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 7, 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))

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 J.P. Morgan Healthcare Conference Presentation attached hereto as Exhibit 99.1 (the "Presentation") at the 37th Annual J.P. Morgan Healthcare Conference on January 9, 2019 at 9:30 a.m. Pacific Time and at various meetings beginning on January 7, 2019, including investor and analyst meetings.

In December 2018, 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.

Item 8.01 Other Events.

As previously disclosed, on December 12, 2018, the Company completed a merger, whereby Keryx Biopharmaceuticals, Inc. ("Keryx") became a wholly owned subsidiary of the Company (the "Merger"). At the consummation of the Merger, each issued and outstanding share of common stock of Keryx, $0.001 par value per share, was converted into 0.37433 of a share of common stock of the Company, $0.00001 par value per share ("Common Stock"), and cash in lieu of fractional shares. At December 31, 2018, the Company had 116,887,518 shares of Common Stock outstanding.

As previously disclosed, on October 31, 2018 and November 6, 2018, Keryx received Paragraph IV certification notice letters regarding Abbreviated New Drug Applications ("ANDAs") submitted to the U.S. Food and Drug Administration ("FDA") by Lupin Atlantis Holdings SA ("Lupin") and Teva Pharmaceuticals USA, Inc. ("Teva"), respectively, requesting approval for generic versions of Auryxia® (ferric citrate) tablets (210 mg iron per tablet). On December 13, 2018, Keryx and its licensors, Panion & BF Biotech, Inc. ("Panion") and Chen Hsing Hsu, M.D., filed a complaint for patent infringement against Lupin and Lupin Ltd. (the "Lupin Defendants") in the United States District Court for the District of Delaware (the "Delaware Court") arising from Lupin's ANDA filing with the FDA, and on December 19, 2018, Keryx and Panion filed a complaint for patent infringement against Teva and Teva Pharmaceutical Industries Limited (the "Teva Defendants") in the Delaware Court arising from Teva's ANDA filing with the FDA. As a result of the timely filing of these lawsuits in accordance with statute, a 30-month stay of approval will be imposed by the FDA on Lupin's and Teva's ANDAs, which stays are expected to remain in effect until April 2021 and May 2021, respectively, absent an earlier judgment by the Delaware Court in each of these lawsuits finding the patents at issue invalid, unenforceable or not infringed. The plaintiffs in each of these lawsuits seek, among other relief, an order that the effective date of FDA approval of the ANDA be a date no earlier than the expiration of each of the patents at issue, equitable relief enjoining the Lupin Defendants and Teva Defendants from infringing these patents, and monetary relief as a result of any such infringement.

On December 24, 2018, Keryx received a Paragraph IV certification notice letter regarding an ANDA submitted to the FDA by Chemo Research S.L. ("Chemo") requesting approval to market, sell and use a generic version of the Auryxia tablets (210 mg iron per tablet). In its notice letter, Chemo alleges that Keryx's U.S. Patents Nos. 9,387,191; 5,753,706; 7,767,851; 8,093,423; 8,299,298; 8,338,642; 8,609,896; 8,754,257; 8,754,258; 8,846,976; 8,901,349; 9,050,316; 9,328,133; and 9,757,416 (the "Patents"), which cover the approved drug substance, drug product and/or methods of using Auryxia, are invalid, unenforceable and/or will not be infringed by Chemo's manufacture, use or sale of the product described in its ANDA. Keryx is currently reviewing the notice letter and intends to vigorously enforce its intellectual property rights relating to Auryxia. By statute, Keryx has 45 days from receipt of the notice letter to initiate a patent infringement lawsuit against Chemo. Such a lawsuit would automatically preclude the FDA from approving Chemo's ANDA until the earlier of 30 months from December 24, 2018 or entry of a district court decision finding the Patents invalid, unenforceable or not infringed.

Going forward, the Company plans to provide updates on any additional Paragraph IV certification notices that Keryx may receive and about patent litigation against ANDA filers through the Company's Quarterly Reports on Form 10-Q and Annual Reports on Form 10-K filed with the SEC.

By providing the information in Items 7.01 and 8.01 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, the SEC filings of the Company's wholly owned subsidiary, Keryx, and other public announcements that the Company or Keryx 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.

