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): September 9, 2021

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

N/A
(Former name or former address, if changed since last report)

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.

John P. Butler, President and Chief Executive Officer of Akebia Therapeutics, Inc. (the "Company"), plans to present the information in the presentation attached hereto as Exhibit 99.1 (the "Presentation") at upcoming investor conferences in September 2021. Spokespersons of the Company also plan to present the information in the Presentation at various meetings beginning on September 9, 2021, including investor and analyst meetings.

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.	Exhibit Description
99.1	Akebia Therapeutics, Inc. Presentation September 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: September 9, 2021

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

Akebia® THERAPEUTICS

BETTERING THE LIVES OF PEOPLE IMPACTED BY KIDNEY DISEASE

John P. Butler, President and CEO
(Nasdaq: AKBA)

September 2021

CAUTIONARY NOTE

ON FORWARD-LOOKING STATEMENTS

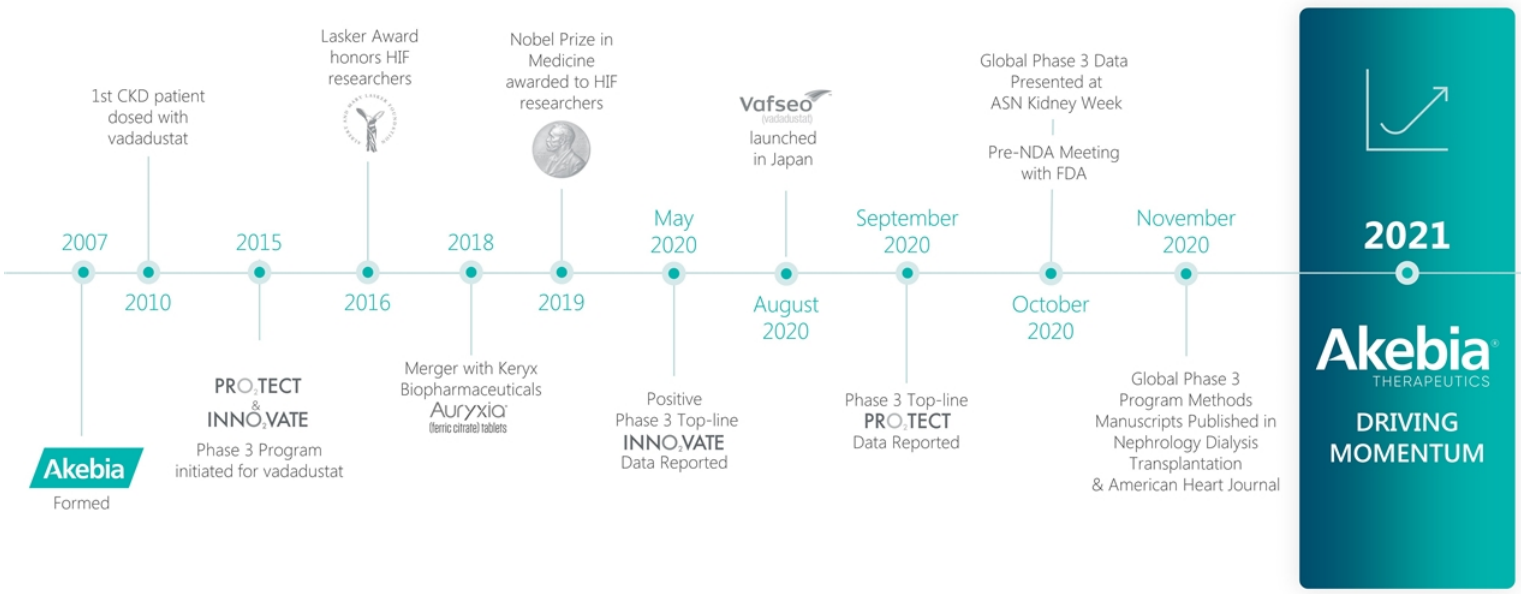
Akebia THERAPEUTICS

Statements in this presentation regarding Akebia's strategy, plans, prospects, expectations, beliefs, intentions and goals are forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, as amended, and include, but are not limited to, statements regarding: vadadustat as a potential first-in-class oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI), and vadadustat's related potential as the new oral standard of care, for the treatment of anemia due to chronic kidney disease (CKD); Akebia's cash runway funding Akebia's current operating plan through at least the next twelve months, assuming timely regulatory approval and receipt of associated regulatory milestones; Akebia's submission of an E.U. Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) and the timing thereof and any related expansion into Europe; establishing vadadustat as a potential oral alternative to injectable erythropoiesis-stimulating agents; the U.S. market opportunity, including first-to-market potential, for vadadustat to treat patients on dialysis, and the overall opportunity within such market; the potential for rapid adoption of vadadustat, if approved by regulatory authorities, as the first oral HIF-PHI for U.S. dialysis patients; the potential for Akebia to receive regulatory and commercial milestone payments upon approval of vadadustat by regulatory authorities; Akebia's ability to leverage Auryxia's commercial foundation for vadadustat in CKD patients, if approved; the level of potential for vadadustat, if approved by regulatory authorities, for the non-dialysis indication; the potential for vadadustat to be used as a therapy to prevent and lessen the severity of acute respiratory distress syndrome and in other indications where vadadustat may have therapeutic benefits and were there is unmet need; the expansion of Akebia's pipeline and portfolio of novel therapeutics, including by leveraging new partnership relationships and Akebia's related research and development activities and engaging in internal discovery and development; and overall market opportunity, clinical opportunity, commercial potential, prevalence, and the growth in, and potential demand for, vadadustat. The terms "believe," "expect," "goal," "look forward," "future," "opportunity," "planned," "potential," "will", "estimate," derivatives of these words, and similar references are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results, performance or experience may differ materially from those expressed or implied by any forward-looking statement as a result of various risks, uncertainties and other factors, including, but not limited to, risks associated with: any delays in the U.S. Food and Drug Administration's (FDA) review of, and potential approval related to, Akebia's New Drug Application (NDA) submission for any reason, including any delay arising from the FDA's potential inability to perform and complete inspections and audits of Akebia or the suppliers, vendors or other third parties with which Akebia works with due to the COVID-19 pandemic; the potential therapeutic