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): January 12, 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 virtually present the information in the J.P. Morgan Healthcare Conference Presentation attached hereto as Exhibit 99.1 (the "Presentation") at the 39th Annual J.P. Morgan Healthcare Conference on January 13, 2021 at 2:50 p.m., Eastern Time. Spokespersons of the Company also plan to present the information in the Presentation at various meetings beginning on January 12, 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	J.P. Morgan Healthcare Conference Presentation
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: January 12, 2021

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

Exhibit 99.1

Akebia® THERAPEUTICS

BETTERING THE LIVES OF PEOPLE IMPACTED BY KIDNEY DISEASE

39th Annual J.P. Morgan Healthcare Conference
January 13, 2021

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

CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS

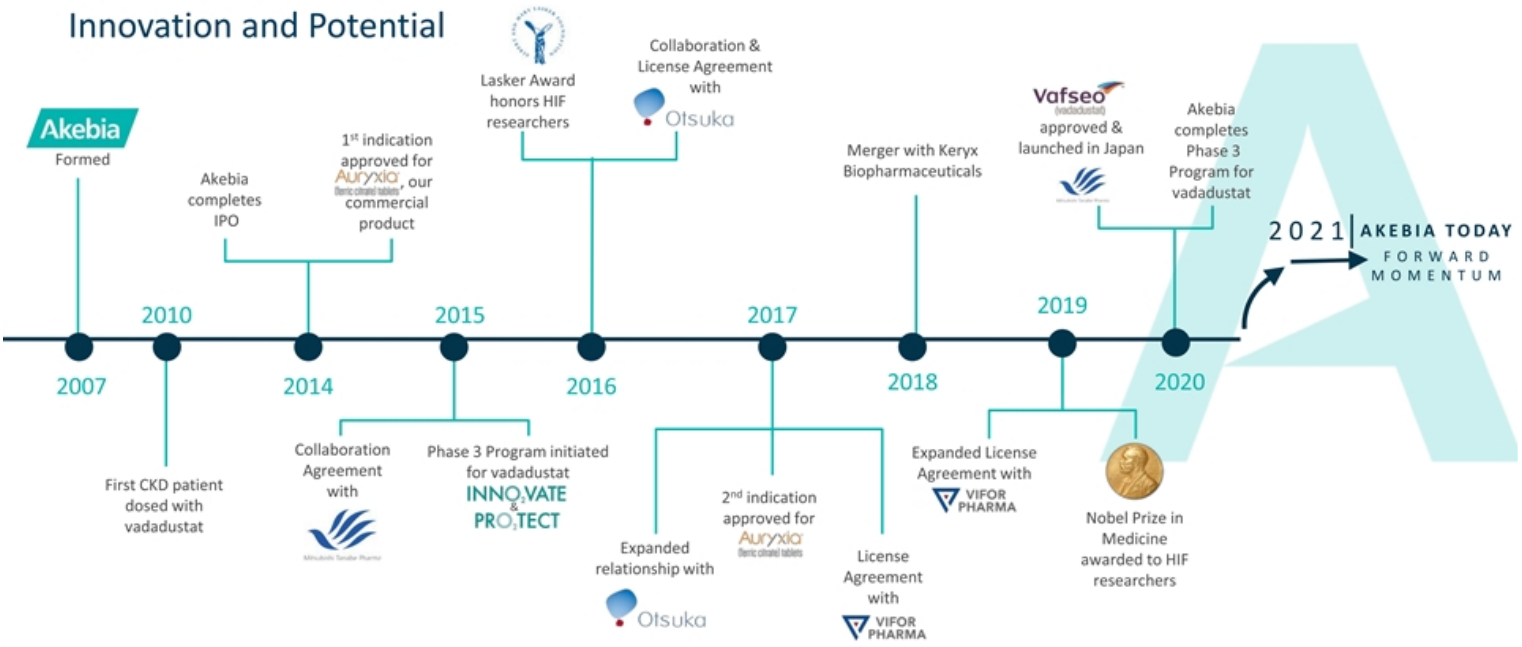
Statements in this presentation regarding Akebia's strategy, plans, prospects, expectations, beliefs, intentions and goals are forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, as amended, including but not limited to submitting a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) and the timing thereof; Akebia's cash runway funding Akebia's current operating plan beyond the expected U.S. launch of vadadustat, assuming regulatory approval; establishing vadadustat as a new oral standard of care for treatment of adult patients with anemia due to chronic kidney disease (CKD) on dialysis; establishing vadadustat as a potential oral alternative to injectable erythropoiesis-stimulating agents; the U.S. market opportunity for vadadustat to treat patients on dialysis and opportunity for growth of such market; vadadustat supporting and enabling growth in the U.S. home dialysis market; the potential for vadadustat upon approval and commercial launch; the potential for rapid adoption of vadadustat in U.S. dialysis patients; sharing vadadustat clinical data, including in peer reviewed journals, as well as the timing thereof; submitting the E.U. Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) and the timing thereof; the potential launch and commercialization of vadadustat if approved by regulatory authorities; the potential for Akebia to receive regulatory and commercial milestone payments upon approval of vadadustat by regulatory authorities; the growth opportunities for Auryxia® (ferric citrate) in 2021 and Akebia's ability to