Cautionary Note on Forward-Looking Statements

This Current Report on Form 8-K, including Exhibit 99.1 hereto, includes forward-looking statements. These statements are not historical facts, but instead represent only the Company's beliefs regarding future events, many of which, by their nature, are inherently uncertain and outside of the Company's control.

For a discussion of risks related to the forward-looking statements in this Current Report on Form 8-K, including the risks related to the ANDA filings discussed in this Current Report on Form 8-K, see the "Risk Factors" section of the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, filed by the Company on November 8, 2018, including the risk factor under the heading "If generic products that compete with Keryx's marketed product, Auryxia, or any future product of the combined company are approved and launched, the combined company's business, financial position or results of operations would be adversely affected," and the "Risk Factors" section of Keryx's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, filed by the Keryx on November 8, 2018, including the risk factor under the heading "If our competitors develop and market products that are less expensive, have a reduced pill burden, are or are promoted as more effective or safer than our drug product, or our drug product does not achieve market acceptance vis-à-vis existing treatments, our commercial opportunities may be reduced or eliminated." For additional important information about forward-looking statements, see also the slide titled "Cautionary Note on Forward-Looking Statements" in Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Exhibit Description
99.1	J.P. Morgan Healthcare Conference Presentation

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 7, 2019

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

Exhibit 99.1

37th Annual J.P. Morgan Healthcare Conference

January 2019

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 quarterly period ended September 30, 2018, filed with the SEC on November 8, 2018, and other filings that Akebia may make with the SEC in the future, and those identified under the heading "Risk Factors" in the Quarterly Report on Form 10-Q of Keryx Biopharmaceuticals, Inc., Akebia's wholly owned subsidiary, for the quarterly period ended September 30, 2018, filed with the SEC on November 8, 2018. 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: Fully integrated biotech company focused on kidney disease with complementary portfolio and financial strength

- Product revenue in two FDA-approved indications with substantial growth potential
- Multiple clinical catalysts over next 18 months for Phase 3 product candidate with multi-billion-dollar global market opportunity
- Expect existing cash resources[1] and estimated product revenue to fund operations into Q3 2020
- Financial strength with $431 million cash position[2], product sales and collaboration revenue

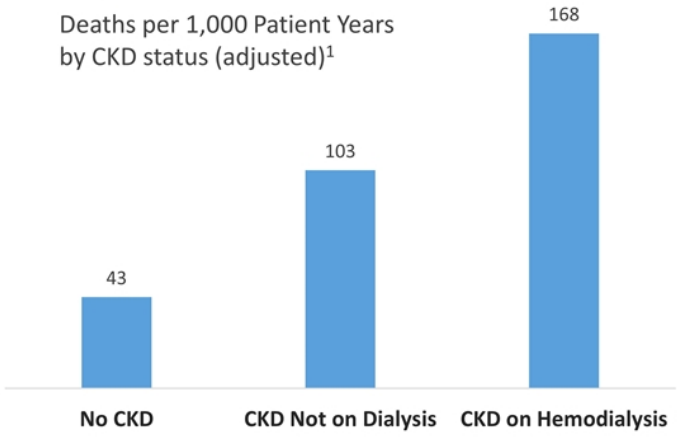
[1] Includes prepaid quarterly committed cost share funding from Akebia's collaborators.
[2] Cash, cash equivalents and available for sale securities, pro forma, unaudited, as of 9/30/2018.

Akebia THERAPEUTICS

Akebia's mission is to advance care for patients with kidney disease

High unmet needs

Deaths per 1,000 Patient Years by CKD status (adjusted)[1]



OUR VISION

Improved health of patients with kidney disease through better disease management and novel therapeutics

SOURCES: [1] United States Renal Data System. 2018 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2018.
NOTE: Adjusted values; Adjusted using direct standardization for age, sex and race.