benefits, safety profile, and effectiveness of Akebia's product candidates, including vadadustat; the potential indications, demand and market opportunity, potential and acceptance of Akebia's product and product candidates, including Akebia's estimates regarding the potential market opportunity for Akebia's product, vadadustat, if approved, or any other product candidates and the size of eligible patient populations; enrollment in clinical and preclinical studies; the timing, likelihood and content of and advice given and decisions made by health authorities, such as the U.S. Food and Drug Administration (FDA) or the EMA, with respect to regulatory filings and approvals, including labeling or other restrictions, the potential approval of vadadustat and Akebia's outlook related thereto, and potential indications for vadadustat; the direct or indirect impact of the COVID-19 pandemic on regulators and Akebia's business, operations, and the markets and communities in which Akebia and its partners, collaborators, vendors and customers operate; manufacturing, supply chain and quality matters and any recalls, write-downs, impairments or other related consequences or potential consequences; hiring, training, management and retention and key personnel changes and transitional periods; the actual funding required to continue to commercialize Akebia's commercial product, to develop and commercialize vadadustat, and to operate Akebia; market acceptance and coverage and reimbursement of Akebia's commercial product and vadadustat, if approved; potential generic entrants for Akebia's commercial product and vadadustat, if approved; early termination of any of Akebia's collaborations; Akebia's and its collaborators' ability to satisfy their obligations under Akebia's collaboration agreements; the competitive landscape for Akebia's commercial product and vadadustat, if approved; the scope, timing, and outcome of any legal, regulatory and administrative proceedings; changes in the economic and financial conditions of the businesses of Akebia and its collaborations partners and vendors; expected reliance on third parties, including with respect to the development, manufacturing, supply and commercialization of Akebia's product and product candidates; Akebia's expectations, projections and estimates regarding its capital requirements, need for additional capital, financing Akebia's future cash needs, costs, expenses, revenues, capital resources, cash flows, financial performance, profitability, tax obligations, liquidity, growth and contractual obligations; Akebia's internal control over financial reporting and disclosure controls and procedures, and remediation of any material weakness or deficiencies identified in its internal controls and procedures; and Akebia's intellectual property position, including its ability to obtain, maintain and enforce patent and other intellectual property protection for Akebia's commercial product, vadadustat and any other product candidates. Other risks and uncertainties include those identified under the heading "Risk Factors" in Akebia's Annual Report on Form 10-K for the year ended December 31, 2020, and its most recent Quarterly Report on Form 10-Q for the period ended June 30, 2021, and other filings that Akebia may make with the U.S. Securities and Exchange Commission in the future. These forward-looking statements (except as otherwise noted) speak only as of the date of this presentation, and except as required by law, 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 FDA or any regulatory authority with the exception of Japan's Ministry of Health, Labour and Welfare.

OUR HISTORY

TRACK RECORD OF EXECUTION AND INNOVATION



In the U.S., vadadustat is an investigational HIF PH inhibitor that is not approved by the FDA.

AKEBIA TODAY
DRIVING MOMENTUM

Akebia THERAPEUTICS

VADADUSTAT

POTENTIAL FIRST-IN-CLASS ORAL HIF-PH INHIBITOR FOR THE TREATMENT OF ANEMIA DUE TO CHRONIC KIDNEY DISEASE (CKD)

- ✓ NDA FILED; PDUFA DATE: MARCH 29, 2022
- ✓ PHASE 3 RESULTS PUBLISHED IN *NEW ENGLAND JOURNAL OF MEDICINE*

KEY VALUE DRIVERS

UNDER FDA REVIEW
- VADADUSTAT FOR ANEMIA DUE TO CKD
  - DIALYSIS
  - NON-DIALYSIS

CLINICAL PROGRAM
- VADADUSTAT INDICATION EXPANSION
  - ACUTE RESPIRATORY DISTRESS SYNDROME (ARDS)[1]

