UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

TIM KARTH, Individually and on Behalf of All Others Similarly Situated,

Plaintiff,

v.

KERYX BIOPHARMACEUTICALS, INC., RON BENTSUR, SCOTT A. HOLMES, GREGORY P. MADISON, and JAMES F. OLIVIERO,

Defendants.

Case No.: 1:16-cv-11745

CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

JURY TRIAL DEMANDED

Plaintiff Tim Karth ("Plaintiff"), by and through his attorneys, alleges upon personal knowledge as to himself, and upon information and belief as to all other matters, based upon the investigation conducted by and through his attorneys, which included, among other things, a review of documents filed by Defendants (as defined below) with the United States Securities and Exchange Commission (the "SEC"), conference call transcripts, news reports, press releases issued by Defendants, and other publicly available documents, as follows:

NATURE AND SUMMARY OF THE ACTION

1. This is a federal securities class action on behalf of all investors who purchased or otherwise acquired Defendant Keryx Biopharmaceuticals, Inc. ("Keryx" or the "Company") securities between September 2, 2013 through August 1, 2016 inclusive (the "Class Period"). This action is brought on behalf of the Class for violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (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.

2. Keryx is a biopharmaceutical company focused on bringing therapies to market to treat people with kidney disease. The Company currently only markets and sells one product in the United States, Auryxia (ferric citrate), prescribed to control serum phosphorus levels in patients with chronic kidney disease on dialysis.

3. Throughout the Class Period, Keryx misled its shareholders to believe that it would, and did, contract with multiple manufacturers to convert Auryxia's active pharmaceutical ingredient ("API") to the finished drug product. The Company did so by repeatedly referencing "third party manufacturers" and "contract manufacturers" in its public filings. In reality, Keryx intended to, and ultimately did, contract with only a single contract manufacturer to produce its only marketed drug. Keryx's filings therefore concealed the true risks associated with the manufacturing and supply of Keryx's only marketed product.

4. On August 1, 2016, Keryx issued a press release stating that because of production difficulties on the part of its only contract manufacturer, the Company would halt the distribution of Auryxia until at least October 2016 and that the Company was also withdrawing its financial guidance for 2016.

5. The same day, Keryx held an earnings call during which the Company's Chief Executive Officer admitted that the Company knew about difficulties in the production of its only marketed drug months prior to informing shareholders of the production issues.

6. On this news, the Company's stock declined by $2.64, or 36%, to close at $4.72 on August 1, 2016, causing tens of millions in losses to investors.

7. Throughout the Class Period, Defendants made 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 intended to and did contract with only a single contract manufacturer to convert its API to finished drug product; (2) that the Company lacked adequate inventory controls; (3) that at some point during the Class Period, Defendants became aware but did not disclose that its contract manufacturer was experiencing difficulties in production; (4) that these production difficulties would cause the depletion of Keryx's Auryxia inventory, and (5) that, as a result of the foregoing, the Company's financial guidance, as well as Defendants' statements about Keryx's business, operations, and prospects, were false and misleading and/or lacked a reasonable basis.

8. 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

9. The federal law claims asserted herein arise under §§ 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, as well as under the common law.

10. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §1331 and § 27 of the Exchange Act, 15 U.S.C. § 78aa.

11. This Court has jurisdiction over each Defendant named herein because each Defendant is an individual or corporation who has sufficient minimum contacts with this District so as to render the exercise of jurisdiction by the District Court permissible under traditional notions of fair play and substantial justice.

12. Venue is proper in this District pursuant to § 27 of the Exchange Act, 15 U.S.C. § 78aa and 28 U.S.C. § 1931(b), as the Company has its principal executive offices located in this District and conducts substantial business here.

13. In connection with the acts, omissions, conduct and other wrongs in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce including but not limited to the United States mail, interstate telephone communications and the facilities of the national securities exchange.