Akebia THERAPEUTICS

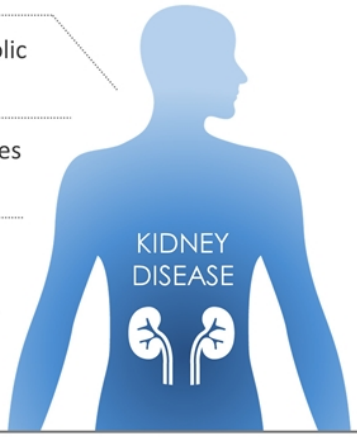
Kidney disease is a major public health challenge in the US and globally

Cardio-metabolic disorders

Genetic diseases of the kidney

Auto-immune disorders

Aging & other



	Acute Kidney Injury	Chronic Kidney Disease	Dialysis or Transplant
US PATIENTS	> 40 million[1]		> 500k[2]
MEDICARE SPENDING	> $79 billion[3]		> $35 bil.[3]
LOCATION	Hospital	Nephrology clinics	Dialysis clinics

Increased mortality, increased hospitalizations, reduced QoL*

KIDNEY INNOVATION ACCELERATOR

US Dept of Health and Human Services and American Society of Nephrology (ASN) public-private partnership to improve the lives of the 850 million people worldwide currently affected by kidney diseases by accelerating innovation in the prevention, diagnosis and treatment of kidney diseases

*Quality of Life.

SOURCES: [1] Centers for Disease Control and Prevention. Chronic Kidney Disease Surveillance System—United States. http://www.cdc.gov/ckd.; [2] United States Renal Data System. 2018 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2018.; [3] Centers for Disease Control and Prevention; Kidney in body. Digital Image. *The Ron & Joy Paul Kidney Center.* https://smhs.gwu.edu/kidneycenter/about-kidney-disease.

Akebia THERAPEUTICS

Akebia: Fully integrated biotech company focused on kidney disease with complementary portfolio and financial strength

CKD ON DIALYSIS		CKD NON-DIALYSIS
HYPERPHOSPHATEMIA IN DIALYSIS	COMMERCIALIZED **Auryxia® (ferric citrate)** *FDA approved in two indications, showing strong commercial momentum*	IRON DEFICIENCY ANEMIA IN NON-DIALYSIS
ANEMIA DUE TO CKD IN DIALYSIS	DEVELOPMENT PROGRAM **Vadadustat, an investigational HIF PH[1] inhibitor** *In global Phase 3 with read-outs expected beginning 2019*	ANEMIA DUE TO CKD IN NON-DIALYSIS

Commercial operations with renal focus

Research, manufacturing and development, including cardiovascular outcomes trials (CVOT) expertise

Expect existing cash resources[2] and estimated product revenue to fund operations into Q3 2020

Financial strength with $431 million cash position[3], product sales and collaboration revenue

Otsuka · Mitsubishi Tanabe Pharma · VIFOR PHARMA · JTI · Johnson & Johnson · PBF 寶齡富錦生技 Panion & BF Biotech Inc.

[1] Hypoxia Inducible Factor Prolyl Hydroxylase.
[2] Includes prepaid quarterly committed cost share funding from Akebia's collaborators.
[3] Cash, cash equivalents and available for sale securities, pro forma, unaudited, as of 9/30/2018.

Akebia THERAPEUTICS

Different market dynamics in dialysis vs. non-dialysis, with opportunity for adoption in large existing dialysis market and for high growth potential in non-dialysis market

CKD ON DIALYSIS	CKD NON-DIALYSIS
Key unmet needs: **cardiovascular (CV) risk, QoL**	Key unmet needs: **CV risk, delay CKD progression, improved convenience, QoL**
High treatment rates	Large patient population with lower treatment rates for CKD conditions
CMS Bundle reimbursement of covered drugs[1]	Payer reimbursement

MULTIPLE COMPLICATIONS ASSOCIATED WITH REDUCTION OF RENAL FUNCTION, INCLUDING:

Akebia THERAPEUTICS

CURRENT FOCUS:
- **Hyperphosphatemia** *(increasing phosphorus levels)*
- **Iron Deficiency Anemia** *(decreasing iron levels)*
- **Anemia due to CKD** *(decreasing erythropoietin (EPO) production)*

Other complications include hypercalcemia, hyperkalemia, hyponatremia, hypernatremia, hyperparathyroidism

[1] Most injectable drugs and biologics and their oral or other form of administration are included, specifically erythropoiesis-stimulating agents (ESAs), vitamin D, IV iron.