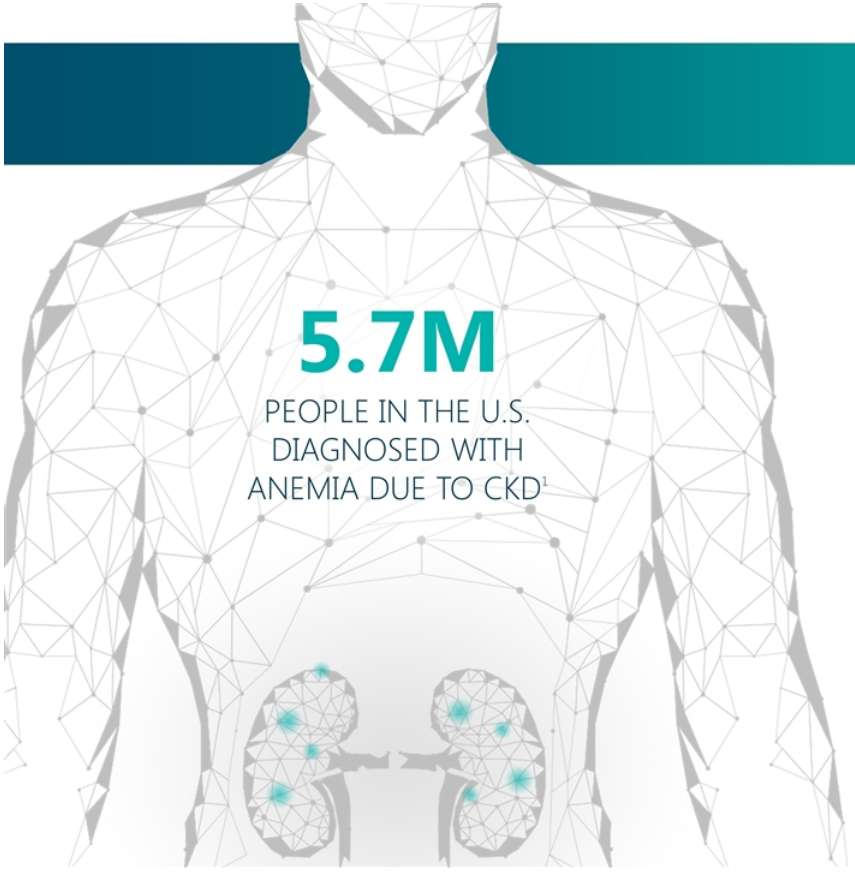
COMMERCIAL PROGRAM
- AURYXIA® (ferric citrate)
  - HYPERPHOSPHATEMIA FOR CKD
  - IRON DEFICIENCY ANEMIA (IDA) FOR CKD

Auryxia® (ferric citrate) tablets

FUNDING THROUGH AT LEAST THE NEXT 12 MONTHS[2]

HIF-PH or HIF-PHI is hypoxia-inducible factor prolyl hydroxylase inhibitor. NDA is New Drug Application. PDUFA is Prescription Drug User Fee Act. 1. In June 2020, Akebia announced an investigator-sponsored clinical study by UTHealth of vadadustat for ARDS. This study is being conducted under an Investigational New Drug application (IND) with UTHealth as the study sponsor. 2. Cash, cash equivalents and available-for-sale securities as of June 30, 2021 were $247.0 million. The Company believes that its cash resources will be sufficient to fund its current operating plan through at least the next twelve months. Additionally, the Company believes its cash runway would extend beyond the next twelve months assuming timely regulatory approval of vadadustat and the receipt of associated regulatory milestones.

ANEMIA DUE TO CKD: UNMET NEEDS



BURDEN OF DISEASE

Quality of life: fatigue, weakness, dizziness, shortness of breath

CLINICAL IMPACT

Anemia due to CKD can contribute to risk of ESKD, cardiovascular (CV) disease, stroke, cognitive impairment, CV-related complications and death

CURRENT STANDARD OF CARE

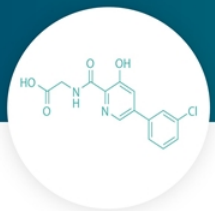
Consists of injectable ESAs which have been associated with frequent hemoglobin overshoots, supra physiologic elevations of EPO, delivered through inconvenient injectable administration

ESKD is End Stage Kidney Disease. ESA is erythropoiesis-stimulating agent. EPO is erythropoietin. Sources: 1 . Stauffer et al, PLOSONE, 2014. 2 2020 USRDS Annual Data Report: https://adr.usrds.org/2020/reference-tables.

VADADUSTAT

POTENTIAL FIRST-IN-CLASS ORAL HIF-PHI

Akebia THERAPEUTICS



INNOVATIVE MoA

An oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) designed to stimulate endogenous EPO production; Based on Nobel Prize winning science

CONVENIENT ORAL DOSING

Positioned to be potential oral standard of care; Potential oral alternative to injectable ESAs

ROBUST CLINICAL RESULTS

First HIF-PHI to have global Phase 3 results published in peer-reviewed journal (*New England Journal of Medicine)*

COMMERCIAL BREADTH

Experienced nephrology focused salesforce complemented by strong commercial partnerships with industry leaders

MoA is mechanism of action. EPO is erythropoietin.

In the U.S., vadadustat is an investigational HIF- PH inhibitor that is not approved by the FDA.

VADADUSTAT

ROBUST AND HIGHLY DIFFERENTIATING CLINICAL DATA

An oral HIF-PH inhibitor designed to stimulate endogenous EPO production

POTENTIAL NEW ORAL STANDARD OF CARE FOR ANEMIA DUE TO CKD

Vadadustat is not approved by the FDA.

CLINICAL DATA HAS SHOWN THAT VADADUSTAT:

- ✓ Increased hemoglobin in predictable and controlled manner
- ✓ Minimized hemoglobin overshoots
- ✓ Maintained EPO within physiologic range

Sources: Data from: Akebia's global Phase 3 program which included two separate programs, INNO$_2$VATE and PRO$_2$TECT. Both INNO$_2$VATE and PRO$_2$TECT were global, multicenter, open label (sponsor blind), active-controlled (darbepoetin alfa - an injectable erythropoiesis stimulating agent (ESA)), non-inferiority studies, which were published in the *New England Journal of Medicine* in April 2021. Akebia's Phase 1 Study in Normal Healthy Volunteers (CI-0002). Akebia's Phase 2b Study in Dialysis-Dependent CKD Patients (CI-0011).

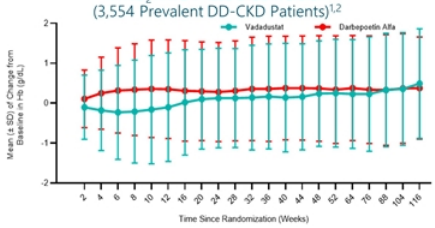
VADADUSTAT

GLOBAL PHASE 3 RESULTS: DIALYSIS

Positive global Phase 3 data demonstrated the efficacy and cardiovascular safety of vadadustat compared to darbepoetin alfa in adult patients with anemia due to CKD on dialysis, including prevalent and incident patients.

