KERYX BIOPHARMACEUTICALS INC
Form 425
November 28, 2018

Merger of Equals to Create a Financially Stronger Company Focused on the Development and Commercialization of Therapeutics for Patients with Chronic Kidney Disease (NASDAQ: AKBA) (NASDAQ: KERX) Filed by Keryx Biopharmaceuticals, Inc. Pursuant to Rule 425 under the Securities Act of 1933 and deemed filed pursuant to Rule 14a-12 of the Securities Exchange Act of 1934 Subject Corporation: Keryx Biopharmaceuticals, Inc. Commission File No.: 000-30929

This document contains forward-looking statements within the meaning of the federal securities law. Such statements are based upon current plans, estimates and expectations that are subject to various risks and uncertainties. The inclusion of forward-looking statements should not be regarded as a representation that such plans, estimates and expectations will be achieved. Words such as “anticipate,” “create,” “expect,” “project,” “intend,” “believe,” “may,” “will,” “sh “plan,” “could,” “target,” “contemplate,” “estimate,” “position,” “predict,” “potential,” “opportunity” and words and terms of s substance used in connection with any discussion of future plans, actions or events identify forward-looking statements. All statements, other than historical facts, including statements regarding the ability of the parties to complete the merger; expectations for the combined company (including that it will continue to identify, develop and commercialize new therapeutic options to address the needs of patients with kidney disease and expectations for pro forma cash); the value proposition of the transaction for Keryx’s stockholders and beliefs about Akebia’s and Keyx’s potential contributions to the combined company; and the consummation of the merger and the potential benefits of the merger are forward looking statements. Important factors that could cause actual results to differ materially from Akebia’s and Keryx’s plans, estimates or expectations could include, but are not limited to: (i) Akebia or Keryx may be unable to obtain stockholder approval as required for the merger; (ii) conditions to the closing of the merger may not be satisfied; (iii) the merger may involve unexpected costs, liabilities or delays; (iv) the effect of the announcement of the merger on the ability of Akebia or Keryx to retain and hire key personnel and maintain relationships with customers, suppliers and others with whom Akebia or Keryx does business, or on Akebia’s or Keryx’s operating results and business generally; (v) Akebia’s or Keryx’s respective businesses may suffer as a result of uncertainty surrounding the merger and disruption of management’s attention due to the merger; (vi) the outcome of any legal proceedings related to the merger; (vii) Akebia or Keryx may be adversely affected by other economic, business, and/or competitive factors, including the receipt by Keryx of notice letters on October 31, 2018, and November 6, 2018, regarding abbreviated new drug applications submitted to the FDA requesting approval to market, sell and use a generic version of Auryxia; (viii) the occurrence of any event, change or other circumstances that could give rise to the termination of the merger agreement; (ix) risks that the merger disrupts current plans and operations and the potential difficulties in employee retention as a result of the merger; (x) the risk that Akebia or Keryx may be unable to obtain governmental and regulatory approvals required for the transaction, or that required governmental and regulatory approvals may delay the transaction or result in the imposition of conditions that could reduce the anticipated benefits from the proposed transaction or cause the parties to abandon the proposed transaction; (xi) risks that the anticipated benefits of the merger or other commercial opportunities may otherwise not be fully realized or may take longer to realize than expected, including expected synergies of $250 million; (xii) the impact of legislative, regulatory, competitive and technological changes, including the recent changes to reimbursement coverage for Auryxia that could have a material adverse effect on Auryxia sales and profitability; (xiii) expectations for future clinical trials, the timing and potential outcomes of clinical trials and interactions with regulatory authorities; and (xiv) other risks to the consummation of the merger, including the risk that the merger will not be consummated within the expected time period or at all. Additional factors that may affect the future results of Akebia and Keryx are set forth in their respective filings with the SEC, including each of Akebia’s and Keryx’s most recently filed Annual Report on Form 10-K, subsequent Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, in the definitive joint proxy statement/prospectus filed by Akebia and Keryx and other filings with the SEC, which are available on the SEC’s website at www.sec.gov. See in particular “Risk Factors” in the joint proxy statement/prospectus, Item 1A of Akebia’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2018 under the heading “Risk Factors” and Item 1A of Keryx’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2018 under the heading “Risk Factors.” The risks and uncertainties described above and in Akebia’s most recent Quarterly Report on Form 10-Q and Keryx’s most recent Quarterly Report on Form 10-Q are not exclusive and further information concerning Akebia and Keryx and their respective businesses, including factors that potentially could materially affect their respective businesses, financial condition or operating results, may emerge from time to time. Readers are urged to consider these factors carefully in evaluating these forward-looking statements, and not to place undue reliance on any forward-looking statements. Readers should also carefully review the risk factors described in other documents that Akebia and Keryx file from time to time with the SEC. The forward-looking statements in these materials speak only as of the date of these materials. Except as required by law, Akebia and Keryx assume no obligation to update or

revise these forward-looking statements for any reason, even if new information becomes available in the future.