Complementary portfolio with strong commercial potential in dialysis and non-dialysis

CKD ON DIALYSIS		CKD NON-DIALYSIS
OPPORTUNITY: **ADOPTION POTENTIAL IN LARGE MARKET**		OPPORTUNITY: **HIGH GROWTH POTENTIAL**
HYPERPHOSPHATEMIA IN DIALYSIS Gain share in $1b[1] US phosphate binder market leveraging competitive profile	**COMMERCIALIZED** **Auryxia** *FDA approved in two indications*	**IRON DEFICIENCY ANEMIA IN NON-DIALYSIS** Majority of patients fail other oral iron therapies creating large US opportunity
ANEMIA DUE TO CKD IN DIALYSIS* Gain rapid adoption in a multi-billion-dollar global market[2] with potential to set new oral SoC	**DEVELOPMENT PROGRAM** **Vadadustat, Investigational HIF PH inhibitor** *Global Phase 3 studies* Read-outs expected: In Japan 2019 for dialysis and non-dialysis, in US/EU Q1 2020 for dialysis and mid-2020 for non-dialysis[3]	**ANEMIA DUE TO CKD IN NON-DIALYSIS*** Seize high growth opportunity in under-treated population with potential to set new oral SoC

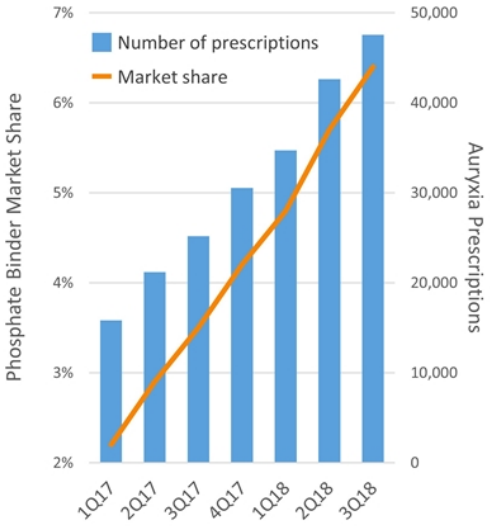
*Subject to the regulatory authorities approval; SOURCES: [1] DRG CKD Dialysis Market Forecast.; [2] Evaluate Pharma ESA WW sales extraction (07/2018).; [3] Subject to the accrual of Major Adverse Cardiovascular Events (MACE).

Akebia THERAPEUTICS

CKD ON DIALYSIS

2018 Auryxia commercial performance shows strong momentum driven by hyperphosphatemia use

DIALYSIS



Total 2018 prescriptions up 91% YTD Nov'18 vs. Nov'17

Market share growth from 2.2% to 6.4% in 18 months

Well positioned to navigate headwinds and harness momentum to drive continued significant growth in 2019

- \+ New Guidelines for hyperphosphatemia
- \+ Competitive profile, and high share of voice
- \- CMS coverage - current decision to exclude IDA[1], leading to PA[2]
- \- DaVita Rx specialty pharma discontinuation

Integration following merger close ongoing

SOURCE: Monthly prescription and market share data as of 11/30/18.

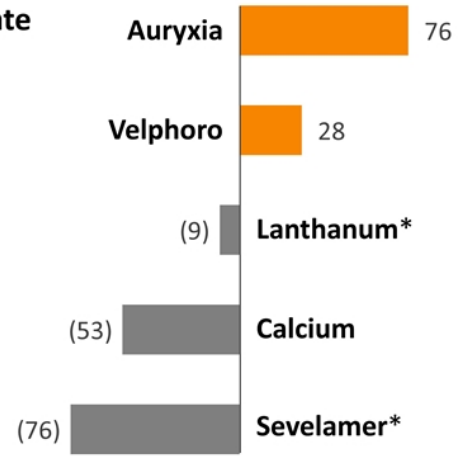
[1] Iron deficiency anemia

[2] Prior authorization.