execute thereon; the potential for vadadustat to be used as a therapy to prevent and lessen the severity of ARDS and in other indications; the expansion of Akebia's pipeline and portfolio of novel therapeutics, including by leveraging new partnership relationships; and market opportunity, clinical opportunity, commercial potential, prevalence, and the growth in, and potential demand for, vadadustat. The terms "believe," "expect," "goal," "look forward," "opportunity," "planned," "potential," "will", derivatives of these words, and similar references 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, among others, the potential therapeutic benefits, safety profile, and effectiveness of our product candidates, including vadadustat; the potential indications, demand and market potential and acceptance of our product and product candidates, including our estimates regarding the potential market opportunity for our product, vadadustat or any other product candidates and the size of eligible patient populations; the timing of or likelihood of regulatory filings and approvals, including labeling or other restrictions, such as the anticipated timing of filing a NDA to the FDA and MAA to the EMA for vadadustat, the potential approval of vadadustat and our outlook related thereto, and potential indications for vadadustat; the potential direct or indirect impact of the coronavirus 2 (SARS-CoV-2) pandemic on Akebia's business, operations, and the markets and communities in which Akebia and its partners, collaborators, vendors and customers operate; manufacturing and quality risks; risks associated with management and key personnel; the actual funding required to continue to commercialize our commercial product, to develop and commercialize vadadustat, and to operate Akebia; market acceptance and coverage and reimbursement of our commercial product and vadadustat, if approved; the risks associated with potential generic entrants for our 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 our commercial product and vadadustat; 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 our product and product candidates; and Akebia's intellectual property position, including its ability to obtain, maintain and enforce patent and other intellectual property protection for our commercial product, vadadustat and any 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 September 30, 2020 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 U.S. Food and Drug Administration or any regulatory authority with the exception of Japan's Ministry of Health, Labour and Welfare.