PARTIES

14. Plaintiff Tim Karth was a shareholder of the Company during the Class Period. As set forth in the accompanying certification, incorporated by reference herein, Plaintiff acquired and held shares of the Company at artificially inflated prices during the Class Period and has been damaged by the revelation of the Company's material misrepresentations and material omissions.

15. Defendant Keryx Biopharmaceuticals, Inc., is a Delaware corporation with its principal place executive offices located at One Marina Park Drive, 12th Floor, Boston,

Massachusetts 02210. The Company trades on the NASDAQ stock exchange under the ticker symbol "KERX" and claims that it is a biopharmaceutical company focused on providing therapies for patients with renal disease in the United States.

16. Defendant Ron Bentsur ("Bentsur") was the Chief Executive Officer and a director of Keryx from May 2009 to April 30, 2015.

17. Defendant Scott A. Holmes ("Holmes") has been the Chief Financial Officer since July 2015.

18. Defendant Gregory P. Madison ("Madison") has been the Chief Executive Officer of Keryx since April 30, 2015 and has been a director of the Company since March 2015.

19. Defendant James F. Oliviero ("Oliviero") was the Chief Financial Officer of Keryx from May 2003 to July 2015.

20. Collectively, Bentsur, Holmes, Madison, and Oliviero are referred to throughout this complaint as the "Individual Defendants."

21. The Individual Defendants, because of their positions at the Company, possessed the power and authority to control the content and form of the Company's annual reports, quarterly reports, press releases, investor presentations, and other materials provided to the SEC, securities analysts, money and portfolio managers and investors, *i.e.*, the market. The Individual Defendants authorized the publication of the documents, presentations, and materials alleged herein to be misleading prior to its issuance and had the ability and opportunity to prevent the issuance of these false statements or to cause them to be corrected. Because of their positions within the Company and their access to material non-public information available to them but not to the public, the Individual 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 being made were false and misleading. The Individual Defendants are liable for the false statements pleaded herein.

SUBSTANTIVE ALLEGATIONS

Background

22. Keryx is a biopharmaceutical company purportedly focused on bringing therapies to market for patients with renal disease. The Company's only U.S. product, Auryxia (ferric citrate), is an oral, absorbable iron-based compound taken to control serum phosphorus levels in patients with chronic kidney disease on dialysis.

23. Keryx submitted its New Drug Application for Zerenex (later re-named Auryxia) to the U.S. Food and Drug Adminisration ("FDA") in September 2013.

24. In January 2014, Keryx executed a contract with Norwich Pharmaceuticals, Inc. ("Norwich") to convert Auryxia's API to finished drug product (Keryx's "Contract Manufacturer"). Norwich has at all times since then been Keryx's only Contract Manufacturer.

25. The FDA approved Auryxia in September 2014 and Keryx began selling Auryxia in the U.S. in December 2014. Auryxia remains Keryx's only marketed product in the U.S.

Materially False and Misleading Statements Issued During the Class Period

26. The Class Period begins on September 2, 2013. On that day, Keryx filed with the SEC its Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, repeatedly referencing "third-party manufacturers" and "contract manufacturers," falsely signifying to investors that it intended to engage multiple manufacturers to produce its drug product. These representations were knowingly false and misleading given that just months later, Keryx contracted with a single Contract Manufacturer to produce its only marketed product. These false and misleading statements and were never corrected by Keryx.

27. The Company's September 2, 2013 Form 10-Q contained certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"), signed by Defendants Bentsur and Oliviero, who each certified:

> 1. I have reviewed this annual report on Form 10-K 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 consolidated 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.

28. On November 4, 2013, Keryx filed with the SEC its Quarterly Report on Form 10-Q for the quarter ended September 30, 2013, repeatedly referencing "third-party manufacturers" and "contract manufacturers," falsely signifying to investors that it intended to engage multiple manufacturers to produce its drug product. These representations were knowingly false and misleading given that just months later, Keryx contracted with a single Contract Manufacturer to produce its only marketed product. These false and misleading statements and were never corrected by Keryx.

