UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(D)
OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): June 4, 2019

AKEBIA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-36352**	**20-8756903**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

245 First Street **Cambridge, Massachusetts**	**02142**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 871-2098

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.00001 per share	**AKBA**	**The Nasdaq Global Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 7.01. Regulation FD Disclosure.

Spokespersons of Akebia Therapeutics, Inc. (the "Company") plan to present the information in the presentation attached hereto as Exhibit 99.1 (the "Presentation") at the Jefferies 2019 Healthcare Conference on June 4, 2019 at 3:00 p.m. Eastern Time and at various meetings beginning on June 4, 2019, including investor and analyst meetings.

In May 2019, the Independent Data Monitoring Committee held another meeting and recommended that the Company's global Phase 3 PRO_2TECT and $INNO_2VATE$ programs for its product candidate, vadadustat, continue and did not recommend any modifications to the programs.

The information in this Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities under that Section. The information contained in this Item 7.01 and Exhibit 99.1 hereto shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission (the "SEC") made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

By providing the information in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1 hereto, the Company is not making an admission as to the materiality of any information herein. The information contained in this Current Report on Form 8-K is intended to be considered in the context of more complete information included in the Company's filings with the SEC and other public announcements that the Company has made and may make from time to time by press release or otherwise. The Company undertakes no duty or obligation to update or revise the information contained in this Current Report on Form 8-K, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosures.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Presentation dated June 4, 2019

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AKEBIA THERAPEUTICS, INC.

Date: June 4, 2019

By: /s/ John P. Butler
Name: John P. Butler
Title: President and Chief Executive Officer

Exhibit 99.1


Akebia®
THERAPEUTICS
DEDICATED TO ADVANCING
CARE FOR PATIENTS WITH
KIDNEY DISEASE

CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS

Statements in this presentation regarding Akebia's strategy, plans, prospects, expectations, beliefs, intentions or goals are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including but not limited to statements regarding the expected period of time our cash resources and estimated product revenue will fund operations; the timing, availability and presentation of clinical trial data and results; the commercial potential, growth potential and market opportunity for our product and, if approved, our product candidates; our strategy, mission and vision; potential for our product candidates to set a new standard of care; the potential benefits of our product candidates; the timing of enrollment, including full enrollment, of our clinical trials; the target enrollments of our clinical trials; the assessments and evaluations we expect from our clinical programs; the potential to be a partner of choice for innovation in renal; and exploring co-development potential for vadadustat and Auryxia. The terms "estimate," "expect," "growth," "momentum," "mission" "opportunity," "positioned," "potential," "vision" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement, including the actual product revenues for Auryxia; the timing of generic entrants for Auryxia, vadadustat or any other product candidates; the rate of enrollment in clinical studies of vadadustat; the risk that clinical trials may not be successful; the risk that existing preclinical and clinical data may not be predictive of the results of ongoing or later clinical trials; manufacturing risks; the quality and manner of the data that will result from clinical studies of vadadustat; the actual funding required to develop and commercialize Akebia's product candidates and operate the company, and the actual expenses associated therewith; efficacy, safety and tolerability of our products and product candidates; the risk that clinical studies need to be discontinued for any reason, including for safety, tolerability, enrollment, manufacturing or economic reasons; early termination of any of Akebia's collaborations or license agreements, and the parties' ability to satisfy their obligations under such agreements; the timing and content of decisions made by regulatory, judicial or similar authorities; the timing of any additional studies initiated for vadadustat; the actual time it takes to initiate and complete research and clinical studies; the success of competitors in developing product candidates for diseases for which Akebia is currently developing its product candidates; the scope, timing, and outcome of any ongoing legal proceedings; changes in the economic and financial conditions of the businesses of Akebia and its partners; and Akebia's ability to obtain, maintain and enforce patent and other intellectual property protection for Auryxia, vadadustat and its other product candidates. Other risks and uncertainties include those identified under the heading "Risk Factors" in Akebia's Quarterly Report on Form 10-Q for the quarter ended March 31, 2019, filed with the SEC, and other filings that Akebia may make with the SEC in the future. These forward-looking statements (except as otherwise noted) speak only as of the date of this presentation, and Akebia does not undertake, and specifically disclaims, any obligation to update any forward-looking statements contained in this presentation. Vadadustat is an investigational drug and has not yet been approved by the U.S. Food and Drug Administration (FDA) or any regulatory authority.