Met Primary Efficacy Endpoint: Mean Change from Baseline in HGB Levels: Dialysis Dependent CKD Patients

INNO$_2$VATE Phase 3 Conversion
(3,554 Prevalent DD-CKD Patients)[1,2]



Mean (SEM) change from baseline, g/dL	Difference (vadadustat - darbepoetin alfa)
Weeks 24-36	-0.17 (0.03) (95% CI, -0.23 to -0.10)
Weeks 40-52	-0.18 (0.03) (95% CI, -0.25 to -0.12)

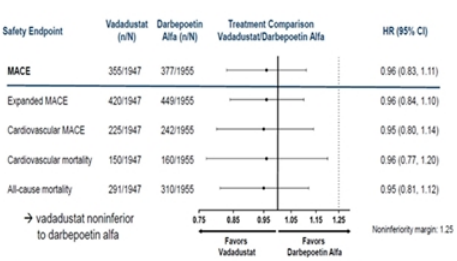
Met Primary Efficacy Endpoint: Mean Change from Baseline in HGB Levels: Dialysis Dependent CKD Patients

INNO$_2$VATE Phase 3 Correction/Conversion
(369 Incident DD-CKD Patients)[1,2]

Mean (SEM) change from baseline, g/dL	Difference (vadadustat - darbepoetin alfa)
Weeks 24-36	-0.31 (0.11) (95% CI, -0.53 to -0.10)
Weeks 40-52	-0.07 (0.13) (95% CI, -0.34 to 0.19)

Met All Primary and Key Secondary Safety (MACE) Endpoints: Dialysis Dependent CKD Patients

INNO$_2$VATE Phase 3 Studies
(Prevalent and Incident DD-CKD Patients)[1,2]



MACE is the composite of all-cause mortality, non-fatal myocardial infarction, or non-fatal stroke. All MACE safety endpoints were adjudicated by a committee blinded to treatment assignment

Source: 1. K.-U. Eckardt, et al. Global Phase 3 Clinical Trials of Vadadustat for Treatment of Anemia in Patients With Dialysis-Dependent Chronic Kidney Disease (DD-CKD). Presented at: American Society of Nephrology Kidney Week; October 22, 2020. (Akebia's Phase 3 randomized, open-label, active-controlled non-inferiority study assessed the efficacy and safety of vadadustat compared to darbepoetin alfa in 3,923 dialysis-dependent subjects with anemia due to CKD, with a treatment duration of 52 weeks.) 2 K.-U. Eckardt, et al. Safety and Efficacy of Vadadustat for Anemia in Patients Undergoing Dialysis. N Engl J Med 2021; 384 1601-12. DOI: 10:1056/NEJMoa2025956

VADADUSTAT

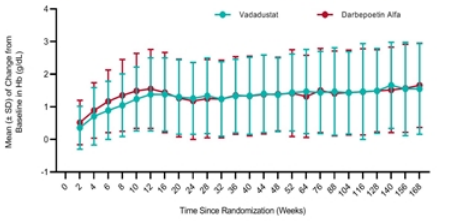
PURSUING A BROAD LABEL FOR PATIENTS NOT ON DIALYSIS

Akebia THERAPEUTICS

Positive global Phase 3 data demonstrated the efficacy of vadadustat compared to darbepoetin alfa in adult patients with anemia due to CKD not on dialysis; however, vadadustat did not meet the primary safety (MACE) endpoint of the PRO_2TECT studies.

Met Primary Efficacy Endpoint: Mean Change from Baseline in HGB Levels: Non-Dialysis Dependent CKD Patients

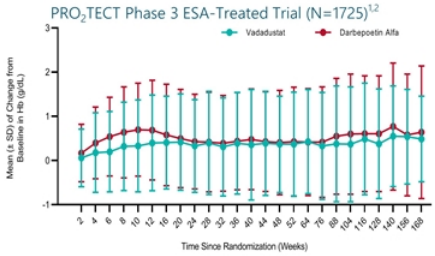
PRO_2TECT Phase 3 ESA-Untreated Trial (N=1751)[1,2]



Mean change from baseline, g/dL	Difference (vadadustat - darbepoetin alfa)
Weeks 24-36	0.05 (95% CI, -0.04 to 0.15)
Weeks 40-52	0.04 (95% CI, -0.06 to 0.14)

Met Primary Efficacy Endpoint: Mean Change from Baseline in HGB Levels: Non-Dialysis Dependent CKD Patients

PRO_2TECT Phase 3 ESA-Treated Trial (N=1725)[1,2]



Mean change from baseline, g/dL	Difference (vadadustat - darbepoetin alfa)
Weeks 24-36	-0.01 (95% CI, -0.09 to 0.07)
Weeks 40-52	0.00 (95% CI, -0.10 to 0.09)

Cardiovascular Data Analysis: PRO_2TECT Studies Global, US and Ex-US

Region was a randomization stratification variable and a prespecified subgroup analysis. Age as a dichotomous variable (<65, ≥65) in the prespecified Cox model.[3]

	Global (N=3471) Event N HR (95% CI)	US (N=1723) (Hb target 10-11 g/dL) Event N HR (95% CI)	Ex-US (N=1748) (Hb target 10-12 g/dL) Event N HR (95% CI)
MACE	726 1.17 (1.01, 1.36)	400 1.06 (0.87, 1.29)	326 1.30 (1.05, 1.62)
Expanded MACE	875 1.11 (0.97, 1.27)	511 1.02 (0.86, 1.21)	364 1.24 (1.01, 1.52)
All-Cause Mortality	626 1.09 (0.93, 1.27)	325 0.92 (0.74, 1.15)	301 1.28 (1.02, 1.61)
CV MACE	376 1.16 (0.95, 1.42)	224 1.20 (0.92, 1.55)	152 1.09 (0.79, 1.50)
CV Mortality	258 1.01 (0.79, 1.29)	136 0.96 (0.68, 1.34)	122 1.05 (0.73, 1.50)

631 MACE events yields ~80% power to show non-inferiority assuming a true hazard ratio of 1.0. Expanded MACE is composite of MACE plus hospitalization for heart failure or thromboembolic event excluding vascular access failure. CV MACE is composite of cardiovascular mortality, nonfatal myocardial infarction, and non-fatal stroke.