29. The Company's November 4, 2013 Form 10-Q was signed by Defendant Oliviero and contained certifications pursuant to SOX, signed by Defendants Bentsur and Oliviero, substantially similar to the certifications described in ¶27, *supra*.

30. On March 13, 2014, Keryx filed with the SEC its Annual Report on Form 10-K for the year ended December 31, 2013. The Company's 10-K repeatedly referenced "third-party manufacturers" and "contract manufacturers," misleading investors to believe that it had engaged multiple manufacturers to produce Auryxia. Such representations were knowingly false given that

the Company had only contracted with a single Contract Manufacturer to produce the Company's only marketed product. The Company's 10-K also provided:

> **SUPPLY AND MANUFACTURING**
>
> 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 candidate for use in clinical trials and for future sales.
>
> We believe that we have established contract manufacturing relationships for the supply of Zerenex to ensure that we will have sufficient material for clinical trials and commercial launch. In addition, we are establishing the basis for long-term commercial production capabilities. We have committed to build inventory in anticipation for the launch of Zerenex in 2014. As with any supply program, obtaining raw materials of the required quality and quantity cannot be guaranteed and we cannot ensure that we will be successful in this endeavor.
>
> Prior to the time of commercial sale, to the extent possible and commercially practicable, we intend to seek to engage additional suppliers for Zerenex to produce Zerenex under current Good Manufacturing Practice, or cGMP, regulations. Our third-party manufacturers have a limited number of facilities in which Zerenex can be produced and will have limited experience in manufacturing Zerenex in quantities sufficient for commercialization. Our third-party manufacturers will have other clients and may have other priorities that could affect their ability to perform the work satisfactorily and/or on a timely basis. Both of these occurrences would be beyond our control.
>
> We expect to similarly rely on contract manufacturing relationships for any products that we may in-license or acquire in the future. However, there can be no assurance that we will be able to successfully contract with such manufacturers on terms acceptable to us, or at all.

31. The Company's March 13, 2014 Form 10-K was signed by Defendant Bentsur and contained certifications pursuant to SOX, signed by Defendants Bentsur and Oliviero, substantially similar to the certifications described in ¶27, *supra*.

32. On May 8, 2014, Keryx filed with the SEC its Quarterly Report on Form 10-Q for the quarter ended March 31, 2014, repeatedly referencing "third-party manufacturers" and "contract manufacturers," misleading investors to believe that it had engaged multiple

manufacturers to produce Auryxia. Such representations were knowingly false given that the Company had only contracted with a single Contract Manufacturer to produce the Company's only marketed product.

33. The Company's May 8, 2014 Form 10-Q was signed by Defendant Oliviero and contained certifications pursuant to SOX, signed by Defendants Bentsur and Oliviero, substantially similar to the certifications described in ¶27, *supra*.

34. On September 7, 2014, Keryx filed with the SEC its Quarterly Report on Form 10-Q for the quarter ended June 30, 2014, repeatedly referencing "third-party manufacturers" and "contract manufacturers," misleading investors to believe that it had engaged multiple manufacturers to produce Auryxia. Such representations were knowingly false given that the Company had only contracted with a single Contract Manufacturer to produce the Company's only marketed product.

35. The Company's September 7, 2014 Form 10-Q was signed by Defendant Oliviero and contained certifications pursuant to SOX, signed by Defendants Bentsur and Oliviero, substantially similar to the certifications described in ¶27, *supra*.

36. On November 6, 2014, Keryx filed with the SEC its Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, repeatedly referencing "third-party manufacturers" and "contract manufacturers," misleading investors to believe that it had engaged multiple manufacturers to produce Auryxia. Such representations were knowingly false given that the Company had only contracted with a single Contract Manufacturer to produce the Company's only marketed product.

37. The Company's November 6, 2014 Form 10-Q was signed by Defendant Oliviero and contained certifications pursuant to SOX, signed by Defendants Bentsur and Oliviero, substantially similar to the certifications described in ¶27, *supra*.