Akebia® THERAPEUTICS

Fully Integrated Biotech Company Focused On Kidney Disease

John P. Butler, President and CEO

FDA-APPROVED

Product revenue in two FDA-approved indications with substantial growth potential

CASH RESOURCES

Expect cash resources[1] to fund operations into Q3 2020. $168 million cash position[2].

MULTIPLE CLINCAL CATALYSTS

Multiple clinical catalysts over next 12 to 18 months for Phase 3 product candidate with multi-billion-dollar global market opportunity

COMMERCIAL OPERATIONS

Experienced nephrology focused commercial sales and marketing organization

1 Includes prepaid quarterly committed cost share funding from Akebia's collaborators | 2 Cash, cash equivalents and available for sale securities as of 3/31/19.

Akebia THERAPEUTICS

Significant Strategic Partnerships

Otsuka

VIFOR PHARMA

Johnson & Johnson

Mitsubishi Tanabe Pharma

JTI JAPAN TOBACCO INTERNATIONAL

PIC/S GMP 藥廠 PBF 寶齡富錦生技 Panion & BF Biotech Inc.

OUR VISION

Improve the Health of Patients with Kidney Disease through Better Disease Management and Novel Therapeutics

CKD On Dialysis

CKD Non-Dialysis

COMMERCIALIZED

HYPERPHOSPHATEMIA IN DIALYSIS

Auryxia®
(Ferric Citrate)
FDA approved in two indications

IRON DEFICIENCY ANEMIA IN NON-DIALYSIS

ANEMIA DUE TO CKD IN DIALYSIS

Vadadustat
(An Investigational HIF PHI inhibitor)
In global Phase 3 with read-outs beginning 2019