Source: 1. G. Chertow, et al. Global Phase 3 Clinical Trials of Vadadustat for Treatment of Anemia in Patients With Non–Dialysis-Dependent Chronic Kidney Disease. Presented at: American Society of Nephrology Kidney Week; October 22, 2020. (Akebia's Phase 3 randomized, open-label, active-controlled non-inferiority study assessed the efficacy and safety of vadadustat compared to darbepoetin alfa in 3,471 non-dialysis-dependent subjects with anemia due to CKD, with a treatment duration of 52 weeks.) 2. G. Chertow, et al. Vadadustat in Patients with Anemia and Non-Dialysis Dependent CKD. N Engl J Med 2021; 384 1589-600. DOI: 10:1056/NEJMoa2035938 3. Akebia's ASN Investor Briefing Webcast October 23, 2020.

VADADUSTAT

PEER REVIEWED PUBLICATIONS OF GLOBAL PHASE 3 DATA AND RESULTS

The NEW ENGLAND JOURNAL of MEDICINE

- Safety and Efficacy of Vadadustat for Anemia in Patients Undergoing Dialysis April 2021
- Vadadustat in Patients with Anemia and Non–Dialysis-Dependent CKD April 2021

ASN American Society of Nephrology

- ASN Webcast October 23, 2020
- ASN Presentation October 23, 2020

AHJ American Heart Journal

- Cardiovascular safety and efficacy of vadadustat for the treatment of anemia in non-dialysis-dependent CKD: Design and baseline characteristics May 2021

ndt NEPHROLOGY DIALYSIS TRANSPLANTATION

- Global Phase 3 programme of vadadustat for treatment of anaemia of chronic kidney disease: rationale, study design and baseline characteristics of dialysis-dependent patients in the INNO2VATE trial November 2020

VADADUSTAT
U.S. DIALYSIS MARKET

Akebia THERAPEUTICS

- Unmet clinical needs of CKD patients on dialysis
- Approx. 556K U.S. patients on dialysis; 90% treated for anemia due to CKD[1]
- Unique market dynamics; Dialysis center clinical protocols
- Fast-growing home dialysis market

$2 Billion Estimated U.S. Dialysis Market Opportunity[2]

Sources: 1. 2020 USRDS Annual Data Report: https://adr.usrds.org/2020/reference-tables. 2 Based on internal estimates and industry reports estimating ESA pricing.

VADADUSTAT

FIRST-TO-MARKET POTENTIAL POSITIONS VADADUSTAT FOR SIGNIFICANT OPPORTUNITY IN $2B U.S. DIALYSIS MARKET

Akebia THERAPEUTICS

NEAR TERM

Become oral standard of care in large dialysis operators (LDOs) and across all home dialysis programs

Leverage exclusive U.S. distribution channel into Fresenius Kidney Care (FKC) with VIFOR PHARMA *

Secure TDAPA[1] reimbursement

Secure U.S. approval

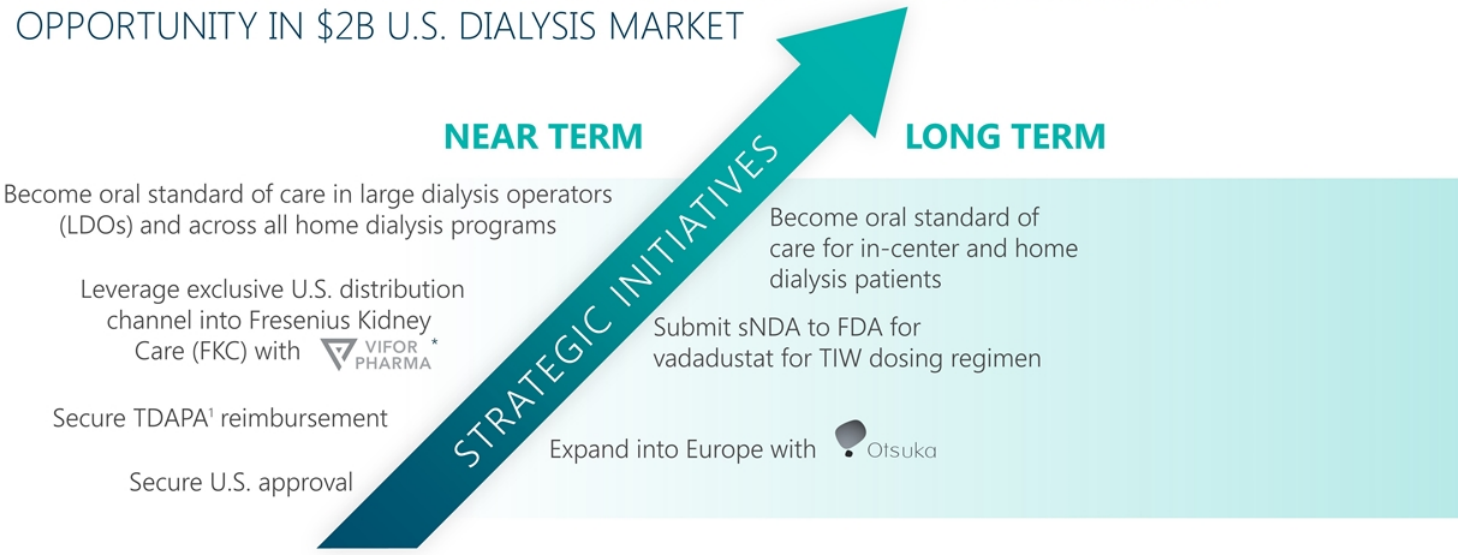
STRATEGIC INITIATIVES

Positioned for potential
RAPID ADOPTION
as first oral HIF-PHI
for U.S. dialysis patients