38. On February 27, 2015, Keryx filed with the SEC its Annual Report on Form 10-K for the year ended December 31, 2014. The Company's Form 10-K was signed by Defendants Bentsur and Oliviero and touted Keryx's manufacturing and supply network:

> **SUPPLY AND MANUFACTURING**
>
> We have limited experience in manufacturing products for clinical or commercial purposes. We intend to continue, in whole or in part, to use third parties to manufacture and analytically test our drug, Auryxia, for use in clinical trials and for sales.
>
> We believe that we have established contract manufacturing relationships for the supply of Auryxia to ensure that we will have sufficient material for clinical trials and the ongoing commercial launch. In addition, we are establishing the basis for long-term commercial production capabilities to supply the potential expanded demand for Auryxia in future years. As with any supply program, obtaining raw materials of the required quality and quantity cannot be guaranteed and we cannot ensure that we will be successful in this endeavor.
>
> As we continue to build inventory for the expanded commercialization of Auryxia, we intend to engage additional suppliers to produce Auryxia under current Good Manufacturing Practice, or cGMP, regulations. Our third-party manufacturers have a limited number of facilities in which Auryxia can be produced and will have limited experience in manufacturing Auryxia in quantities sufficient for commercialization. Our third-party manufacturers will have other clients and may have other priorities that could affect their ability to perform the work satisfactorily and/or on a timely basis. Both of these occurrences would be beyond our control.
>
> We expect to similarly rely on contract manufacturing relationships for any products that we may in-license or acquire in the future. However, there can be no assurance that we will be able to successfully contract with such manufacturers on terms acceptable to us, or at all.

39. The Company's February 27, 2015 Form 10-K was signed by Defendant Bentsur and contained certifications pursuant to SOX, signed by Defendants Bentsur and Oliviero, substantially similar to the certifications described in ¶27, *supra*.

40. On May 4, 2015 Keryx filed with the SEC its Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, repeatedly referencing "third-party manufacturers" and "third party contract manufacturers," despite the fact that during this period, Keryx had only one contract manufacturer.

41. The Company's May 4, 2015 Form 10-Q was signed by Defendant Oliviero and contained certifications pursuant to SOX, signed by Defendants Madison and Oliviero, substantially similar to the certifications described in ¶27, *supra*.

42. On August 6, 2015 Keryx filed with the SEC its Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, repeatedly referencing "third-party manufacturers" and "third party contract manufacturers," despite the fact that during this period, Keryx had only one contract manufacturer.

43. The Company's August 6, 2015 Form 10-Q was signed by Defendant Holmes and contained certifications pursuant to SOX, signed by Defendants Madison and Holmes, substantially similar to the certifications described in ¶27, *supra*.

44. On October 29, 2015 Keryx filed with the SEC its Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, repeatedly referencing "third-party manufacturers" and "third party contract manufacturers," despite the fact that during this period, Keryx had only one contract manufacturer.

45. The Company's October 29, 2015 Form 10-Q was signed by Defendant Holmes and contained certifications pursuant to SOX, signed by Defendants Madison and Holmes, substantially similar to the certifications described in ¶27, *supra*.

46. On February 25, 2016, Keryx issued a press release entitled "Keryx Biopharmaceuticals Announces Fourth Quarter and Year-End 2015 Financial Results." The Company filed the same press release on Form 8-K with the SEC. Therein, the Company stated, among other things:

> 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**
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> **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® (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.

47. On February 26, 2016 Keryx filed with the SEC its Annual Report on Form 10-K for the year ended December 31, 2015, signed by Defendant Madison and reiterating the financial results and 2016 guidance contained in the Company's February 25, 2016 press release. The Company's Form 10-K also touted Keryx's manufacturing and supply network:

SUPPLY AND MANUFACTURING

We have limited experience in manufacturing products for clinical or commercial purposes. We intend to continue, in whole or in part, to use third parties to manufacture and analytically test our drug, Auryxia, for use in clinical trials and for sales.