ANEMIA DUE TO CKD IN NON-DIALYSIS

DEVELOPMENT PROGRAM

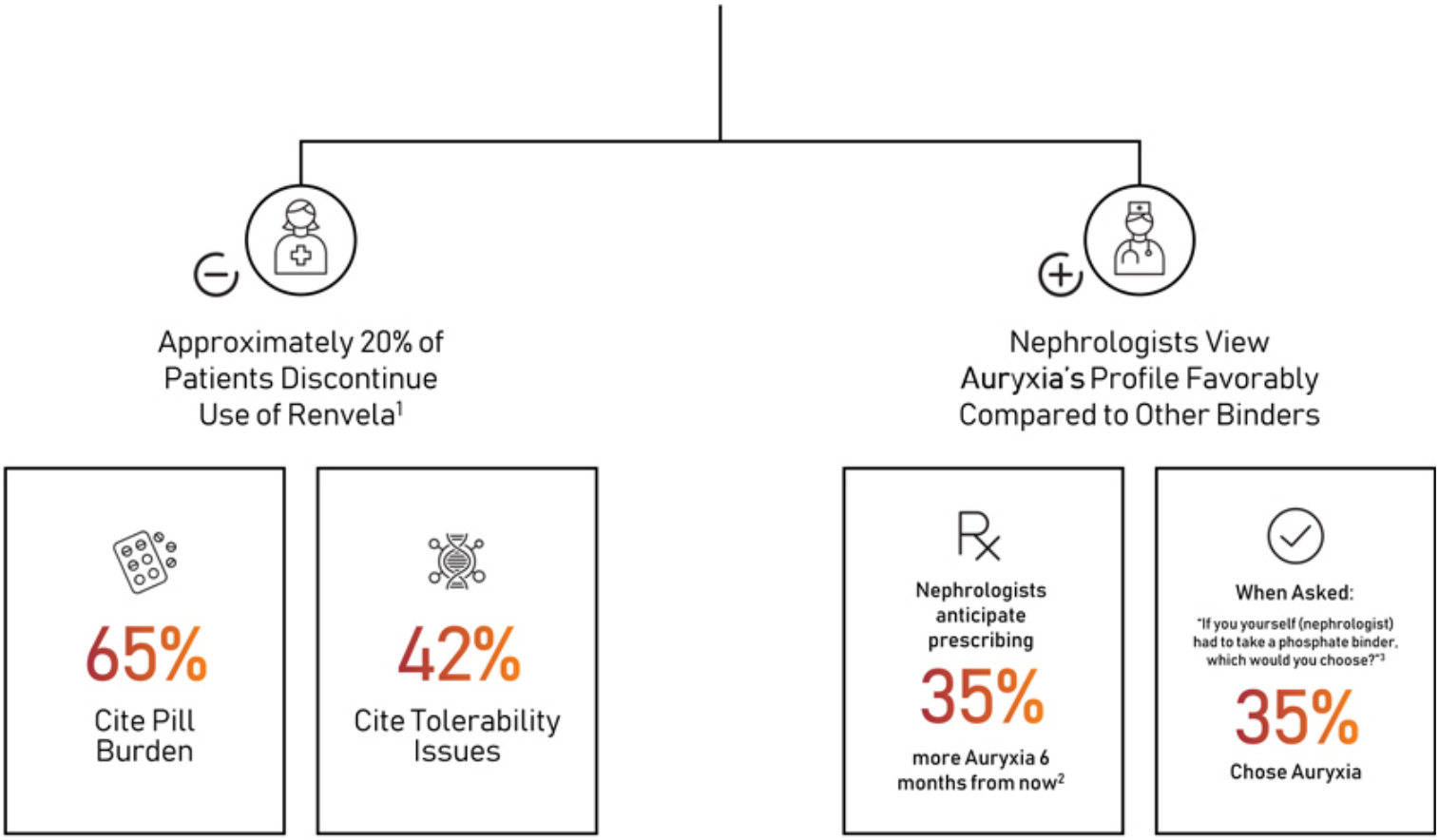
Auryxia

Akebia THERAPEUTICS

Dialysis

AURYXIA OPPORTUNITY IN THE HYPERPHOSPHATEMIA MARKET:

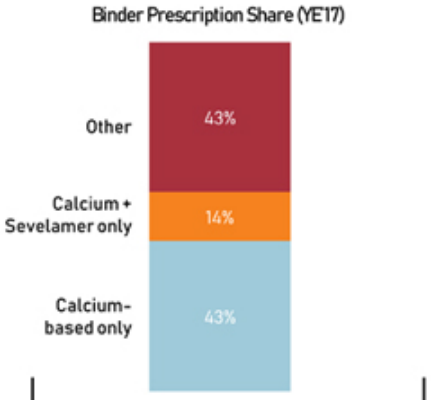
Patient Dissatisfaction With Standard Of Care And Nephrologist Positive Perception



SOURCES: 1 Spherix Global Insights Bone and Mineral Metabolism, quantitative market research survey, Q4 2018, n=195 nephrologists, "Considering your use of Auryxia, Velphoro and Renvela, what percent of all the patients you prescribed these agents for in the past six months have since discontinued the brand (e.g. have been switched to a different brand or discontinued altogether)?", "To what extent are the following reasons that patients typically discontinue AURYXIA, VELPHORO, RENVELA 1= Rarely/Never, 5= Very Frequently/ Almost Always".; 2 Auryxia ATU Q4 2018, n = 104 nephrologists.; 3 Spherix Global Insights Bone and Mineral Metabolism, quantitative market research survey, Q4 2018, n=195 nephrologists.

Dialysis

KDIGO TREATMENT GUIDELINE UPDATE FAVORABLE FOR AURYXIA



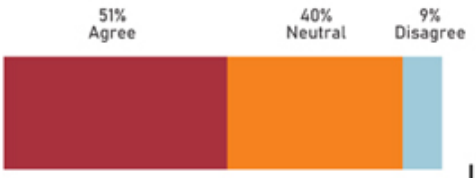
CALCIUM-BASED BINDERS COMPRISE SIGNIFICANT PORTION OF MARKET[1]...

"In adult patients with CKD G3a-G5D receiving phosphate-lowering treatment, we suggest restricting dose of calcium-based phosphate binders"

- KDIGO 2017 Practice Guideline Update[2]

...RECENT GUIDELINE LIMITS THEIR USE

"As a result of KDIGO CKD-MBD guideline update, I anticipate decreasing my use of ca-based binders in my dialysis patients[3]"



...NEPHROLOGISTS ANTICIPATE ADOPTION OF UPDATED GUIDELINE

SOURCES: 1 Phosphate Binder Use, by type. DOPPS Practice Monitor. https://www.dopps.org/dpm/DPMSlideBrowser.aspx. Accessed 12.21.2018.; 2 KDIGO 2017 Clinical Practice Guideline Update for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease-Mineral and Bone Disorder (CKD-MBD). Kidney International Supplements (2017) 7, 1–59.; 3 Spherix Global Insights Bone and Mineral Metabolism, quantitative market research survey, Q4 2018, n=195 nephrologists, "Please rate your level of agreement with the following statement: As a result of KDIGO CKD-MBD guideline update, I anticipate decreasing my use of ca-based binders in my dialysis patients".

