

KERYX BIOPHARMACEUTICALS INC

Form 425

November 16, 2018

Creating a Financially Strong Company Focused on the Development and Commercialization of Therapeutics for Patients with Kidney Disease November 16, 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: November 16, 2018 Merger of Akebia Therapeutics, Inc. and Keryx Biopharmaceuticals, Inc. The presentation below was provided by Akebia Therapeutics, Inc. to certain stockholders ahead of meetings planned for November 16, 2018.



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 the definitive proxy statement/prospectus, 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](http://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](http://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, 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](http://www.sec.gov). Akebia and Keryx make available free of charge at [www.akebia.com](http://www.akebia.com) and [www.keryx.com](http://www.keryx.com), respectively (in the "Investors" section), copies of materials they file with, or furnish to, the SEC. Participants in the Solicitation Akebia, Keryx and their respective directors, executive officers and certain employees and other persons may be deemed to be participants in the solicitation of proxies from the stockholders of Akebia and Keryx in connection with the proposed merger. 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](http://www.sec.gov), Akebia's website at [www.akebia.com](http://www.akebia.com) and Keryx's website at [www.keryx.com](http://www.keryx.com).

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 portfolio<sup>1</sup>; US CKD patient population is expected to grow<sup>2</sup> >\$250 million Expected cost savings<sup>4</sup> \$431 million Combined cash position<sup>3</sup> Subject to vadadustat's FDA approval; 1.7mm patients who are non-dialysis dependent and 500,000 dialysis-dependent patients in the United States, across the continuum of CKD; US Census Bureau 2017; NHANES 2009-2014 United States Renal Data System, [https://www.usrds.org/2018/view/v1\\_01.aspx](https://www.usrds.org/2018/view/v1_01.aspx) Pro forma cash and cash equivalents (unaudited) as of 9/30/18 To be realized within five years following closing The proposed merger establishes a leading renal player with enhanced position and market opportunity... ..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 Vadadustat Phase 3 Clinical Trials Overview Akebia Overview Status: Public (Nasdaq: AKBA) 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 Hypoxia Inducible Factor - Prolyl Hydroxylase Inhibitor Subject to major adverse cardiovascular events (MACE) Non-Dialysis Dependent (NDD) Dialysis Dependent (DD) 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

Business Description Quarterly Net Product Sales (\$ in millions) Sources: FactSet (November 2018), Keryx Biopharmaceuticals, Inc. public filings. Keryx Overview Status: Public (Nasdaq: KERX) Headquarters: Boston, MA Employees: ~200 Commercial stage biopharmaceutical company, focused on the treatment of kidney disease Markets Auryxia® (ferric citrate), an oral, absorbable, iron-based medicine in the US In the US, Auryxia is approved by the FDA for two CKD-related indications: iron deficiency anemia in non-dialysis dependent (NDD) patients and hyperphosphatemia in dialysis dependent (DD) patients Marketed in Japan under the trade name Riona® by Japan Tobacco and its subsidiary Torii Pharmaceutical Quarterly Prescriptions

Transaction Summary Terms Stock for stock merger Each share of Keryx common stock to be converted into 0.37433 shares of Akebia common stock 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 had \$431 million of cash and cash equivalents (unaudited) as of September 30, 2018 CEO & Board of Directors CEO: John P. Butler (current CEO of Akebia) Board to consist of four Akebia directors; five Keryx directors; and a new independent Chairperson, Adrian Adams, selected by Akebia and Keryx 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 Akebia common stock Shareholder Vote and Closing Shareholder vote scheduled for December 11, 2018 Closing expected by year end



Akebia Board of Directors Unanimously Approved the Transaction Transaction was the result of a deliberate, thoughtful process, thorough due diligence, and extensive negotiations that commenced 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 Evercore and JP Morgan were engaged and provided fairness opinions to Akebia's Board 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 the need for expected future dilution Potential to lower Akebia cost of capital Expected to increase cash balance and significantly accelerate time to cashflow breakeven Every member of Akebia board intends to vote shares in favor of the combination, including Chairperson of Akebia Board, who holds approximately 5% of Akebia's outstanding common stock and entered into a voting agreement