We believe that we have established contract manufacturing relationships for the supply of Auryxia to ensure that we will have sufficient material for clinical trials and the ongoing commercial launch. In addition, we are establishing the basis for long-term commercial production capabilities to supply the potential expanded demand for Auryxia in future years. As with any supply program, obtaining raw materials of the required quality and quantity cannot be guaranteed and we cannot ensure that we will be successful in this endeavor.

> As we continue to build inventory for the expanded commercialization of Auryxia, we intend to engage additional suppliers to produce Auryxia under current Good Manufacturing Practice, or cGMP, regulations. Our third-party manufacturers have a limited number of facilities in which Auryxia can be produced and will have limited experience in manufacturing Auryxia in quantities sufficient for commercialization. Our third-party manufacturers will have other clients and may have other priorities that could affect their ability to perform the work satisfactorily and/or on a timely basis. Both of these occurrences would be beyond our control.
>
> We expect to similarly rely on contract manufacturing relationships for any products that we may in-license or acquire in the future. However, there can be no assurance that we will be able to successfully contract with such manufacturers on terms acceptable to us, or at all.

48. The Company's February 26, 2016 Form 10-K contained certifications pursuant to SOX, signed by Defendants Madison and Holmes, substantially similar to the certifications described in ¶27, *supra*.

49. On April 28, 2016, Keryx issued a press release entitled "Keryx Biopharmaceuticals Announces First Quarter 2016 Financial Results." The Company filed the same press release on Form 8-K with the SEC. Therein, the Company stated, among other things:

> 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.

50. The same day, Keryx filed its Quarterly Report with the SEC on Form 10-Q for the quarter ended March 31, 2016. The Company's Form 10-Q was signed by Defendant Holmes, and reaffirmed the Company's financial results previously announced on August 4, 2015. The Form 10-Q contained certifications pursuant to SOX, signed by Defendants Madison and Homes, substantially similar to the certifications described in ¶27, *supra*.

51. Also on April 28, 2016, Keryx held an earnings conference call to discuss the Company's first quarter 2016 financial results. During this call, Defendant Madison assured investors of the Company's strong financial position and a solid infrastructure:

> We achieved a major milestone in the first quarter with positive top-line results from our pivotal Phase 3 study evaluating Auryxia for treatment of iron deficiency anemia in non-dialysis-dependent CKD patients. The study met its primary endpoint and all prespecified secondary endpoints with statistical significance.
>
> With these results, we enhance our understanding and provide a greater clarity on the potential to expand the label of Auryxia in this important indication. We are

maintaining a strong financial position heading into the first quarter, with more than $170 million in cash.

And finally, with a solid commercial infrastructure in place and the potential to expand Auryxia's label, we recently added two new Board members with deep relevant industry experience to guide Keryx as we continue to grow and evolve.

Disclosures at the End of the Class Period

52. On August 1, 2016, Keryx issued a press release withdrawing the Company's 2016 financial guidance and stating that it was halting the distribution of Auryxia until at least October 2016 due to a production-related issue at the Company's contract manufacturer. The press release stated, in relevant part:

Keryx Biopharmaceuticals, Inc. (Nasdaq:KERX) today announced that an interruption in the supply of Auryxia® (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®) manufactured and sold by Keryx's Japanese partner.

Second Quarter Business Update

- Auryxia net U.S. product sales for the second quarter of 2016 were $8.3 million compared with $1.8 million in the second quarter of 2015. Second quarter 2016 sales resulted from approximately 13,150 prescriptions, which represents 44 percent growth compared to the first quarter of 2016.
- Keryx has met with the FDA to discuss expanding the label of ferric citrate to include the treatment of iron deficiency anemia (IDA) in stages 3 – 5 non-dialysis dependent chronic kidney disease (CKD) patients based on the results of the company's Phase 3 pivotal study in this patient population. The company expects to file a supplemental new drug application (sNDA) with the FDA late in the third quarter of 2016.
- Keryx submitted several abstracts for potential presentation at the upcoming American Society of Nephrology's (ASN) 2016 Kidney Week taking place November 15 – 20, 2016 based on its pivotal Phase 3 trial in this patient population.