AURYXIA: SOLID PERFORMANCE

Total Pro-forma Unaudited Full-Year Auryxia Sales Increased 72% To

$96MM

IN 2018 COMPARED TO 2017

Total Prescriptions Increased

85%

IN 2018 COMPARED TO 2017

6.6% Market Share In 2018

4.2% Market Share In 2017

HIGHEST SHARE GAIN OF ALL PHOSPHATE BINDERS

Well Positioned to Drive Continued Growth in 2019

Source: IQVIA NPA, Dialysis SP TRx Data *2018 Annual Auryxia revenue is pro-forma unaudited combined full-year Auryxia sales including sales recorded by Keryx prior to the merger on December 12, 2018.

AURYXIA: IMPROVING Q2FY19 OUTLOOK

Highest prescription demand in first

4 WEEKS

of any quarter since Auryxia launch

May 9, 2019 Q1FY19 Press Release

Highest prescription demand in first

8 WEEKS

of any quarter since Auryxia launch

June 4, 2019 Jefferies Conference Presentation

Well Positioned to Drive Continued Growth in 2019

Non-Dialysis

AURYXIA OPPORTUNITY IN THE IRON DEFICIENCY ANEMIA (IDA) MARKET:

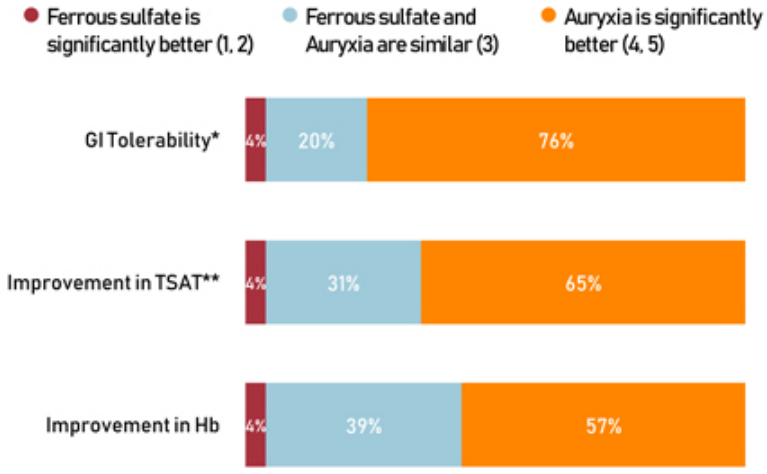
Nephrologists Believe Auryxia Has Strong Potential In IDA

Nephrologist Perspective On Auryxia to Potentially Address The Unmet Need[1]

48% Very likely to use after traditional oral iron failure

44% Very likely to use in place of traditional oral iron

Nephrologist Perspective On How Auryxia Compares to Traditional Oral Iron[2]



Disclaimer: Not Based On Head-to-head Data

* Gastrointestinal; ** Transferrin saturation SOURCES: 1 Auryxia ATU market research survey Q3 2018 (n= 102 nephrologists).; 2 Auryxia ATU market research survey Q4 2018 (n= 74 nephrologists), only polled nephrologists currently using Auryxia.

Non-Dialysis

DR. GEOFF BLOCK ET AL PRESENTED RESULTS FROM AN INVESTIGATOR-SPONSORED STUDY OF FERRIC CITRATE AT ERA-EDTA 2018

- Single-center, open-label, randomized trial comparing ferric citrate (FC) and standard of care in subjects with advanced non-dialysis CKD (Stage 4/5)
- Assessed hypothesis that "provision of fixed dose FC to subjects with advanced CKD, independent of serum phosphate or degree of anemia, would improve multiple biochemical aspects simultaneously and reduce the need for exogenous ESA or intravenous (IV) iron"[1]
- Baseline characteristics were comparable with the exception of diabetes (FC 47%, SOC 77%, p=0.001)[1]
- Accepted for publication

A Randomized Trial of Ferric Citrate in Advanced Chronic Kidney Disease

Geoffrey A Block, Martha Persky, Gerard Smits, Laura Kooienga, Rupal Mehta, Tamara Isakova, Myles Wolf and Glenn Chertow

"The data from this study suggest that administering ferric citrate to late-stage pre-dialysis patients not only improves biochemical parameters associated with chronic kidney disease, but also has the potential to delay the need for dialysis," said Geoffrey Block, M.D,, Director of Clinical Research at Denver Nephrology.