TIW is three times weekly.
*Pursuant to the Vifor Amended Agreement, Akebia granted Vifor (International) Ltd. ("Vifor Pharma") an exclusive license to sell vadadustat to Fresenius Kidney Care and to certain other third party dialysis organizations in the U.S., upon approval of vadadustat by the FDA, the earlier of reimbursement under TDAPA (defined below) or inclusion in the ESRD bundle and a milestone payment from Vifor. Source: 1 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.

VADADUSTAT

FIRST-TO-MARKET POTENTIAL POSITIONS VADADUSTAT FOR SIGNIFICANT OPPORTUNITY IN $2B U.S. DIALYSIS MARKET



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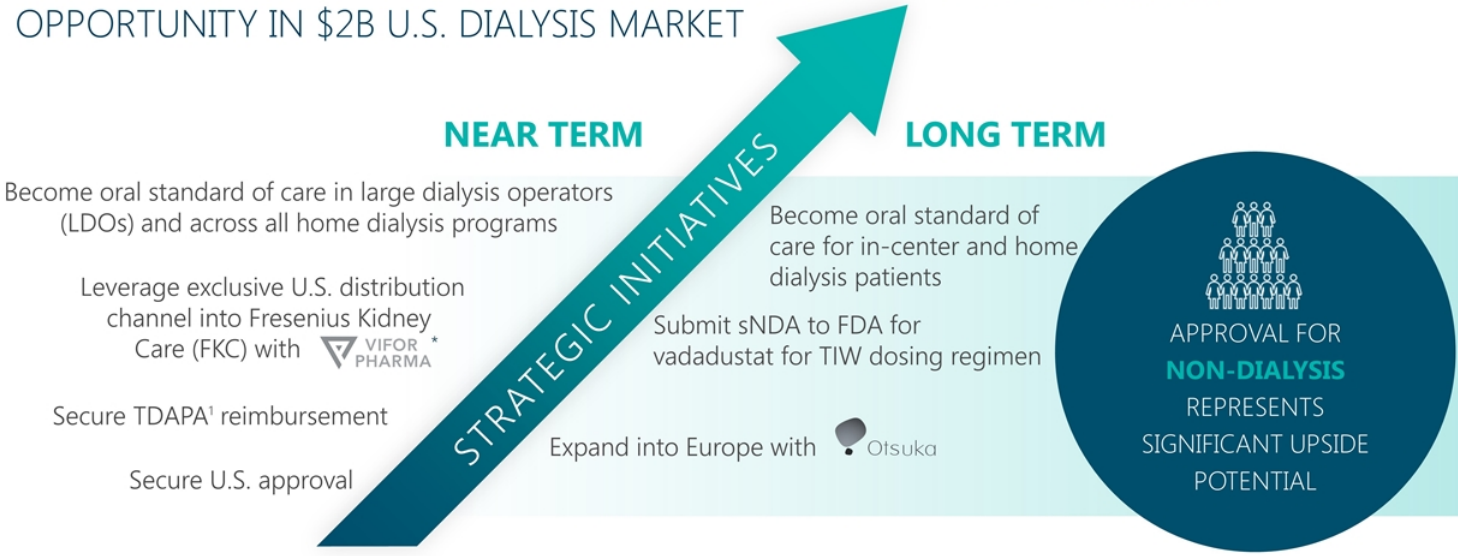
VADADUSTAT

FIRST-TO-MARKET POTENTIAL POSITIONS VADADUSTAT FOR SIGNIFICANT OPPORTUNITY IN $2B U.S. DIALYSIS MARKET



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ADVANCING VADADUSTAT
FOR POTENTIAL ADDITIONAL INDICATIONS

Akebia THERAPEUTICS

ACUTE RESPIRATORY DISTRESS SYNDROME (ARDS)

Ongoing investigator-sponsored clinical study by UTHealth evaluating vadadustat as potential therapy to prevent and lessen the severity of acute respiratory distress syndrome (ARDS)

Randomized double-blind, placebo-controlled study, up to 400 adult patients

UTHealth awarded $5.1M in funding from U.S. Dept. of Defense

In June 2020, Akebia announced an investigator-sponsored clinical study by UTHealth of vadadustat for ARDS. This study is being conducted under an Investigational New Drug application (IND) with UTHealth as the study sponsor.

FUTURE OPPORTUNITIES

LEVERAGE KIDNEY FOCUSED PORTFOLIO TO PURSUE EXPANSION OPPORTUNITIES FOR PATIENTS WITH KIDNEY DISEASE

1. ARDS is acute respiratory distress syndrome. 2. Praliciguat is an investigational oral sGC stimulator. On June 4, 2021, Akebia entered into a License Agreement with Cyclerion Therapeutics Inc. pursuant to which Cyclerion granted the Company an exclusive global license under certain intellectual property rights to research, develop and commercialize praliciguat.