Second Quarter Ended June 30, 2016 Financial Results

"Although we are withdrawing our financial guidance for 2016, we believe we are well positioned financially to manage through this interruption in supply of Auryxia," said Scott Holmes, chief financial officer of Keryx. "With our strong balance sheet and an appropriately aligned cost structure, we will ensure that we continue to make the necessary investments to emerge from this unexpected event in the best possible position."
At June 30, 2016, the company had cash and cash equivalents of $155.8 million.

Total revenues for the quarter ended June 30, 2016 were approximately $9.3 million, compared with$2.5 million during the same period in 2015. Total revenues for the second quarter consisted of Auryxia net U.S. product sales of $8.3 million and license revenue of $1.0 million associated with royalties received on Riona® (ferric citrate) net sales from Keryx's Japanese partner. At June 30, 2016,

Keryx had deferred revenue of $3.4 million, which represents Auryxia product shipped to customers, not yet dispensed as a patient prescription.

Cost of goods sold for the quarter ended June 30, 2016 was $5.1 million, as compared with $0.3 million during the same period in 2015. Cost of goods sold for the quarter ended June 30, 2016included $1.9 million in inventory write-offs associated with the production issue mentioned above.

Research and development expenses for the quarter ended June 30, 2016 were $7.0 million, as compared to $8.0 million during the same period in 2015. The decrease was primarily due to a reduction in clinical expenses 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 June 30, 2016 were $20.2 million, as compared with $20.8 million during the same period in 2015.

Net loss for the quarter ended June 30, 2016 was $44.7 million, or $0.42 per share, compared to a net loss of $26.9 million, or $0.26 per share, for the comparable quarter in 2015. The company's net loss for the quarter ended June 30, 2016 included $18.5 million in non-cash interest expense related to amortization of the debt discount on its convertible senior notes issued in October 2015, as well as a $2.7 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 second quarter ended June 30, 2016 were $27.2 million, which included $4.8 million in non-cash expenses, thereby making cash operating expenses $22.4 million for the second quarter. During the same period in 2015, total operating expenses were $28.7 million, which included $4.6 million in non-cash expenses, thereby making cash operating expenses $24.1 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

As a result of the supply interruption, Keryx is withdrawing its 2016 financial guidance.

53. Also on August 1, 2016, the Company held an earnings call during which Defendant Madison admitted that it the Company had been aware of production difficulties for months:

> Now, let me go into a bit more detail on some of the key areas of the supply interruption and steps we are taking to rebuild supply. We currently have a single source drug product contract manufacturer, or CMO. This manufacturer turns active ingredients, or API, of Auryxia into tablets, and they have been successfully producing commercial batches for approximately two years.
>
> ***In [the] past few months***, we began experiencing difficulties converting active pharmaceutical ingredients, or API, to finish drug product, which resulted in variable yields, as compared to our historical rate. We had been manag[ing] supply levels efficiently even with increased demand generated by our field team in the second quarter.

(emphasis added).

CLASS ACTION ALLEGATIONS

54. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of a class of all persons and entities who purchased or otherwise acquired Keryx securities between September 2, 2013 through August 1, 2016, inclusive. Excluded from the Class are Defendants, directors and officers of the Company, as well as their families and affiliates.

55. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Keryx securities were actively traded on the NASDAQ stock exchange. 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 hundreds or thousands of members in the proposed Class. As of April 28, 2016, the Company 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.

56. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

a. Whether the Exchange Act was violated by Defendants;

b. Whether Defendants omitted and/or misrepresented material facts;

c. Whether Defendants' statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;

d. Whether Defendants knew or recklessly disregarded that their statements were false and misleading;

e. Whether the price of the Company's stock was artificially inflated; and

f. The extent of damage sustained by Class members and the appropriate measure of damages.

