KERYX BIOPHARMACEUTICALS INC
Form 425
October 29, 2018

Strategic Fit + Financial Strength Merger Creates a Leading Fully Integrated Biopharmaceutical in Renal Disease October 29, 2018 Filed by Akebia Therapeutics, Inc. Pursuant to Rule 425 under the Securities Act of 1933 Commission File No.: 001-36352 Subject Company: Keryx Biopharmaceuticals, Inc. Commission File No.: 000-30929 Akebia Therapeutics, Inc. Commission File No.: 001-36352 Date: October 29, 2018

Forward-Looking Statements These materials contain forward-looking statements within the meaning of the federal securities law. Such statements are based upon current plans, estimates and expectations that are subject to various risks and uncertainties. The inclusion of forward-looking statements should not be regarded as a representation that such plans, estimates and expectations will be achieved. Words such as “anticipate,” “create,” “expect,” “project,” “intend,” “believe,” “may,” “will,” “should,” “plan,” “could,” “target,” “contemplate,” “estimate,” “position,” “predict,” “potential,” “op words and terms of similar substance used in connection with any discussion of future plans, actions or events identify forward-looking statements. All statements, other than historical facts, including statements regarding the expected timing of the closing of the merger; the ability of the parties to complete the merger considering the various closing conditions; all financial, market share and timing projections; the potential benefits of vadadustat; expected timing of Akebia’s Otsuka funding option; the timing of availability of top-line results from clinical trials of vadadustat; the potential to establish a new standard of care; the expected timing of enrollment in clinical trials; revenue growth; the market opportunity, commercial momentum and growth potential of Auryxia; the expected benefits of the merger, such as efficiencies, the expected management team, cost savings and the expected timing thereof, synergies, the ability to deliver value, the potential to maximize sales, the ability to build launch momentum for vadadustat in the U.S., enhanced revenues, growth potential, market profile, financial strength, and financial flexibility, the potential for accelerating profitability and reducing capital needs; the competitive ability and position of the combined company; the strategy of the combined company; the potential of the combined company to address common forms of anemia in CKD, deliver innovative therapies, improve patient outcomes, and identify, develop and commercialize new therapeutic options; the potential market opportunity of the combined company; the expected cash runway of the combined company; and any assumptions underlying any of the foregoing, 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; (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; (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 studies 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, and Akebia’s registration statement on Form S-4 on October 1, 2018, as amended on October 25, 2018 and October 29, 2018 that includes a preliminary joint proxy statement of Akebia and Keryx that also constitutes a preliminary prospectus of Akebia (the “Preliminary S-4”), which are available on the SEC’s website at www.sec.gov. See in particular “Risk Factors” in the Preliminary S-4, Item 1A of Akebia’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2018 under the heading “Risk Factors,” and Item 1A of Keryx’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2018 under the heading “Risk Factors.” The risks and uncertainties described above and in the Preliminary S-4, 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.

Additional Information About Akebia Therapeutics, Inc. Akebia Therapeutics, Inc. is a biopharmaceutical company headquartered in Cambridge, Massachusetts, focused on delivering innovative therapies to patients with kidney disease through hypoxia-inducible factor biology. For more information, please visit our website at www.akebia.com, which does not form a part of this release. About Keryx Biopharmaceuticals, Inc. Keryx Biopharmaceuticals, Inc., headquartered in Boston, Massachusetts, is focused on the development and commercialization of innovative medicines that provide unique and meaningful advantages to people with kidney disease. The Keryx team works with passion to advance the care of people with this complex disease. This dedication has resulted in two FDA-approved indications for Keryx's medicine, Auryxia® (ferric citrate) tablets. For more information about Keryx, please visit www.keryx.com. Additional Information and Where to Find It 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 on October 1, 2018, as amended on October 25, 2018 and October 29, 2018 that includes a preliminary joint proxy statement of Akebia and Keryx that also constitutes a preliminary prospectus of Akebia (the "Preliminary S-4"). The registration statement is not complete and will be amended further. Akebia and Keryx will mail or otherwise provide to their respective shareholders a definitive joint proxy statement/prospectus regarding the proposed transaction. BEFORE MAKING ANY VOTING DECISION, AKEBIA'S AND KERYX'S RESPECTIVE SHAREHOLDERS ARE URGED TO READ THE DEFINITIVE JOINT PROXY STATEMENT/PROSPECTUS IN ITS ENTIRETY WHEN IT BECOMES AVAILABLE 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 shareholders will be able to obtain a free copy of the definitive 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 (in the "Investors" section) and www.keryx.com (in the "Investors & Media" section), copies of materials they file with, or furnish to, the SEC. Participants in the Solicitation Akebia, Keryx and their respective directors, executive officers and certain employees and other persons may be deemed to be participants in the solicitation of proxies from the shareholders of Akebia and Keryx in connection with the proposed merger. Security holders may obtain information regarding the names, affiliations and interests of Akebia's directors and officers in Akebia's Annual Report on Form 10-K for the fiscal year ended December 31, 2017, which was filed with the SEC on March 12, 2018 and its definitive proxy statement for the 2018 annual meeting of shareholders, which was filed with the SEC on April 30, 2018. Security holders may obtain information regarding the names, affiliations and interests of Keryx's directors and officers in Keryx's Annual Report on Form 10-K for the fiscal year ended December 31, 2017, which was filed with the SEC on February 21, 2018, and the Amendment No. 1 on Form 10-K/A, which was filed with the SEC on April 30, 2018, and its definitive proxy statement for the 2018 annual meeting of shareholders, which was filed with the SEC on May 31, 2018. To the extent the holdings of Akebia's securities by Akebia's directors and executive officers or the holdings of Keryx securities by Keryx's directors and executive officers have changed since the amounts set forth in Akebia's or Keryx's respective proxy statement for its 2018 annual meeting of shareholders, such changes have been or will be reflected on Statements of Change in Ownership on Form 4 filed with the SEC. Additional information regarding the interests of such individuals in the proposed merger are included in the Preliminary S-4. These documents 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.