Strong momentum for Auryxia in phosphate binder market

DIALYSIS

Change in Phosphate Binder TRx (000s) 2017 to 2018[1]



*Brand + Generic

Phosphate Binder Market Needs[2]

- Non-calcium
- Less pill burden
- Favorable tolerability profile
- Palatable formulation

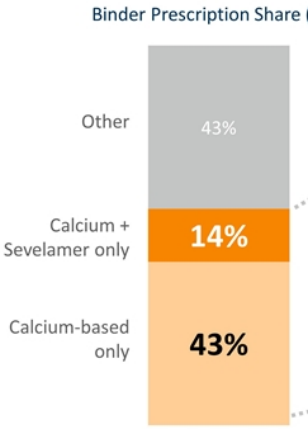
SOURCES: [1] IQVIA NPA Data; Fresenius Rx, DaVita Rx & USRC Dispense Data.; [2] Combined information from physician-reported phosphate binder attribute scoring from both Spherix syndicated market research (RealTime Dynamix quarterly reports) and Reason Research ATU tracking studies.

Akebia THERAPEUTICS

Major growth opportunity for Auryxia in the hyperphosphatemia market following treatment guideline update

DIALYSIS

Calcium-based binders comprise significant portion of market[1]…



…recent guideline limits their use

"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]

…nephrologists anticipate adoption of updated guideline

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

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".

Akebia THERAPEUTICS

Patient dissatisfaction with standard of care (SoC) and nephrologist positive perception of Auryxia create two-pronged tailwinds in the hyperphosphatemia market

DIALYSIS

~20% patients discontinue use of Renvela[1]

65%

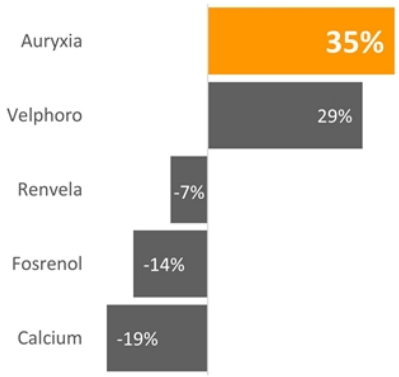
cite pill burden

42%

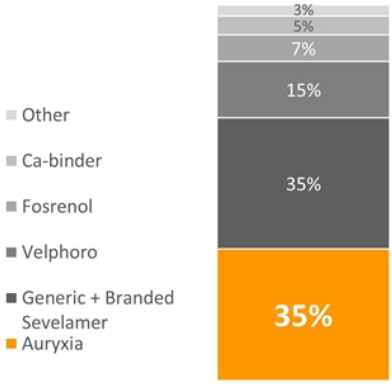
cite tolerability issues

Nephrologists view Auryxia's profile favorably compared to other binders

Nephrologists anticipate prescribing 35% more Auryxia 6 months from now[2]



"If you yourself (nephrologist) had to take a phosphate binder, which would you choose?"[3]



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.

Akebia THERAPEUTICS

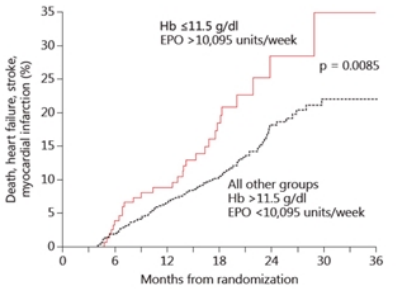
Vadadustat is an oral HIF PH inhibitor designed to stimulate endogenous EPO production, with the potential to increase hemoglobin while avoiding supra-physiological EPO levels

DIALYSIS

High EPO level is associated with increased CV risk

Kaplan-Meier Survival Curves[1]

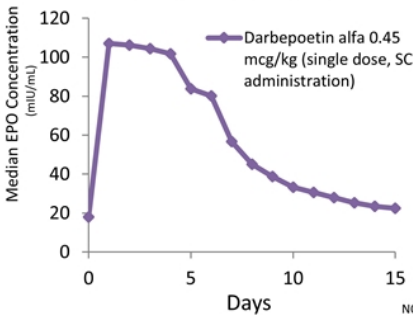
Death, Heart Failure, Stroke, Myocardial Infarction



SoC with injectable ESAs result in supra-physiological EPO levels

EPO vs Time with Darbepoetin Alfa (SC)