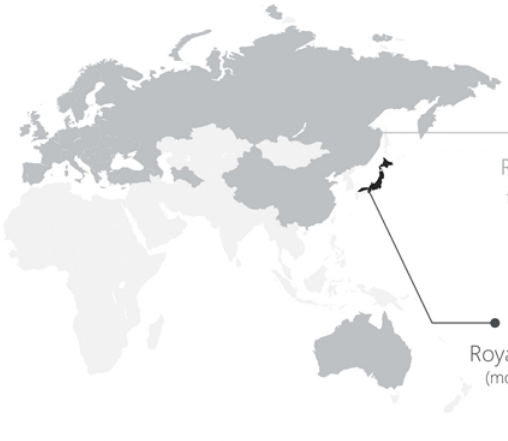
VADADUSTAT

AKEBIA MAINTAINS SIGNIFICANT ECONOMIC RIGHTS AND INFLUENCE OVER GLOBAL VADADUSTAT BRAND

United States
Akebia to share profit equally on all U.S. sales of vadadustat with Otsuka **(50/50)**

Akebia and Otsuka to share (50/50) a majority of the profit from Vifor Pharma sales of vadadustat to Fresenius Kidney Care (FKC) and certain other third party dialysis organizations[1]

Latin America
100% of Product Revenue to Akebia



Europe[2]
Royalties to Akebia tiered up to **30%**
Otsuka

Japan[3]
Royalties to Akebia
(monetized in 2021)
Mitsubishi Tanabe Pharma

1. Pursuant to the Vifor Amended Agreement, Akebia granted Vifor (International) Ltd. ("Vifor Pharma") an exclusive license to sell vadadustat to FKC and to certain other third party dialysis organizations in the U.S., upon approval of vadadustat by the FDA and other conditions discussed in Akebia's SEC filings. Akebia will receive a majority of the profit from Vifor Pharma's sales of vadadustat to FKC and certain other third party dialysis organizations. Akebia will then share revenue from this profit share with Otsuka pursuant to the Otsuka U.S. Agreement. Akebia currently retains rights to commercialize vadadustat for use in other dialysis organizations in the U.S., which will be done in collaboration with Otsuka following FDA approval. 2. Also includes Russia, China, Canada, Australia and Middle East. 3. In February 2021, Akebia announced a $60 million non-dilutive transaction with HealthCare Royalty Management, LLC to monetize the Company's rights to receive royalties and sales milestones on vadadustat net sales under its collaboration agreement with Mitsubishi Tanabe Pharma Corporation (MTPC), subject to annual and aggregate caps. MTPC has the exclusive rights to commercialize vadadustat in Japan and certain other Asian countries. For additional information on the transaction, see Akebia's SEC filings.

Auryxia®

Akebia THERAPEUTICS

Auryxia is the only iron-based, non-calcium, non-chewable phosphate binder indicated for the treatment of hyperphosphatemia in adult patients with CKD on dialysis.

FDA approved in two indications:

- Hyperphosphatemia in patients with CKD on dialysis
- Iron Deficiency Anemia (IDA) in patients with CKD not on dialysis

$128.9M
net product revenue in 2020

~556K U.S.
dialysis patients[1]

Compelling product profile
with favorable MoA, efficacy and tolerability

Supported by Akebia's **U.S. nephrology focused salesforce**

Sources: 1. 2020 USRDS Annual Data Report: https://adr.usrds.org/2020/reference-tables

CONTINUED MOMENTUM

STRATEGIC FOCUS AND ANTICIPATED 2021 MILESTONES

Prepare for potential commercialization of vadadustat

- ☑ U.S. NDA filed with FDA; PDUFA date: March 29, 2022
- ☑ Phase 3 results published in *New England Journal of Medicine*
- ☐ EU MAA[1] submission expected in 2021

Support commercial portfolio

- ☑ Increase awareness and grow adoption of Auryxia
- ☐ Leverage Auryxia as commercial foundation for vadadustat in CKD

Advance vadadustat clinical development

- ☑ Ongoing investigator-sponsored clinical study by UTHealth evaluating vadadustat for ARDS
- ☐ Identify and initiate planning for programs where vadadustat may have therapeutic benefits and where there is unmet need

Expand pipeline & portfolio of novel therapeutics

- ☑ In-licensed praliciguat, June 2021
- ☐ Explore partnerships to expand our portfolio and leverage our expertise in R&D
- ☐ Engage in internal discovery and development

1. Akebia is working in close collaboration with its partner, Otsuka Pharmaceutical Co. Ltd., to prepare a Marketing Authorization Application for vadadustat for submission to the European Medicines Agency, expected this year.

VADADUSTAT

SUMMARY OF TREATMENT EMERGENT ADVERSE EVENTS (TEAEs) AND TEAES OCCURING IN >10% OF PATIENTS

DIALYSIS PROGRAM

INNO$_2$VATE Phase 3 Studies (Prevalent and Incident DD-CKD Patients)[1,2]

	INCIDENT DD-CKD, No. of subjects (%)		PREVALENT DD-CKD, No. of subjects (%)	
	Vadadustat (N=179)	Darbepoetin alfa (N=186)	Vadadustat (N=1768)	Darbepoetin alfa (N=1769)
Any TEAEs	150 (83.8)	159 (85.5)	1562 (88.3)	1580 (89.3)
Any TEAEs, drug-related	7 (3.9)	5 (2.7)	169 (9.6)	68 (3.8)
Any serious TEAEs	89 (49.7)	105 (56.5)	973 (55.0)	1032 (58.3)
Any TEAEs, drug-related	1 (0.6)	4 (2.2)	29 (1.6)	27 (1.5)
Any TEAEs leading to study treatment discontinuation	5 (2.8)	2 (1.1)	91 (5.1)	20 (1.1)
Any drug-related TEAEs leading to study treatment discontinuation	2 (1.1)	0	42 (2.4)	5 (0.3)
Any TEAE leading to death	15 (8.4)	18 (9.7)	266 (15.0)	276 (15.6)
Deaths	15 (8.4)	20 (10.8)	276 (15.6)	290 (16.4)
Common AEs (>10%)				
Hypertension	29 (16.2)	24 (12.9)	187 (10.6)	244 (13.8)
Diarrhea	18 (10.1)	18 (9.7)	230 (13.0)	178 (10.1)
Pneumonia	13 (7.3)	15 (8.1)	195 (11.0)	172 (9.7)
Hyperkalemia	8 (4.5)	10 (5.4)	160 (9.0)	191 (10.8)