Forward-Looking Statements

In connection with the proposed merger, Akebia has filed with the U.S. Securities and Exchange Commission (the "SEC") a Registration Statement on Form S-4, which, as amended, includes a final prospectus with respect to the shares of Akebia's common stock to be issued in the proposed merger and a definitive joint proxy statement of Keryx and Akebia with respect to the proposed merger. The Registration Statement was declared effective by the SEC on October 30, 2018 and the definitive joint proxy statement was mailed or otherwise made available to Keryx's and Akebia's respective stockholders on October 31, 2018. BEFORE MAKING ANY VOTING DECISION, KERYX'S AND AKEBIA'S RESPECTIVE STOCKHOLDERS ARE URGED TO READ THE JOINT PROXY STATEMENT/PROSPECTUS IN ITS ENTIRETY AND ANY OTHER DOCUMENTS FILED BY EACH OF AKEBIA AND KERYX WITH THE SEC IN CONNECTION WITH THE PROPOSED MERGER OR INCORPORATED BY REFERENCE THEREIN BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION AND THE PARTIES TO THE PROPOSED TRANSACTION. Investors and stockholders can obtain a free copy of the joint proxy statement/prospectus and other documents containing important information about Akebia and Keryx, once such documents are filed with the SEC, through the website maintained by the SEC at www.sec.gov. Akebia and Keryx make available free of charge at www.akebia.com and www.keryx.com, respectively (in the "Investors" section), copies of materials they file with, or furnish to, the SEC. Participants in the Merger Solicitation Akebia, Keryx and their respective directors, executive officers and certain employees and other persons may be deemed to be participants in the solicitation of proxies from the stockholders of Akebia and Keryx in connection with the proposed merger. Information regarding the interests of such individuals in the proposed merger, by security holdings or otherwise, is included in the joint proxy statement/prospectus relating to the proposed merger that has been filed with the SEC. In addition, security holders may obtain information regarding the names, affiliations and interests of Akebia's directors and officers in Akebia's Annual Report on Form 10-K for the fiscal year ended December 31, 2017, which was filed with the SEC on March 12, 2018, and its definitive proxy statement for the 2018 annual meeting of stockholders, which was filed with the SEC on April 30, 2018, and information regarding the names, affiliations and interests of Keryx's directors and officers in Keryx's Annual Report on Form 10-K for the fiscal year ended December 31, 2017, which was filed with the SEC on February 21, 2018, and the Amendment No. 1 on Form 10-K/A, which was filed with the SEC on April 30, 2018, and its definitive proxy statement for the 2018 annual meeting of stockholders, which was filed with the SEC on May 31, 2018. To the extent the holdings of Akebia securities by Akebia's directors and executive officers or the holdings of Keryx securities by Keryx's directors and executive officers have changed since the amounts set forth in the joint proxy statement/prospectus, such changes have been or will be reflected on Statements of Change in Ownership on Form 4 filed with the SEC. These documents (when available) may be obtained free of charge from the SEC's website at www.sec.gov, Akebia's website at www.akebia.com and Keryx's website at www.keryx.com. This document does not constitute a solicitation of proxy, an offer to purchase or a solicitation of an offer to sell any securities. Additional Information and Where to Find It

Proposed Merger Creates a Leader in Kidney Disease Therapeutics 2.2 million CKD patients in the US with potential to be treated by combined drug portfolio3 > $250 million Expected combined synergies1 $431 million Combined cash position2 To be realized over five years following closing Pro forma cash and cash equivalents as of 9/30/18, unaudited Subject to vadadustat's FDA approval; 1.7 million patients who are non-dialysis dependent and 500,000 dialysis-dependent patients in the United States, across the continuum of CKD The proposed merger establishes a leading renal player with enhanced position and market opportunity… …by creating potential for accelerated growth and organizational synergies… …combining experienced renal management teams… …and strengthening the financial profile and flexibility to enable continued growth

Business Description Quarterly Net Product Sales ($ in millions) Source: FactSet, Company Filings Keryx Overview Status: Public (NASDAQ: KERX) Founded: 1998 Headquarters: Boston, MA Employees: ~200 Commercial stage biopharmaceutical company focused on the treatment of chronic kidney disease Markets Auryxia (ferric citrate), an oral medicine in the United States (“US”) In the US, Auryxia is approved by the FDA in two indications: iron deficiency anemia for patients with chronic kidney disease not on dialysis and hyperphosphatemia for patients with chronic kidney disease on dialysis Ferric citrate was approved in Japan; the Company sublicensed the exclusive rights for the development and commercialization to Japan Tobacco and Torii Quarterly Prescriptions