"With the impact of ferric citrate across multiple aspects of CKD, it is worth further investigation to determine which of these many factors is contributing to the reduced risk of renal replacement therapy observed in this study."

*Keryx Biopharmaceuticals, Inc. (now a wholly owned subsidiary of Akebia) provided funding and study medication for this investigator initiated study.; SOURCE 1 Geoffrey Block, Martha Block, Gerard Smits, Laura Kooienga, Rupal Mehta, Tamara Isakova, Myles Wolf, Glenn Chertow. Randomized trial of the effects of ferric citrate in patients with advanced chronic kidney disease. ERA-EDTA 2018.


Vadadustat
Akebia
THERAPEUTICS

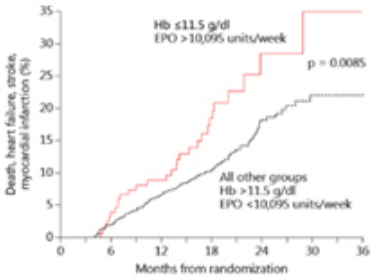

Vadadustat
AN INVESTIGATIONAL ORAL HIF PH INHIBITOR DESIGNED TO STIMULATE ENDOGENOUS EPO PRODUCTION
with the potential to establish a new standard of care
Vadadustat now in Phase 3 cardiovascular outcomes trials for anemia due to CKD in non-dialysis and dialysis subjects. Vadadustat is an investigational HIF PH inhibitor that is not approved by the FDA or any other regulatory authority.

Vadadustat is an oral HIF PH inhibitor designed to stimulate endogenous EPO production, with the potential to increase hemoglobin while avoiding supra-physiological EPO levels

HIGH EPO LEVEL IS ASSOCIATED WITH INCREASED CV RISK

Kaplan-Meier Survival Curves[1]

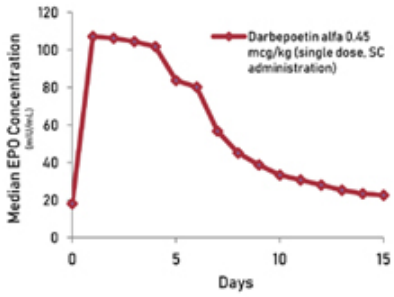
Death, Heart Failure, Stroke, Myocardial Infarction



SoC WITH INJECTABLE ESAs RESULT IN SUPRA-PHYSIOLOGICAL EPO LEVELS

EPO vs Time with Darbepoetin Alfa (SC)

PK-PD Model in CKD Subjects[2]

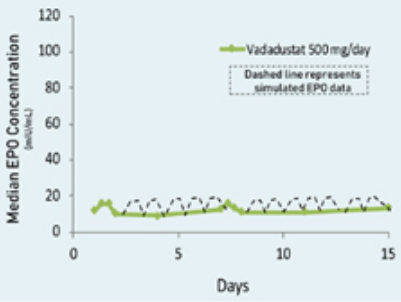


VADADUSTAT, ORAL HIF PH INHIBITOR, AVOIDED SUPRA-PHYSIOLOGICAL EPO LEVELS

NOT A HEAD-TO-HEAD COMPARISON

EPO vs Time with vadadustat (Oral)

Phase 1 Study in Healthy Volunteers[3]



SOURCES: 1 McCullough P.A., et al. Am J Nephrol 2013;37:549-558 (DOI:10.1159/000351175). Permission granted by S. Karger AG, Basel.; 2 Doshi S et al. Journal of Clinical Pharmacology, 2010;50:755-905. 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.; 3 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.

Non-Dialysis

GLOBAL PHASE 3 PROGRAM FOR VADADUSTAT FOR NON-DIALYSIS

NDA/MAA Core Package

Cardiovascular Outcomes PRO$_2$TECT Phase 3 Studies
Anemia due to CKD in Non-Dialysis Dependent Subjects

PRO$_2$TECT CORRECTION

Not ESA Treated
Vadadustat vs
Darbepoetin Alfa

N ≈ 3,700

PRO$_2$TECT CONVERSION

ESA Treated
Vadadustat vs
Darbepoetin Alfa

PRIMARY EFFICACY ENDPOINT:
Change in hemoglobin (Hb) from baseline

PRIMARY SAFETY ENDPOINT:
Major Adverse Cardiovascular Events (MACE)