Akebia® THERAPEUTICS

OUR HISTORY

Innovation and Potential



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

2021 | AKEBIA TODAY

FORWARD MOMENTUM

VADADUSTAT

AN ORAL HIF-PH INHIBITOR FOR THE TREATMENT OF ANEMIA DUE TO CHRONIC KIDNEY DISEASE (CKD)

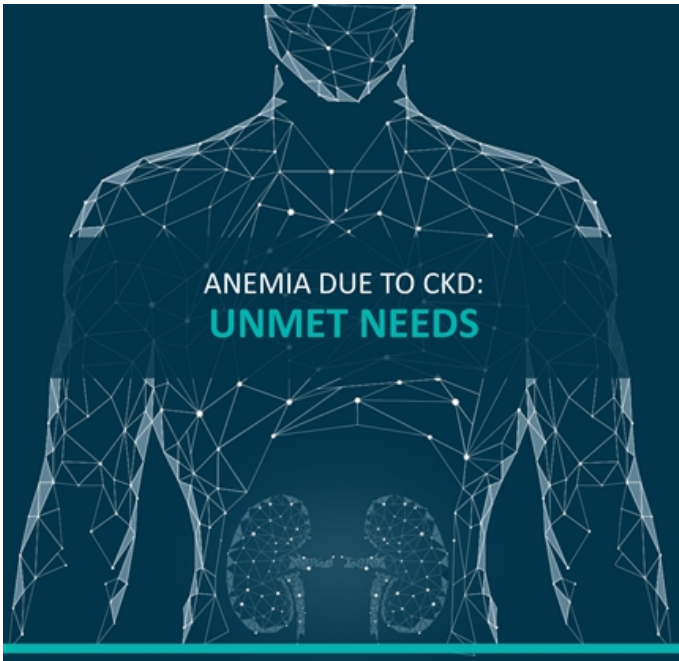
- ✓ PHASE 3 PROGRAM COMPLETED
- ✓ U.S. NDA SUBMISSION ON TRACK; EXPECTED AS EARLY AS POSSIBLE IN 2021

ADOPTION OF VADADUSTAT IN JAPAN FOR BOTH DIALYSIS AND NON-DIALYSIS ADULT PATIENTS Vafseo (vadadustat)

NEPHROLOGY FOCUSED COMMERCIAL TEAM IN THE U.S. WITH Auryxia (ferric citrate) tablets

FUNDING BEYOND THE EXPECTED U.S. LAUNCH OF VADADUSTAT [1]

HIF-PH or HIF-PHI is hypoxia-inducible factor prolyl hydroxylase inhibitor. NDA is New Drug Application. 1. Cash, cash equivalents and available-for-sale securities as of September 30, 2020 were $269.3 million. The Company expects its cash resources to fund its current operating plan beyond the expected U.S. launch of vadadustat, assuming regulatory approval.



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

5.7M

PEOPLE IN THE U.S. DIAGNOSED WITH ANEMIA DUE TO CKD[1]

>500K

PEOPLE IN THE U.S. ON DIALYSIS WITH ANEMIA DUE TO CKD[2]

CURRENT STANDARD OF CARE

Consists of injectable ESAs, which have been associated with significant CV risk

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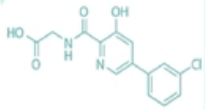
ESKD is End Stage Kidney Disease. ESA is erythropoiesis-stimulating agent. Sources: 1 . Stauffer et al, PLOSONE, 2014. 2 2020 USRDS Annual Data Report: https://adr.usrds.org/2020/reference-tables.

VADADUSTAT | LEAD INVESTIGATIONAL PRODUCT CANDIDATE



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

Potential oral alternative to injectable ESAs

ROBUST CLINICAL RESULTS

Positive Phase 3 clinical results in adult patients with anemia due to CKD on dialysis

COMMERCIAL BREADTH

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 CLINICAL DATA

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

POTENTIAL NEW ORAL STANDARD OF CARE FOR ANEMIA DUE TO CKD IN ADULT PATIENTS ON DIALYSIS

Vadadustat is not approved by the FDA.

INNO$_2$VATE: Phase 3 Program

- ✓ Demonstrated efficacy and cardiovascular safety of vadadustat for the treatment of anemia due to CKD in adult patients on dialysis

Clinical data also demonstrated that vadadustat:

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

Sources: Data from: Akebia's global INNO$_2$VATE program which included two separate Phase 3 studies (*Correction/Conversion* and *Conversion*), and collectively enrolled 3,923 adult patients on dialysis with anemia due to CKD. Both INNO$_2$VATE studies were global, multicenter, open label (sponsor blind), active-controlled (darbepoetin alfa - an injectable erythropoiesis stimulating agent (ESA)), non-inferiority studies; Akebia's Phase 1 Study in Normal Healthy Volunteers (CI-0002); and, Akebia's Phase 2b Study in Dialysis-Dependent CKD Patients (CI-0011).