Akebia Overview Non-Dialysis Dependent (NDD) Dialysis Dependent (DD) Not ESA Treated Vadadustat vs Darbepoetin Alfa ESA Treated Vadadustat vs Darbepoetin Alfa Hypoxia Inducible Factor - Prolyl Hydroxylase Inhibitor Chronic Kidney Disease Subject to accrual of major adverse cardiovascular events (MACE) Business Description Status: Public (NASDAQ: AKBA) Founded: 2007 Headquarters: Cambridge, MA Employees: ~140 Clinical stage biopharmaceutical company, focused on the treatment of kidney disease through the biology of hypoxia inducible factor Lead product candidate is vadadustat, an investigational, oral Phase 3 HIF-PHI1 for anemia due to chronic kidney disease Global, up to ~7,300 patients, active-controlled, open-label, non-inferiority, cardiovascular outcome studies ongoing Top-line results for non-dialysis dependent trials expected mid-20202; top-line results for dialysis dependent trials top-line results expected Q1 20202 Collaborations with Otsuka and Mitsubishi Tanabe, and license agreement with Vifor Pharma Vadadustat Phase 3 Clinical Trials Overview New-Onset Dialysis Vadadustat vs Darbepoetin Alfa ESA Treated Vadadustat vs Darbepoetin Alfa Primary Efficacy Endpoint: Change in hemoglobin (Hb) from baseline Primary Safety Endpoint: Major Adverse Cardiovascular Events (MACE)

Transaction Summary Terms Stock for stock merger Each share of Keryx be converted into 0.37433 shares of Akebia Fully-Diluted Pro-Forma Ownership Keryx stockholders to own 50.6% of the pro forma company and Akebia stockholders to own 49.4% (based on fully diluted market capitalizations at signing and additional equity expected to be issued to The Baupost Group) The Baupost Group LLC, Keryx's largest stockholder, will convert its $165MM convertible bond prior to closing Cash Position Pro forma company had $431mm of cash and cash equivalents (unaudited) as of September 30, 2018 CEO & Board of Directors CEO: John P. Butler (CEO of Akebia today) Board to consist of four Akebia directors, five Keryx directors and a newly appointed independent chairperson, Adrian Adams Closing Conditions Subject to approval of Akebia and Keryx stockholders Subject to other customary closing conditions Voting Agreements The Baupost Group LLC, holder of ~21% of outstanding Keryx common stock Muneer A. Satter, Chairperson of Akebia's Board and holder of ~5% of Akebia Shareholder Vote & Closing Shareholder vote scheduled for December 11, 2018 Closing expected by year end

The Keryx Board, and a Special Committee established for reviewing strategic alternatives, conducted a thorough process Concluded that Keryx has risks as a standalone company Negotiations, diligence, and alternative review were facilitated through independent financial and legal advisors The Board and Special Committee directed management and its financial advisors to pursue other partners and acquirors, which included reaching out to 15 other parties Negotiated with and conducted due diligence on Akebia over a six-month period to achieve the best possible result The Keryx Board unanimously backs the transaction The combined company will be a world-class, renal-focused pharmaceutical company The Board believes that Akebia’s contribution of capital, product pipeline and executive talent are complementary to Keryx and fairly priced in the merger-of-equals construct Substantial cost savings and synergies are available to the combined company The Keryx Board Unanimously Supports the Transaction

Potential need for dilutive, near-term capital raise with limited financial flexibility due to restrictive convertible debt covenants and volatile market Executive management team risks, including a currently incomplete team, and potential challenge in attracting candidates to complete the team (particularly a permanent CEO) Inefficiencies and risks involved in being a commercial biopharma company with a single product Limited ability to pursue business development opportunities Key Considerations for Keryx as a Standalone Company

Strong Strategic and Financial Fit Leading Renal Company Portfolio Auryxia, an FDA-approved drug in two chronic kidney disease related indications A Phase 3, investigational oral drug for anemia due to chronic kidney disease; and other preclinical compounds under development FDA-approved drug generating revenue and late-stage product candidate with long-term growth potential Core Capabilities and Infrastructure Established US Commercial and Medical infrastructures Strong reputation in nephrology community Successful R&D expertise Global alliances expertise Fully integrated capabilities to bring novel compounds through development to commercialization Management and Team 130 employees within Commercial and Medical organizations Successful and well-respected CEO, CFO and renal leadership team ~90 employees within global R&D organization Fully staffed executive and functional teams, with wide range of experience and success Cash and Cash Equivalents $431 million Pro Forma Cash and Cash Equivalents Position1 As of 09/30/18, unaudited figures

