the impact this interruption of supply will cause for patients and their healthcare providers,” said Greg Madison, chief executive officer of Keryx Biopharmaceuticals. “Our field-based teams have been doing an outstanding job educating the community on the benefits of Auryxia and will be a critical resource during this supply interruption as we continue to support healthcare providers and their patients with hyperphosphatemia.”

### **About the Supply Interruption**

Keryx has determined that a supply interruption is going to occur due to a production-related issue in converting API to finished drug product at its contract manufacturer. This issue has resulted in variable production yields of finished drug product and, as a result, the company has exhausted its reserve of finished drug product. At this time, current inventories of Auryxia are not sufficient to

ensure uninterrupted patient access to this medicine. The supply interruption does not affect the safety profile of currently available Auryxia. Keryx is working with its existing manufacturer to resolve the production-related issue and rebuild adequate supply. In addition, since approval of Auryxia in 2014, Keryx has been working to bring a secondary manufacturer online to supply finished drug product. The company recently filed for approval of this manufacturer with the U.S. Food and Drug Administration (FDA) and the FDA has assigned a Prescription Drug User Fee Act (PDUFA) action date of November 13, 2016. The company expects to restore adequate supply of Auryxia and to make Auryxia available to patients during the fourth quarter of 2016.

This supply interruption does not affect the supply of ferric citrate (marketed as Riona<sup>®</sup>) manufactured and sold by Keryx's Japanese partner.

23. On this news, Keryx's stock price fell \$2.64 per share, or 35.8%, to close at \$4.72 per share on August 1, 2016, on unusually heavy trading volume.

#### **CLASS ACTION ALLEGATIONS**

24. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class, consisting of all persons and entities that acquired Keryx's securities between February 25, 2016, and August 1, 2016, inclusive, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

25. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Keryx's common stock actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are at least hundreds or thousands of members in the proposed Class. Millions of Keryx shares were traded publicly during the Class Period on the NASDAQ. As of April 22, 2016, Keryx had

105,820,947 shares of common stock outstanding. Record owners and other members of the Class may be identified from records maintained by Keryx or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

26. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

27. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

28. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period omitted and/or misrepresented material facts about the business, operations, and prospects of Keryx; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

29. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it impossible for members of the Class to individually

redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

### **UNDISCLOSED ADVERSE FACTS**

30. The market for Keryx's securities was open, well-developed and efficient at all relevant times. As a result of these materially false and/or misleading statements, and/or failures to disclose, Keryx's securities traded at artificially inflated prices during the Class Period. Plaintiff and other members of the Class purchased or otherwise acquired Keryx's securities relying upon the integrity of the market price of the Company's securities and market information relating to Keryx, and have been damaged thereby.

31. During the Class Period, Defendants materially misled the investing public, thereby inflating the price of Keryx's securities, by publicly issuing false and/or misleading statements and/or omitting to disclose material facts necessary to make Defendants' statements, as set forth herein, not false and/or misleading. The statements and omissions were materially false and/or misleading because they failed to disclose material adverse information and/or misrepresented the truth about Keryx's business, operations, and prospects as alleged herein.

32. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Keryx's financial well-being and prospects. These material misstatements and/or omissions had the cause and effect of creating in the market an unrealistically positive assessment of the Company and its financial well-being and prospects, thus causing the Company's securities to be overvalued and artificially inflated at all relevant

times. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at artificially inflated prices, thus causing the damages complained of herein when the truth was revealed.

### **LOSS CAUSATION**

33. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiff and the Class.

34. During the Class Period, Plaintiff and the Class purchased Keryx's securities at artificially inflated prices and were damaged thereby. The price of the Company's securities significantly declined when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, causing investors' losses.

### **SCIENTER ALLEGATIONS**

35. As alleged herein, Defendants acted with scienter since Defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and/or misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, Defendants, by virtue of their receipt of information reflecting the true facts regarding Keryx, his/her control over, and/or receipt and/or modification of Keryx's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning Keryx, participated in the fraudulent scheme alleged herein.