Source: Akebia's definitive proxy statement/prospectus filed with the SEC on October 30, 2018 Note: The events above represent a summary of the background of the merger; please refer to definitive proxy statement/prospectus filed with the SEC on October 30, 2018 for the full details Rigorous and Objective Process Led by a Highly Engaged Board 12/8/17: With the consent of the Akebia Board, John Butler contacted Greg Madison, former Keryx CEO, to discuss the potential for a transaction Discussions between Akebia and Keryx's executive teams as well as internally with Akebia Board, management and advisors Dec Jan Feb Mar Apr May Jun Oct 1/5/18: Akebia Board authorized Akebia management to send a non-binding offer letter to Keryx 1/7/18: Keryx sent a non-binding response letter 1/10/18: Akebia sent a counter-proposal, indicating that it was willing to pursue a merger of equals subject to due diligence and the conversion of Baupost's convertible notes at no cost to Akebia Mr. Madison informed Mr. Butler that Keryx was not interested in pursuing a transaction with Akebia at that time, and subsequently explored other strategic alternatives, engaging in high level preliminary discussions with other strategic parties 4/29/18: Ms. Morrison, Keryx's Interim CEO, contacted Mr. Butler to indicate that Keryx would consider renewing discussions regarding a potential transaction with Akebia Legal counsel from both parties negotiated the merger agreement, with direction from Akebia's Transaction Committee Akebia, Keryx and Baupost negotiated and agreed on final conversion terms for the Baupost notes, which terms were approved by the Akebia Board 6/28/18: Transaction announced Baupost entered into a confidentiality agreement with Akebia to conduct due diligence on Akebia and its clinical program Akebia completed a public stock offering, raising \$89.3 mm in gross proceeds 5/4/18: Akebia Board meeting with management to discuss renewing interactions with Keryx; Akebia Board directed Akebia management to continue preparatory work for a potential transaction 5/17/18: Akebia Board created a Transaction Committee to oversee Akebia's activities with respect to the potential transaction and Abrams & Bayliss LLP was engaged to serve as legal counsel to the Transaction Committee 5/24/18: Akebia Board authorized Akebia to send a non-binding offer letter to Keryx 5/30/18: Keryx responded with a counter-proposal Akebia, Keryx and Merger Sub entered into the First Amendment to the Merger Agreement, revising the composition of the Akebia Board post-closing The Akebia Board met more than 13 times prior to announcement, including in multiple executive sessions The Akebia Transaction Committee met more than 7 times prior to announcement, including in multiple executive sessions Rigorous diligence overseen by the Akebia Transaction Committee and conducted by Akebia management and experienced, internationally recognized independent advisors with extensive experience in similar transactions: Financial advisors: Evercore and J.P. Morgan Legal advisor to Akebia: Latham & Watkins LLP Legal advisor to Akebia Transaction Committee: Abrams & Bayliss LLP

...and an Experienced and Independent Transaction Committee Scott Canute Director Since 2016 Dr. Michael Clayman Director Since 2014 Dr. Maxine Gowen Director Since 2014 Dr. Duane Nash Director Since 2013 Michael Wyzga Director Since 2014 30+ years of experience in biopharmaceutical industry Director at Immunomedics, Flexion Therapeutics and Proteon Therapeutics Principal & Founder of Magis Consulting, a biopharmaceutical consulting company, since July 2012 25+ years in medical research Director at Anokion and Kanyos Bio President & CEO of Flexion Therapeutics since its inception in 2007 M.D., UC San Diego 25+ years in the therapeutics industry Director at Idera Pharmaceuticals and the Biotechnology Innovation Organization Former President & CEO of Trevena since she founded the company in 2007 Ph.D., Cell Biology, University of Sheffield, U.K. 20+ years of medical experience and 15+ years of law and management experience Former director at Aerpio Pharmaceuticals President of Vital Therapies M.D., Dartmouth; J.D., University of California, Berkeley 20+ years in the biotechnology industry Independent director and biotech consultant at MSW Consulting Director of Idenix Pharmaceuticals, during Merck & Co's acquisition in 2014 Former President & CEO, Radius Health Fully Independent Transaction Committee

Historical Exchange Ratio Keryx Price Range Benchmarks Source: FactSet as of June 27, 2018 (unless otherwise indicated) Based on Akebia's closing share price as of June 27, 2018 and the transaction exchange multiplier of 0.37433x Displayed range represents a composite of the maximum and minimum discounted cash flow (DCF) values from fairness opinions issued by Evercore and JP Morgan as disclosed in the Akebia's definitive proxy statement/prospectus filed with the SEC on October 30, 2018. JP Morgan DCF analysis indicated a range of implied per share equity values for Keryx of \$4.45 to \$5.35 taking into account NOL limitations, or if 100% of the pro forma synergies are taken into account up to \$6.85. Evercore DCF analysis indicated a range of implied per share equity values for Keryx of \$4.78 to \$5.23 taking into account NOL limitations, not accounting for synergies Range of publicly available share price targets of research analysts' estimates known to Evercore as of June 25, 2018 Ranges calculated as of June 27, 2018, day prior to merger announcement Transaction Price is Attractive and at the Low End of the Range of Several Key Value Metrics Favors Akebia Favors Keryx 2 Transaction Exchange Ratio Implied Transaction Price1 \$3.89 4 4 3