Potential to Deliver Innovative Therapies to Advance Care and Improve Outcomes for Kidney Disease Patients Iron deficiency anemia (NDD) Anemia associated with CKD (DD&NDD) In development, subject to regulatory approval Hyperphosphatemia (DD) Approved and Target Indications The combined company will continue to identify, develop and commercialize new therapeutic options to address the needs of patients with kidney disease + The companies believe that Auryxia and vadadustat, if FDA-approved, have the potential to deliver an all-oral treatment approach for patients with anemia due to CKD CKD: chronic kidney disease NDD: non-dialysis-dependent DD: dialysis-dependent

Akebia’s HIF-PHIs Represent Opportunity for a New Class of Treatment HIF-PHIs Represent Opportunity for A New Class of Treatment: Have Potential to Be Oral Alternatives to iESAs Rely on the Same Pathway the Body Uses to Adapt to Lower Oxygen Availability Potential for a Differentiated Profile Injectable erythropoiesis-stimulating agents Thamer et. al. Am J Kidney Dis. 2014 Nov; 64(5):706-13, Akebia market research iESAs1: Standard of Care for Anemia Due to CKD for More Than 20 years iESAs Are Associated with Significant Safety Concerns: A Proportion of NDD Patients Are Not Treated with iESAs Due to Safety and Administration Considerations2 DD Patients Rely on iESAs for Treatment An Investigational HIF-PHI That Represents an Innovative Potential Approach to Treatment of Anemia Due to Chronic Kidney Disease

Combined Company Portfolio

Complementary Core Capabilities Strong commercial sales and marketing capabilities Medical affairs team Strong reputation in nephrology community Existing revenue source World-class investigational and R&D capabilities in renal care Global alliances expertise

Michel Dahan SVP, Chief Business Officer Karen Tubridy SVP, Chief Development Officer Nicole R. Hadas SVP, General Counsel & Secretary Experienced and Highly Skilled Leadership Team Jason A. Amello SVP, CFO & Treasurer John P. Butler President & CEO Tamara Dillon SVP, Chief Human Resources Officer Rita Jain, M.D. SVP, Chief Medical Officer Former CEO of Inspiration Biopharmaceuticals Former Divisional President of Genzyme's renal business Currently serves on the Board of Zynerba Pharmaceuticals and formerly served as Chairman of the American Kidney Fund Board of Trustees Former EVP, CFO & Treasurer of Ziopharm Oncology Former SVP, Corporate Controller and Chief Accounting Officer of Genzyme Currently serves on the Board of Acer Therapeutics Former VP at AbbVie Former Divisional VP at Abbott Laboratories Former Senior Assistant Attending at North Shore University Hospital in New York, with academic appointment as Assistant Professor of Medicine at NYU School of Medicine Former Head of Human Resources at Global Discovery Chemistry Former Senior Director of Human Resources at Genzyme Former SVP & General Counsel at Inspiration Biopharmaceuticals Former Senior Corporate Counsel at Genzyme Former Vice President of Commercial Development and Strategic Planning at Inspiration Biopharmaceuticals Led Inspiration's global marketing and commercial development for two global launches Former International Product Director at Ipsen Former Chief Development Officer at Eleven Biotherapeutics Former SVP, Clinical Development and Medical Affairs at Inspiration Biopharmaceuticals Former Clinical Operations and Regulatory Affairs, Translational Medicine, Alexion Pharmaceuticals

Strong Board Synergies Pro Forma Akebia + Keryx Board Diverse and Experienced Board Committed to Creating Shareholder Value Board will have a mix of current Akebia and Keryx directors, and a new independent Chairperson, Adrian Adams, selected by Akebia and Keryx Boards Director backgrounds are diverse and complementary, bringing together commercial experience, renal expertise and financial acumen, in addition to public company leadership Directors will have a mix of tenures John P. Butler Scott A. Canute Adrian Adams Cynthia Smith Dr. Maxine Gowen Continuing Akebia Directors New Independent Chairperson Michael Rogers Jodie Morrison Michael T. Heffernan Dr. Steven C. Gilman Mark Enyedy Continuing Keryx Directors