VADADUSTAT GLOBAL PHASE 3 PROGRAM

INNO$_2$VATE

Two Phase 3 Studies
3,923 Adult Patients on Dialysis

(Prevalent and Incident Populations)

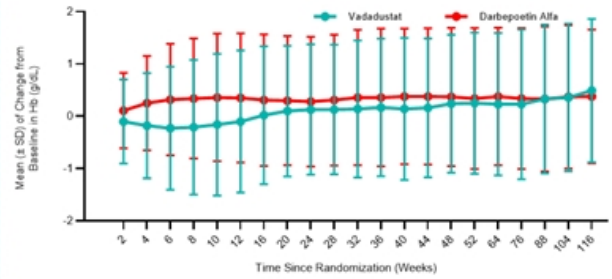
Vadadustat efficacy demonstrated in two Phase 3 studies:

- ✓ Achieved primary and key secondary efficacy endpoints (mean change in hemoglobin (HGB) levels)
  - Weeks 24 to 36 (primary)
  - Weeks 40 to 52 (secondary)

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.)

Mean Change from Baseline in HGB Levels: Dialysis Dependent CKD Patients

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



Mean Change from Baseline in HGB Levels: Dialysis Dependent CKD Patients

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

VADADUSTAT GLOBAL PHASE 3 PROGRAM

INNO$_2$VATE

Two Phase 3 Studies
3,923 Adult Patients on Dialysis

(Prevalent and Incident Populations)

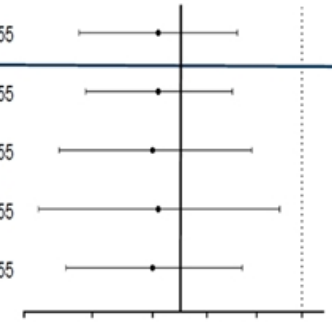
Vadadustat cardiovascular safety demonstrated across two Phase 3 studies:

✓ Achieved primary and key secondary safety endpoints

Primary and Key Secondary Safety Endpoints: Dialysis Dependent CKD Patients

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

Safety Endpoint	Vadadustat (n/N)	Darbepoetin Alfa (n/N)	HR (95% CI)
MACE	355/1947	377/1955	0.96 (0.83, 1.11)
Expanded MACE	420/1947	449/1955	0.96 (0.84, 1.10)
Cardiovascular MACE	225/1947	242/1955	0.95 (0.80, 1.14)
Cardiovascular mortality	150/1947	160/1955	0.96 (0.77, 1.20)
All-cause mortality	291/1947	310/1955	0.95 (0.81, 1.12)



→ vadadustat noninferior to darbepoetin alfa

Noninferiority margin: 1.25

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. 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.) MACE is the composite of all-cause mortality, non-fatal myocardial infarction, or non-fatal stroke.

VADADUSTAT GLOBAL PHASE 3 PROGRAM

INNO$_2$VATE

Two Phase 3 Studies
3,923 Adult Patients
on Dialysis

(Prevalent and Incident Populations)

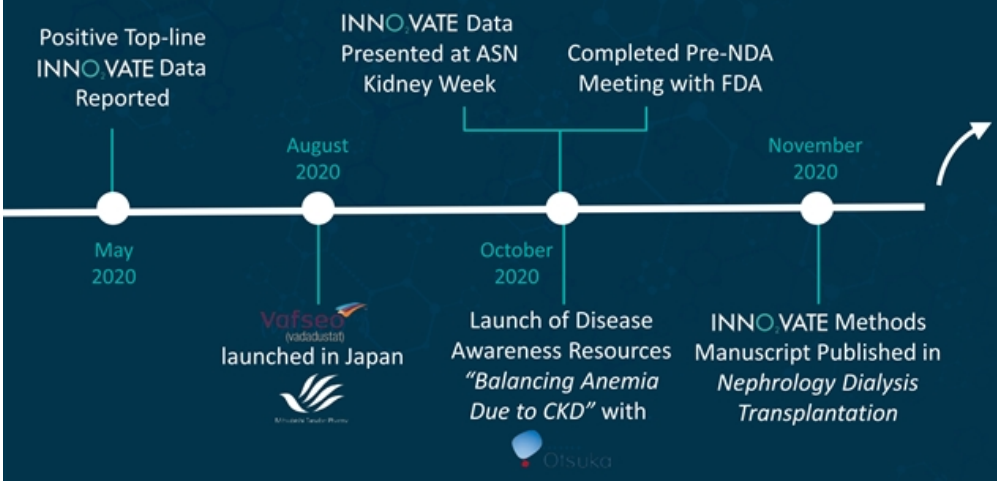
Summary of Treatment Emergent Adverse Events (TEAEs) and TEAEs Occurring in >10% of Patients in Either Treatment Group