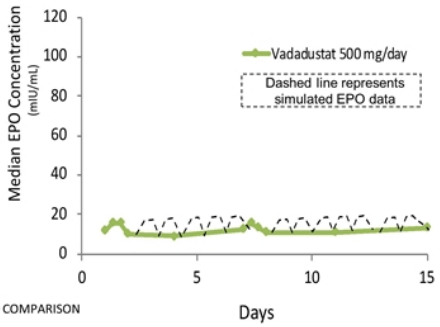
PK-PD Model in CKD Subjects[2]



Vadadustat, oral HIF PH inhibitor, avoided supra-physiological EPO levels

EPO vs Time with vadadustat (Oral)

Phase 1 Study in Healthy Volunteers[3]



NOT A HEAD-TO-HEAD COMPARISON

Vadadustat now in Phase 3 cardiovascular outcomes trials for anemia due to CKD in non-dialysis and dialysis patients.
Vadadustat is an investigational HIF PH inhibitor that is not approved by the FDA or any other regulatory authority.

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;50:75S-90S. Original figure redrawn to depict darbepoetin alfa serum concentration (ng/mL/(mcg/kg)) converted to mU/mL. Data from 6 clinical studies conducted with extensive PK sampling in CKD patients following subcutaneous (SC) administration of a single dose or first dose of a monthly dosing regimen ranging from 0.4-0.6mcg/kg, dose normalized to 0.45 mcg/kg.; [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.

Akebia THERAPEUTICS

Global Phase 3 program for vadadustat designed to assess efficacy, safety and cardiovascular outcomes, with additional data to support value proposition

DIALYSIS

NDA/MAA core package

Cardiovascular Outcomes INNO$_2$VATE Phase 3 Studies

INNO$_2$VATE CORRECTION CONVERSION
New-Onset Dialysis
Vadadustat vs Darbepoetin Alfa

N ≈ 3600

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)

Additional Non-Primary Endpoints (EPs):
Individual MACE components
Chronic Heart Failure
Thrombotic Events
Hospitalizations
Hb excursions
Time in range (Hb)
IV iron use

NDA/MAA filings

Support value proposition

FO$_2$RWARD-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, N≈125

Modified QD and TIW dosing
Includes ESA Hyporesponders
Conversion from epoetin alfa

EXPLO$_2$RE
Open-label, Sponsor-Blind, parallel arm study evaluating efficacy and safety of Modified QD dosing of vadadustat compared to epoetin alfa, N≈ 300

Efficacy and adjudicated safety EPs consistent with INNO$_2$VATE (but not powered for MACE)
Conversion from ESA, Modified QD dosing
PRO[2]

TRILO$_2$GY-2
Open-label, Sponsor-Blind, parallel arm study evaluating efficacy and safety of TIW dosing of vadadustat compared to epoetin alfa, N≈ 300

Efficacy and adjudicated safety EPs consistent with INNO$_2$VATE (but not powered for MACE)
Conversion from ESA, TIW dosing
PRO

Supplemental filing

[1] Dialysis-dependent
[2] Patient-reported outcomes

Akebia THERAPEUTICS

Concentration into large US dialysis networks creates major opportunity for vadadustat

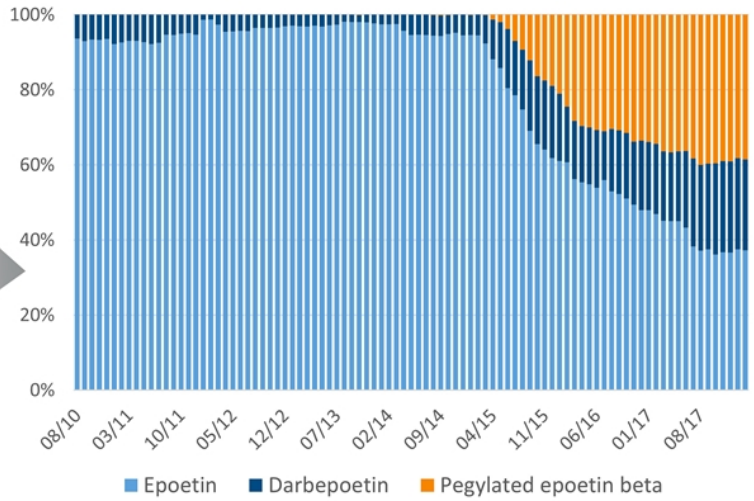
DIALYSIS

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*

TDAPA[2] creates major additional opportunity for value creation for Akebia

Mircera Uptake into Fresenius Dialysis Centers[1]



*Subject also to 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.