Non-Dialysis

GLOBAL PHASE 3 PROGRAM FOR VADADUSTAT FOR NON-DIALYSIS

Additional Non-Primary Endpoints

- INDIVIDUAL MACE COMPONENTS
- CHRONIC HEART FAILURE
- THROMBOTIC EVENTS
- HOSPITALIZATIONS
- HB EXCURSIONS
- TIME IN RANGE (HB)
- IV IRON USE
- CKD PROGRESSION

Dialysis

GLOBAL PHASE 3 PROGRAM FOR VADADUSTAT FOR DIALYSIS

NDA/MAA Core Package

Cardiovascular Outcomes INNO$_2$VATE Phase 3 Studies
Anemia due to CKD in Dialysis Subjects

INNO$_2$VATE CORRECTION CONVERSION

New-Onset Dialysis
Vadadustat vs
Darbepoetin Alfa

N ≈ 3,900

INNO$_2$VATE CONVERSION

ESA Treated
Vadadustat vs
Darbepoetin Alfa

PRIMARY EFFICACY ENDPOINT:
Change in hemoglobin (Hb) from baseline

PRIMARY SAFETY ENDPOINT:
Major Adverse Cardiovascular Events (MACE)

Dialysis

GLOBAL PHASE 3 PROGRAM FOR VADADUSTAT FOR DIALYSIS

Additional Ongoing/Planned Studies to Support Value Proposition

FO$_2$RWARD-2

Phase 2, Open-label, efficacy, safety, PK/PD in DD[1]-CKD, control arm epoetin alfa, modified once daily (QD) and Three Times a Week (TIW) dosing, and ESA Hyporesponders,

EXPLO$_2$RE

Open-label, Sponsor-Blind, parallel arm study evaluating efficacy and safety of Modified QD dosing of vadadustat compared to ESA

TRILO$_2$GY-2

Open-label, Sponsor-Blind, parallel arm study evaluating efficacy and safety of TIW dosing of vadadustat compared to ESA

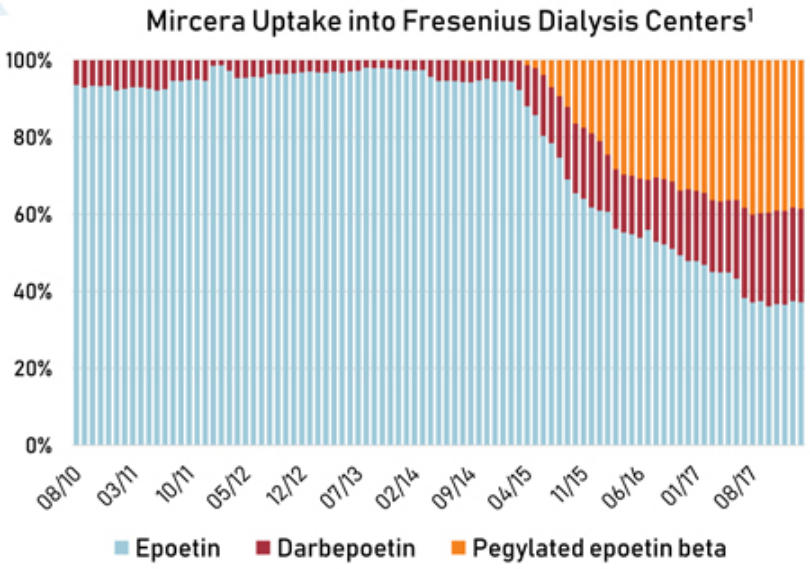
[1] Dialysis-dependent

Dialysis

STRONG DISTRIBUTION CHANNEL TO U.S. DIALYSIS NETWORK

VIFOR PHARMA

- Unique market dynamics with treatment adoption driven by protocols
- Agreement with Vifor (International) Ltd. positions vadadustat for rapid uptake in Fresenius LDO subject to FDA approval*
- Recent amendment expands agreement, facilitating access to up to 60% of U.S dialysis patients
- TDAPA[2] creates major additional opportunity for value creation for Akebia



*Subject to the earlier of reimbursement under TDAPA (defined below) or inclusion in the ESRD bundle. SOURCES: 1 ESA Use, by type. DOPPS Practice Monitor. https://www.dopps.org/dpm/DPMSlideBrowser.aspx. Accessed 12/19/2018.; 2 TDAPA: Transitional drug add-on payment adjustment, CMS Ruling CMS-1691-F. Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments to Correct Existing Regulations Related to the CBP for Certain DMEPOS.

Expected Near-Term Clinical Catalysts

*Subject to accrual of MACE events.


Akebia®
THERAPEUTICS
THANK YOU | QUESTIONS?