Strategic Fit and Strong Financial Profile Establishes a Leading Renal Company Strong Capital Efficiency Leveraging Combined Cash Position and Auryxia Revenue Growth Potential Multibillion-Dollar Market Opportunity for Akebia's Product Candidate Vadadustat; Phase 3 Read-Outs Expected in 2019 and 2020* Pro Forma Cash at End of Q2 2018 is $452 Million (unaudited); Potential Cost Savings Within 5 Years from Closing >$250M Substantial Revenue Growth Potential for Keryx's AURYXIA® (ferric citrate), With Strong Growth Drivers in 2019, 2020 and Beyond Fully-Integrated Operations, Experienced Management Team and Synergistic Portfolio Expected To Create Partner of Choice in Renal * Subject to the accrual of Major Adverse Cardiovascular Events (MACE)

Compelling Portfolio With Commercial Synergies Non-Dialysis: Dialysis: AURYXIA Is Approved in the U.S. for Iron Deficiency Anemia (IDA) in Non-Dialysis AURYXIA Is Approved in the U.S. for Hyperphosphatemia in Dialysis Vadadustat, an Oral HIF-PHI Investigational Product in Phase 3 Development for Anemia Due to CKD, Has Potential to Increase Endogenous EPO Levels and Iron Mobilization Creates Strong Corporate Brand Recognition in Nephrology Leverages Keryx's Established Relationships in the Field Builds Launch Momentum for Vadadustat, Subject to FDA Approval Positions Akebia as Partner of Choice in Renal

Auryxia Shows Strong Momentum in 2018 Key Performance Metrics as of Q2 20181 Quarterly Scripts Doubled to 42,500 from 21,100 in Same Q y/o/y 198 Tablets Per Script Indicates Hyperphosphatemia Drives Near-Term Growth Exit Market Share of Approximately 6%2: Fastest Growing Phosphate Binder 1. Source: Keryx Biopharmaceuticals, Inc. 2. Keryx consolidated data based on data received from IMS and specialty pharmacies (Fresenius Rx, DaVita Rx)