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

	Incident DD-CKD, No. (%)		Prevalent DD-CKD, No. (%)	
	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 serious 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)

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. 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.)

ADVANCING VADADUSTAT FOR PATIENTS ON DIALYSIS



2021 MILESTONES

- Publication of INNO2VATE Data in Peer Reviewed Journal; Expected in 2021
- U.S. NDA Submission to FDA Expected as Early as Possible in 2021
- Working with Otsuka to Prepare EU MAA Submission to EMA; Expected in 2021

FDA is U.S. Food and Drug Administration. NDA is New Drug Application. MAA is Marketing Authorization Application. EMA is European Medicines Agency. Otsuka Pharmaceutical Co. Ltd. ("Otsuka") is Akebia's collaborator.

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

Akebia THERAPEUTICS

VADADUSTAT | HIGH GROWTH OPPORTUNITY IN U.S. DIALYSIS MARKET

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

- 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 with dialysis center clinical protocols
- Emphasis on growing home dialysis market

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.

Akebia THERAPEUTICS

VADADUSTAT | WELL POSITIONED UPON APPROVAL AND LAUNCH

Go-to-market strategy positions vadadustat for potential rapid adoption in up to 60% of U.S. dialysis patients*

- ✓ Convenient oral dosing for all dialysis patients with unique opportunity to support and grow U.S. home dialysis market
- ✓ Favorable reimbursement model with TDAPA[1]
- ✓ Experienced nephrology focused salesforce in the U.S. with Auryxia® (ferric citrate) tablets
- ✓ Exclusive U.S. distribution channel into Fresenius Medical Care with Vifor Pharma*

*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.

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VADADUSTAT | FUTURE REVENUE STRUCTURES

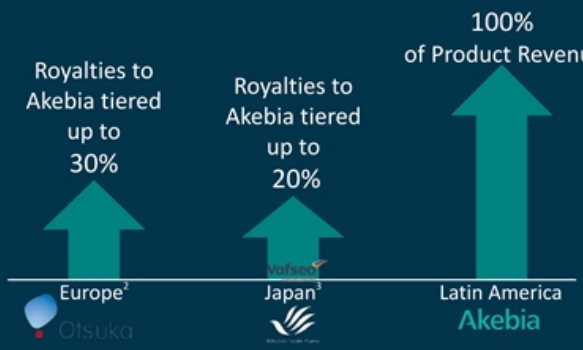
In addition to potential regulatory and commercial milestone payments, Akebia will receive the following on net sales of vadadustat, subject to approval:

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's sales of vadadustat to Fresenius Kidney Care and other third party dialysis organizations[1]

International



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2021 Creating Future Value for Akebia

STRATEGIC OBJECTIVES

1 PREPARE FOR POTENTIAL COMMERCIALIZATION OF VADADUSTAT FOR DIALYSIS PATIENTS

- U.S. NDA submission to FDA expected as early as possible in 2021
- EU MAA submission expected in 2021

2 EXECUTE ON AURYXIA GROWTH OPPORTUNITIES

- Leverage Auryxia as clinical catalyst and commercial beachhead for vadadustat in CKD

3 SELECTIVELY TARGET ADDITIONAL INDICATIONS FOR VADADUSTAT

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

4 EXPAND PIPELINE & PORTFOLIO OF **NOVEL** THERAPEUTICS

- Explore partnerships to expand our portfolio and leverage our expertise in R&D

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


Akebia®
THERAPEUTICS
THANK YOU | QUESTIONS?