**APPLICABILITY OF PRESUMPTION OF RELIANCE  
(FRAUD-ON-THE-MARKET DOCTRINE)**

36. The market for Keryx's securities was open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, Keryx's securities traded at artificially inflated prices during the Class Period. On July 26, 2016, the Company's stock price closed at a Class Period high of \$7.53 per share. Plaintiff and other members of the Class purchased or otherwise acquired the Company's securities relying upon the integrity of the market price of Keryx's securities and market information relating to Keryx, and have been damaged thereby.

37. During the Class Period, the artificial inflation of Keryx's stock was caused by the material misrepresentations and/or omissions particularized in this Complaint causing the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Keryx's business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of Keryx and its business, operations, and prospects, thus causing the price of the Company's securities to be artificially inflated at all relevant times, and when disclosed, negatively affected the value of the Company stock. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at such artificially inflated prices, and each of them has been damaged as a result.

38. At all relevant times, the market for Keryx's securities was an efficient market for the following reasons, among others:

(a) Keryx stock met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) As a regulated issuer, Keryx filed periodic public reports with the SEC and/or the NASDAQ;

(c) Keryx regularly communicated with public investors *via* established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and/or

(d) Keryx was followed by securities analysts employed by brokerage firms who wrote reports about the Company, and these reports were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

39. As a result of the foregoing, the market for Keryx's securities promptly digested current information regarding Keryx from all publicly available sources and reflected such information in Keryx's stock price. Under these circumstances, all purchasers of Keryx's securities during the Class Period suffered similar injury through their purchase of Keryx's securities at artificially inflated prices and a presumption of reliance applies.

40. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the Class's claims are, in large part, grounded on Defendants' material misstatements and/or omissions. Because this action involves Defendants' failure to disclose material adverse information regarding the Company's business operations and financial prospects—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the

sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

**NO SAFE HARBOR**

41. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as “forward-looking statements” when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of Keryx who knew that the statement was false when made.

**FIRST CLAIM**  
**Violation of Section 10(b) of The Exchange Act and**  
**Rule 10b-5 Promulgated Thereunder**  
**Against All Defendants**

42. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

43. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing

public, including Plaintiff and other Class members, as alleged herein; and (ii) cause Plaintiff and other members of the Class to purchase Keryx's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, defendants, and each of them, took the actions set forth herein.

44. Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Keryx's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

45. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about Keryx's financial well-being and prospects, as specified herein.

46. These defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Keryx's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary in order to make the statements made about Keryx and its business operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a

course of business which operated as a fraud and deceit upon the purchasers of the Company's securities during the Class Period.

47. Each of the Individual Defendants' primary liability, and controlling person liability, arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of these defendants, by virtue of their responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) each of these defendants enjoyed significant personal contact and familiarity with the other defendants and was advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (iv) each of these defendants was aware of the Company's dissemination of information to the investing public which they knew and/or recklessly disregarded was materially false and misleading.

48. The defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Keryx's financial well-being and prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and/or misstatements of the Company's business, operations, financial well-being, and prospects throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to

obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

49. As a result of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of Keryx's securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of the Company's securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trades, and/or in the absence of material adverse information that was known to or recklessly disregarded by Defendants, but not disclosed in public statements by Defendants during the Class Period, Plaintiff and the other members of the Class acquired Keryx's securities during the Class Period at artificially high prices and were damaged thereby.

50. At the time of said misrepresentations and/or omissions, Plaintiff and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff and the other members of the Class and the marketplace known the truth regarding the problems that Keryx was experiencing, which were not disclosed by Defendants, Plaintiff and other members of the Class would not have purchased or otherwise acquired their Keryx securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

51. By virtue of the foregoing, Defendants have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

52. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases

and sales of the Company's securities during the Class Period.

**SECOND CLAIM**  
**Violation of Section 20(a) of The Exchange Act**  
**Against the Individual Defendants**

53. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

54. The Individual Defendants acted as controlling persons of Keryx within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, and their ownership and contractual rights, participation in and/or awareness of the Company's operations and/or intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiff contends are false and misleading. The Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

55. In particular, each of these Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

56. As set forth above, Keryx and the Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and/or omissions as alleged in this Complaint. By virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to Section

20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

- (a) Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;
- (b) Awarding compensatory damages in favor of Plaintiff and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;
- (c) Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and
- (d) Such other and further relief as the Court may deem just and proper.

**JURY TRIAL DEMANDED**

Plaintiff hereby demands a trial by jury.

Dated: August 2, 2016

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