Substantial Growth Opportunity in Hyperphosphatemia for Auryxia in 2019, 2020 and Beyond Opportunity in Promotionally- Sensitive Market: Sanofi Has Ceased Promotional Activities Estimated Market Share to Reach Peak Sales of $534.8M in 20232,3 Auryxia Potential Growth Drivers Potential to Capture Market Share From Calcium-Based Binders Consistent with Guidelines Update4 1. Keryx consolidated data based on data received from IMS and specialty pharmacies (Fresenius Rx, DaVita Rx) 2. Preliminary Registration Statement on Form S-4 filed by Akebia Therapeutics, Inc. with the U.S. Securities and Exchange Commission on October 1, 2018, as amended on October 25, 2018 and October 29, 2018 (see "The Merger—Certain Akebia Management Unaudited Prospective Financial Information – Akebia Management Keryx Projections"). This estimate of peak sales is unaudited and was based upon Akebia assumptions made in preparation for the June 28, 2018, merger announcement, including upon publicly filed financial information of Keryx, certain financial information provided to Akebia management by Keryx, and certain assumptions made by the Akebia management, including estimates of revenue growth for U.S. sales of Auryxia and associated operational costs, and has not been updated since that time. Furthermore, this estimate of peak sales was not adjusted for a number of critical risks, including the recent changes to reimbursement coverage for Auryxia that could have a material adverse effect on Auryxia sales and profitability. See the Forward-Looking Statements section herein for additional information regarding risks. 3. Akebia management internal estimates based on market research. This Auryxia market share estimate formed the basis of certain information included in the Preliminary Registration Statement on Form S-4 filed by Akebia Therapeutics, Inc. with the U.S. Securities and Exchange Commission on October 1, 2018, as amended on October 25, 2018 and October 29, 2018 (see "The Merger—Certain Akebia Management Unaudited Prospective Financial Information – Akebia Management Keryx Projections") and was based upon Akebia assumptions made in preparation for the June 28, 2018, merger announcement, including upon publicly filed financial information of Keryx, certain financial information provided to Akebia management by Keryx, and certain assumptions made by the Akebia management, including estimates of revenue growth for U.S. sales of Auryxia and associated operational costs, and has not been updated since that time. Furthermore, this market share estimate was not adjusted for a number of critical risks, including the recent changes to reimbursement coverage for Auryxia that could have a material adverse effect on Auryxia sales and profitability. See the Forward-Looking Statements section herein for additional information regarding risks. 4. KDIGO 2017 Clinical Practice Guideline Update for the Diagnosis, Evaluation, Prevention and Treatment of Chronic Kidney Disease-Mineral and Bone Disorder (CKD_MBD); Vol. 7, Issue 1. July 2017 5. Reason Research Q3 2018 Auryxia ATU 6. Spherix Global Anemia 1Q Pulse (2018); aided awareness data Physicians Express Favorable Perception of Auryxia in IDA Majority of physicians surveyed recognize benefits of Auryxia's profile5 Majority of surveyed nephrologists report satisfaction with Auryxia6

HIF-PHIs Represent Opportunity for a New Class of Treatment iESAs*: 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 Considerations1 DD Patients Rely on iESAs for Treatment *Injectable erythropoiesis-stimulating agents 1. Thamer et. al. Am J Kidney Dis. 2014 Nov; 64(5):706-13, Akebia market research 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

Vadadustat: An Investigational HIF-PHI That Represents an Innovative Potential Approach to Treatment of Anemia Due to CKD EPO, erythropoietin; PH, prolyl hydroxylase; RBC, red blood cell. Maxwell PH, Eckardt K-U. HIF prolyl hydroxylase inhibitors for the treatment of renal anemia and beyond. Nat Rev Nephrol. 2015;12(3):157-168. Cells produce HIF constantly EPO production Iron mobilization RBC production Vadadustat is a Phase 3, investigational, oral HIF-PHI that is not approved by the FDA. Low oxygen or HIF-PHI (vadadustat) administered Normal oxygen HIF-PH enzyme inhibited HIF is stabilized HIF- HIF- Gene transcription HIF PH enzyme binds with HIF HIF is degraded Potential to Stimulate Endogenous EPO Production and Mobilize Iron by Inhibiting HIF-PH

Unmet Needs Less Variability in Hemoglobin Levels Lower Risk of CV Events Lower Risk of Hypertension Efficacy in Hyporesponders More Convenient Dosing for NDD Kaplan-Meier Survival Curves1 Death, Heart Failure, Stroke, Myocardial Infarction (%) 1 McCullough P.A., et al. Am J Nephrol 2013;37:549-558 (DOI:10.1159/000351175); Permission granted by S. Karger AG, Basel. Vadadustat Development Program Informed By Key Unmet Needs In Anemia Due to CKD

Vadadustat Avoided Supra-Physiological EPO Levels Akebia Therapeutics, Inc. Data on File (2010). Data from Phase 1 study in healthy volunteers with vadadustat once daily dosing. Pre-dose EPO concentrations were evaluated on Days 1, 4, 7, 11, 15 and 22. Post-dose data to assess acute rise in EPO following vadadustat dosing was only completed on Day 1 and Day 7 (8 and 16 hours post-dose). Dashed line represents estimated EPO levels based on post-dose data from Day 1 and Day 7. Doshi S et al. Journal of Clinical Pharmacology, 2010;50:75S-90S. Original figure redrawn to depict darbepoetin alfa serum concentration (ng/mL/(mcg/kg)) converted to mU/mL. Data from 6 clinical studies conducted with extensive PK sampling in CKD patients following subcutaneous (SC) administration of a single dose or first dose of a monthly dosing regimen ranging from 0.4-0.6mcg/kg, dose normalized to 0.45 mcg/kg. EPO vs. Time by Study Median EPO Concentration (mIU/mL) Median EPO Concentration (mIU/mL) Vadadustat (Oral) Phase 1 Study in Healthy Volunteers1 Darbepoetin Alfa (SC) Published Data in a PK-PD Model in CKD Patients2 Not a head-to-head comparison Dashed line represents simulated EPO data Vadadustat is a Phase 3, investigational, oral HIF-PHI that is not approved by the FDA