Strong Strategic and Financial Fit Leading Renal Company Portfolio A Phase 3, investigational oral drug for anemia due to chronic kidney disease; and other preclinical compounds under development Auryxia, an FDA-approved drug in two chronic kidney disease related indications FDA-approved drug generating revenue and late-stage product candidate with long-term growth potential Cash and Cash Equivalents \$431 million Pro Forma Cash and Cash Equivalents Position 1 Core Capabilities and Infrastructure Successful R&D expertise Global alliances expertise Established US Commercial and Medical infrastructures Strong reputation in nephrology community Fully integrated capabilities to bring novel compounds through development to commercialization Management and Team Successful and well-respected CEO, CFO and renal leadership team ~90 employees within global R&D organization ~130 employees within Commercial and Medical organizations Fully staffed executive and functional teams, with wide range of experience and success As of 09/30/18, unaudited figures

Potential to Deliver Innovative Therapies to Advance Care for Kidney Disease Patients Iron deficiency anemia (NDD CKD) Anemia due to CKD (DD&NDD) – In development, subject to regulatory approval Hyperphosphatemia (DD CKD) 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

Combined Company Portfolio

Transaction Has Potential to Enhance Capital Resources and Increase Value for Akebia Shareholders in the Near-, Mid- and Long-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 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 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 Pro Forma Offers Stronger Balance Sheet Potential vs. Standalone Potential1 Estimated Stand Alone cash balance Estimated Pro Forma cash balance \$0 2018 2023 Cash runway Standalone is Through 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. Substantial funding gap estimated to be closed by transaction Near Term Mid Term Long Term



Diverse and Experienced Board Committed to Creating Shareholder Value 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. Hefferman Dr. Steven C. Gilman Mark Enyedy Continuing Keryx Directors 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 Combined Company Board

Experienced, Highly-Skilled and Diverse Leadership Team Karen Tubridy SVP, Chief Development Officer 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 Jason A. Amello SVP, CFO & Treasurer 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 John P. Butler President & CEO Former CEO of Inspiration Biopharmaceuticals Former Divisional President of Genzyme's renal business Currently serves on the Board of Zynerva Pharmaceuticals and formerly served as Chairman of the American Kidney Fund Board of Trustees Michel Dahan SVP, Chief Business Officer 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 Tamara Dillon SVP, Chief Human Resources Officer Former Head of Human Resources at Global Discovery Chemistry Former Senior Director of Human Resources at Genzyme Nicole R. Hadas SVP, General Counsel & Secretary Former SVP & General Counsel at Inspiration Biopharmaceuticals Former Senior Corporate Counsel at Genzyme Rita Jain, M.D. SVP, Chief Medical Officer 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 Operational expertise, Relevant Experience, Top Management

Source: Wall Street Research Note: Permission to use quotes was neither sought nor obtained The Transaction Was Well Received by Wall Street Analysts Morgan Stanley (9/7/18) “We see logic in the transaction as there should be synergy between the two companies. If vadadustat is able to succeed in its PhIII clinical program, we think the company will be more equipped to manage its potential.” Ladenburg (6/29/18) “We view Auryxia and vadadustat as complementary products as Auryxia addresses the IDA and vadadustat has the potential to address the erythropoietin deficiency in the same CKD patient population.” RBC (6/28/18) “The merger provides Akebia access to an established CKD commercial infrastructure and therefore should realize financial synergies (~\$250 million guided by management within 5yrs), while strengthening the combined entity's balance sheet.” BTIG (6/28/18) “We believe this is a nice strategic move for Akebia. [...] Keryx provides Akebia with a reasonably efficient way to establish a US sales effort as Vadadustat completes P3.” HCW (8/10/18) “From Akebia's perspective, the merger offers a highly experienced, readily leveraged marketing and sales infrastructure. We believe this infrastructure should improve the future launch of vadadustat in partnership with Otsuka.” Maxim (8/8/18) “The merger should provide a complementary portfolio of renal assets for CKD-related morbidities, including the addition of Akebia’s P3 asset vadadustat for CKD anemia.” Piper Jaffray (8/8/18) “We continue to think the deal makes good strategic sense, particularly given physician survey feedback that we think portends well for the Auryxia sales trajectory.” Mizuho (7/2/18) “We like the merger from a strategic and financial standpoint over time. We believe Keryx and Akebia products are complementary and will provide multiple avenues of value creation for the ‘new’ Akebia.” Needham (6/29/18) “Synergies between the two companies could create a market leader in oral therapeutics for treatment of kidney related anemia.”

An Attractive Combination for All Stakeholders Strong strategic and financial fit Complementary portfolio, infrastructure and teams Financial strength due to pro forma cash and cash equivalents position and revenue-generating, FDA-approved asset Unanimous support from independent, experienced Board Thorough diligence and transaction review Chairperson (owner of approximately 5% of Akebia stock) entered into voting agreement in support of transaction Strong support from research analysts Potential to advance care and improve outcomes for kidney disease patients In the US alone, 2.2 million CKD patients<sup>1</sup>, of whom approximately 1.7 million are NDD patients<sup>2</sup>, have the potential to be treated by the combined drug portfolio 1. US Census Bureau 2017; NHANES 2009-2014 2. Spherix Caseload Dynamix, Chronic Kidney Disease, January 2016