Transaction Has Potential to Enhance Capital Resources and Increase Value for Shareholders in the Near, Mid and Long Term Near Term Strong pro forma cash and cash equivalent position with $431 million as of Q3 2018 (unaudited) Akebia gains access to FDA-approved renal asset Improves company financial risk profile Mid Term Auryxia's potential growth expected to fund pro forma operations and cover majority of capital needs beginning in 2020 Reduces need for future dilution while accelerating cash flow and earnings Long Term Retain vadadustat strong value-creation potential Leverage Keryx's relationships to build launch momentum for vadadustat >$250 million of cost savings expected within 5 years post-closing Combination Offers Stronger Balance Sheet vs. Standalone1 Pro Forma cash balance $0 2018 2023 Cash runway for Pro Forma is Q1 2020 1. . Definitive Proxy Statement/Prospectus filed by Akebia Therapeutics, Inc. with the U.S. Securities and Exchange Commission on October 30, 2018 (see "The Merger—Certain Akebia Management Unaudited Prospective Financial Information"). These cash balance estimates are unaudited and were based upon Akebia assumptions made in preparation for the June 28, 2018, merger announcement, including assumptions related to timing for clinical trial completion and commercial launch, estimated operational costs, including R&D, manufacturing and general and administrative costs, and estimates of revenue growth for U.S. sales of Auryxia, and have not been updated since that time. Furthermore, these cash balance estimates are not adjusted for a number of critical risks, including the risks and probability of success of vadadustat, delays of any clinical trials or commercial launch, the financial implications of Akebia's collaborations and other relationships with third parties, the recent changes to reimbursement coverage for Auryxia that could have a material adverse effect on Auryxia sales and profitability, and the receipt by Keryx of a notice letters on October 31, 2018 and November 6, 2018 regarding abbreviated new drug applications submitted to the FDA requesting approval to market, sell and use a generic version of the Auryxia. See the Forward-Looking Statements section herein for additional information regarding risks.

Keryx’s Process was Deliberate and Thoughtful Keryx full board and special committee met frequently throughout the process The Keryx Board explores other possible strategic opportunities, including contacting 13 new parties Akebia raises $89.3 million Akebia proposes merger Keryx Board formally created a special transaction committee The parties continued to negotiate the terms of the potential merger Keryx contacts two alternative partners All parties, including Keryx and Akebia management and Boards, legal and financial advisors, evaluated the potential combination Keryx Board ends discussions with Akebia Representatives from Keryx management, met with a Baupost consultant to gather additional information on Akebia Keryx contacted Akebia to discuss renewing negotiations All parties, including Keryx and Akebia management and Boards, legal and financial advisors, conducted diligence Following further negotiations, Akebia sent a non-binding offer letter The parties continued to negotiate the terms of the potential merger Discussions between executive management and Board begin after Akebia reached out to Keryx May June Jan. Mar. Apr. Feb. Dec. Akebia has Type-C meeting with FDA The parties continue performing diligence Akebia and Keryx continue negotiations including over how Baupost’s convertible debt will be treated The members of the Keryx Board, upon the unanimous recommendation of the Keryx Special Committee, unanimously approved the Merger Agreement and the transactions contemplated by the Merger Agreement

Analyst Commentary “We believe Keryx’s growing revenue base from Auryxia combined with its commercial infrastructure focused on the nephrology space… strongly complements Akebia’s renal focused late-stage pipeline and its R&D organization.” - Matthew Kaplan, Ladenburg Thalmann “ Keryx and Akebia to merge building an integrated company with pipeline upside.” - Reni Benjamin, Raymond James “ Akebia and Keryx merger has clear strategic fit and synergies.” - Jason Butler, JMP Securities “Our Keryx/Akebia merger model indicates the new company is worth ~$13/share —This represents ~40% upside to the sum of the KERX and AKBA valuations… pre the merger announcement.” -Yigal Nochomovitz, Citi “ [We] think the combination makes good strategic sense long term.” - Christopher Raymond, Piper Jaffray “ This combination offers greater scale and growth potential, while addressing issues on both sides.” - Ed Arce, H.C. Wainwright Source: Wall Street Research Note: Permission to use quotes was neither sought nor obtained

Strong strategic and financial fit Complementary products, infrastructure and teams Financial strength due to balance sheet cash and revenue-generating, FDA-approved asset Unanimous support from independent, experienced Board and Special Committee Thorough diligence and transaction review Largest shareholder (The Baupost Group LLC) with approximately 21% of outstanding Keryx shares will vote FOR Support from financial advisors and research analysts Independent financial advisor provided fairness opinion Transaction has received strong support from sell-side research analysts Summary

Merger of Equals to Create a Financially Stronger Company Focused on the Development and Commercialization of Therapeutics for Patients with Chronic Kidney Disease (NASDAQ: AKBA) (NASDAQ: KERX)