NON-DIALYSIS PROGRAM

PRO$_2$TECT Phase 3 Studies (NDD-CKD Patients)[3,4]

	ESA-untreated NDD-CKD, No. of subjects (%)		ESA-treated NDD-CKD, No. of subjects (%)	
	Vadadustat (N=878)	Darbepoetin alfa (N=870)	Vadadustat (N=861)	Darbepoetin alfa (N=862)
Any TEAE	798 (90.0)	797 (91.6)	767 (89.1)	756 (87.7)
Any TEAE, drug-related	95 (10.8)	57 (6.6)	100 (11.6)	44 (5.1)
Any serious TEAE	573 (65.3)	561 (64.5)	504 (58.5)	488 (56.6)
Any serious TEAE, drug-related	23 (2.6)	15 (1.7)	13 (1.5)	9 (1.0)
Any TEAE leading to study treatment discontinuation	84 (9.6)	60 (6.9)	79 (9.2)	44 (5.1)
Any drug-related TEAE leading to study treatment discontinuation	13 (1.5)	4 (0.5)	16 (1.9)	2 (0.2)
Any TEAE leading to death	177 (20.2)	165 (19.0)	135 (15.7)	137 (15.9)
Deaths	180 (20.5)	168 (19.3)	139 (16.1)	139 (16.1)
Common AEs (≥10%)				
Diarrhea	122 (13.8)	87 (10.0)	119 (13.8)	76 (8.8)
End-stage renal disease	305 (34.7)	306 (35.2	237 (27.5)	245 (28.4)
Fall	84 (9.6)	87 (10.0)	69 (8.0)	65 (7.5)
Hyperkalemia	108 (12.3)	136 (15.6)	81 (9.4)	85 (9.9)
Hypertension	155 (17.7)	192 (22.1)	124 (14.4)	128 (14.8)
Peripheral edema	110 (12.5)	91 (10.5)	85 (9.9)	87 (10.1)
Pneumonia	86 (9.8)	75 (8.6)	86 (10.0)	84 (9.7)
Urinary tract infection	113 (12.9)	104 (12.0)	105 (12.2)	125 (14.5)

Sources: 1. K.-U. Eckardt, et al. Global Phase 3 Clinical Trials of Vadadustat for Treatment of Anemia in Patients With Dialysis-Dependent Chronic Kidney Disease. Presented at: American Society of Nephrology Kidney Week; October 22, 2020. 2. K.-U. Eckardt, et al. Safety and Efficacy of Vadadustat for Anemia in Patients Undergoing Dialysis. N Engl J Med 2021; 384 1601-12. DOI: 10:1056/NEJMoa2025956 3. G. Chertow, et al. Global Phase 3 Clinical Trials of Vadadustat for Treatment of Anemia in Patients With Non–Dialysis-Dependent Chronic Kidney Disease. Presented at: American Society of Nephrology Kidney Week; October 22, 2020. 4. G. Chertow, et al. Vadadustat in Patients with Anemia and Non-Dialysis Dependent CKD. N Engl J Med 2021; 384 1589-600. DOI: 10:1056/NEJMoa2035938

Important Safety Information

CONTRAINDICATION

AURYXIA® (ferric citrate) is contraindicated in patients with iron overload syndromes, e.g., hemochromatosis

WARNINGS AND PRECAUTIONS

Iron Overload: Increases in serum ferritin and transferrin saturation (TSAT) were observed in clinical trials with AURYXIA in patients with chronic kidney disease (CKD) on dialysis treated for hyperphosphatemia, which may lead to excessive elevations in iron stores. Assess iron parameters prior to initiating AURYXIA and monitor while on therapy. Patients receiving concomitant intravenous (IV) iron may require a reduction in dose or discontinuation of IV iron therapy

Risk of Overdosage in Children Due to Accidental Ingestion: Accidental ingestion and resulting overdose of iron-containing products is a leading cause of fatal poisoning in children under 6 years of age. Advise patients of the risks to children and to keep AURYXIA out of the reach of children

ADVERSE REACTIONS

The most common adverse reactions reported with AURYXIA in clinical trials were:

Hyperphosphatemia in CKD on Dialysis: Diarrhea (21%), discolored feces (19%), nausea (11%), constipation (8%), vomiting (7%) and cough (6%)

Iron Deficiency Anemia in CKD Not on Dialysis: Discolored feces (22%), diarrhea (21%), constipation (18%), nausea (10%), abdominal pain (5%) and hyperkalemia (5%)

SPECIFIC POPULATIONS

Pregnancy and Lactation: There are no available data on AURYXIA use in pregnant women to inform a drug-associated risk of major birth defects and miscarriage. However, an overdose of iron in pregnant women may carry a risk for spontaneous abortion, gestational diabetes and fetal malformation. Data from rat studies have shown the transfer of iron into milk, hence, there is a possibility of infant exposure when AURYXIA is administered to a nursing woman

To report suspected adverse reactions, contact Akebia at 1-844-445-3799.
Please see full Prescribing Information
Learn more at AURYXIA.com.

Akebia THERAPEUTICS

Akebia® THERAPEUTICS

THANK YOU

QUESTIONS?