Vadadustat Phase 3 Development Program Overview Global Phase 3 Development Program: Active-Controlled, Open-Label, Non-Inferiority, Cardiovascular Outcome Studies With Up to 7,300 Patients Ongoing 17 Phase 1 and Phase 2 Trials Provide Foundation for the Phase 3 Program Globally Collaborations with Otsuka and Mitsubishi Tanabe Not ESA Treated Vadadustat vs Darbepoetin Alfa ESA Treated Vadadustat vs Darbepoetin Alfa New-Onset Dialysis* Vadadustat vs Darbepoetin Alfa ESA Treated Vadadustat vs Darbepoetin Alfa * ≤16 weeks of dialysis treatment, with or without prior ESA treatment Non-Dialysis Dependent (NDD) Dialysis Dependent (DD) Primary Efficacy Endpoint: Change in hemoglobin (Hb) from baseline Primary Safety Endpoint: Major Adverse Cardiovascular Events (MACE) Top-Line Results Expected Q1 2020, Subject to MACE Top-Line Results Expected Mid-2020, Subject to MACE

Transaction Has Potential to Enhance Capital Resources and Increase Value for Akebia Shareholders in the Near-, Mid- and Long-Term Near Term Strong Pro Forma Cash Position with $452M as of Q2 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 Expected to Cover Majority of Capital Needs Post Q1 2020 Reduces Need for Future Dilution Long Term Retain Vadadustat Strong Value-Creation Potential Plan to Leverage Keryx's Established Relationships Expected to Generate >$250M of Cost Savings Within 5 Years Post-Closing Pro Forma Offers Stronger Balance Sheet vs. Standalone1 Stand Alone cash balance Pro Forma cash balance $0 2018 2023 Cash runway for Pro Forma and Standalone is Q1 2020 1. Preliminary Registration Statement on Form S-4 filed by Akebia Therapeutics, Inc. with the U.S. Securities and Exchange Commission on October 1, 2018, as amended on October 25, 2018 and October 29, 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, and the recent changes to reimbursement coverage for Auryxia that could have a material adverse effect on Auryxia sales and profitability. See the Forward-Looking Statements section herein for additional information regarding risks.

Akebia Pipeline Catalysts 13

Akebia Board of Directors Unanimously Approved the Transaction Transaction Was the Result of Extensive Negotiations Commencing in December 2017 Board Was Fully Engaged Throughout the Process Transaction Committee consisting of independent directors and advised by separate counsel oversaw deal process and negotiations Two independent financial advisors were engaged and provided fairness opinions Board Believes Merger with Keryx Represents Best Opportunity to Build Shareholder Value Strong strategic fit: complementary portfolio, infrastructure and management teams Lowers overall corporate risk inherent to a development-stage biopharmaceutical company Strengthens Akebia financially Auryxia expected to generate positive cash flow, providing internal funding source for Akebia pipeline development and lowering expected future dilution Expected to lower Akebia cost of capital Expected to increase cash balance and significantly accelerate time to cashflow breakeven Every Member of Akebia Board Expected to Vote Shares in Favor of Combination

Transaction Establishes Leading Renal Company with Potential to Create Sustainable Near- and Long-Term Growth Capital Efficiencies Major Opportunity to Drive Auryxia Growth Near-Term Opportunity to Realize Multibillion-Dollar Vadadustat Sales Long-Term, Subject to FDA approval Reduced Need for Capital Fully Integrated Renal Company Expected Product and Organizational Synergies Experienced Management Team Positioned to Be Partner of Choice in Renal Strategic Fit Financial Strength

Thank You

Appendix

Combination Highlights Terms Stock for stock merger Each share of Keryx be converted into 0.37433 shares of Akebia Ownership Akebia stockholders to own 49.4% of the pro forma company and Keryx stockholders to own 50.6% (based on fully diluted market capitalizations at signing and additional equity expected to be issued to The Baupost Group) Cash Position Pro forma company has $452mm of cash (unaudited) as of June 30, 2018 Baupost, Keryx's leading stockholder, will convert its $165MM convertible bond prior to closing of the transaction CEO & Board of Directors CEO: John P. Butler Chairperson to be appointed by Keryx and Akebia Boards Closing Conditions Subject to approval of Akebia and Keryx stockholders Subject to other customary closing conditions Voting Agreements The Baupost Group, holder of approximately 21% of outstanding Keryx common stock Muneer A. Satter, Chairperson of Akebia's Board and holder of approximately 5% of outstanding Akebia common stock Shareholder Vote Expected by the end of 2018