57. Plaintiff's claims are typical of those of the Class because Plaintiff and the Class sustained damages from Defendants' wrongful conduct alleged herein.

58. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests that conflict with those of the Class.

59. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. 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.

LOSS CAUSATION

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

61. During the Class Period, Plaintiff and the Class purchased Keryx securities at artificially inflated prices and were damaged thereby.

62. On August 1, 2016, the Company disclosed that it would be withdrawing its financial guidance for 2016 and would be halting the distribution of its only marketed drug due to production difficulties on the part of Keryx's only contract manufacturer, contrary to its public statements made beginning on February 27, 2015 and described above. At the time the market closed on August 1, the value of shares of the Company's stock declined by $2.64, or 36%, in a single day. This decline is directly attributable to the August 1, 2016 disclosures by Keryx that the distribution of its only U.S. marketed drug was being halted and that it was clawing back its financial guidance for 2016.

SCIENTER ALLEGATIONS

63. As alleged herein, Defendants acted with scienter in that 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.

FRAUD ON THE MARKET

64. Plaintiff will rely upon the presumption of reliance established by the fraud-on-the-market doctrine that, among other things:

a. Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

b. The omissions and misrepresentations were material;

c. The Company's common stock traded in efficient markets;

d. The misrepresentations alleged herein would tend to induce a reasonable investor to misjudge the value of the Company's common stock; and

e. Plaintiff and other members of the class purchased the Company's common stock between the time Defendants misrepresented or failed to disclose material facts and the time that the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

65. At all relevant times, the markets for the Company's stock were efficient for the following reasons, among others: (i) the Company filed periodic public reports with the SEC; and (ii) the Company regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the major news ire services and through other wide-ranging public disclosures such as communications with the financial press, securities analysts, and other similar reporting services. Plaintiff and the Class relied on the price of the Company's common stock, which reflected all information in the market, including the misstatements by Defendants.

NO SAFE HARBOR

66. The statutory safe harbor provided for forward-looking statements under certain conditions do not apply to any of the allegedly false statements pleaded in this Complaint. The specific statements pleaded herein were not identified as forward-looking statements when made.

67. To the extent there were any forward-looking statements, 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.

CAUSES OF ACTION

Count I
Violation of § 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder (Against All Defendants)

68. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

69. During the Class Period, Defendants disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

70. Defendants violated § 10(b) of the Exchange Act and Rule 10b-5 in that they (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 those who purchased or otherwise acquired the Company's securities during the Class Period.

71. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for the Company's common stock. Plaintiff and the Class would not have purchased the Company's common stock at the price paid, or at all, if

they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements.

Count II
Violation of § 20(a) of the Exchange Act
(Against The Individual Defendants)

72. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

73. The Individual Defendants acted as controlling persons of the Company within the meaning of § 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions at the Company, the Individual Defendants had the power and authority to cause or prevent the Company from engaging in the wrongful conduct complained of herein. The Individual Defendants were provided with or had unlimited access to the Company's reports, press releases, public filings and other statements alleged by Plaintiffs to be false or misleading both prior to and immediately after their publication, and had the ability to prevent the issuance of those materials or to cause them to be corrected so as not to be misleading.

74. 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.

75. 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 pursuant to Rule 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure on behalf of the Class as defined herein, and a certification of Plaintiff as class representative pursuant to Rule 23 of the Federal Rules of Civil Procedure and appointment of Plaintiff's counsel as Lead Counsel;

(b) awarding compensatory and punitive 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 pre-judgment and post-judgment interest thereon.

(c) awarding Plaintiff and other members of the Class their costs and expenses in this litigation, including reasonable attorneys' fees and experts' fees and other costs and disbursements; and

(d) awarding Plaintiff and the other Class members such other relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury in this action of all issues so triable.

Dated: August 26, 2016

Respectfully submitted,

BLOCK & LEVITON LLP

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