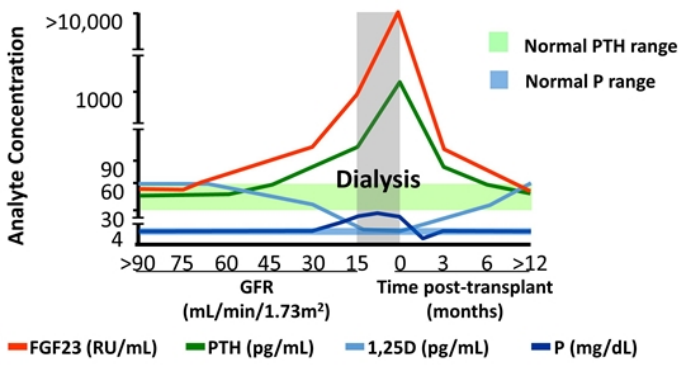
CKD NON-DIALYSIS

Akebia THERAPEUTICS

Advanced non-dialysis CKD is characterized by progressive laboratory abnormalities, with opportunity for better disease management

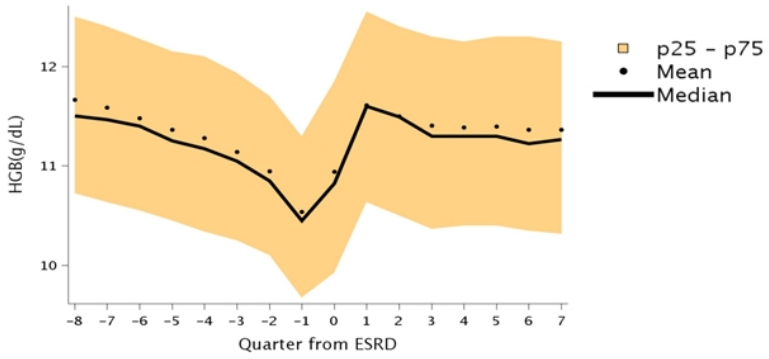
NON-DIALYSIS

Phosphorus (P), Vitamin D (1,25D), PTH and FGF 23[1,2]



Temporal aspects of disordered phosphorus metabolism in progressive CKD and after kidney transplantation. The x-axis in the pre-dialysis period represents GFR (left); in the post-dialysis period, it represents time after kidney transplantation (right). The y axis represents circulating concentrations of the individual analytes with the temporal changes in and normal ranges of individual analytes color coded (C-terminal FGF23 [RU/ml] in red; 1,25D [pg/ml] in purple; PTH [pg/ml] in green; and phosphate [mg/dl] in blue).

Hemoglobin before and after dialysis initiation[3]



The Transition of Care in Chronic Kidney Disease (TC-CKD) Special Study Center examines the transition of care to renal replacement therapy (RRT; i.e., dialysis or transplantation) in patients with very- late-stage (advanced) non-dialysis dependent (NDD) CKD. These are often people with an estimated glomerular filtration rate (eGFR) <25 ml/min/1.73 m2. The primary databases used in these analyses were created from a linkage between the national USRDS data and two large longitudinal databases of NDD- CKD patients—the national Veterans Health Administration (VHA) database and the regional (Southern California) Kaiser Permanente (KP-SC) database.

SOURCES: [1] Gutierrez O, Isakova T, Rhee E, Shah A, Holmes J, Collerone G, Juppner H, Wolf M: Fibroblast growth factor-23 mitigates hyperphosphatemia but accentuates calcitriol deficiency in chronic kidney disease. J Am Soc Nephrol 16: 2205–2215, 2005.; [2] Pereira RC, Juppner H, Azucena-Serrano CE, Yadin O, Salusky IB, Wesseling-Perry K : Patterns of FGF-23, DMP1, and MEPE expression in patients with chronic kidney disease. Bone 45: 1161–1168, 2009. [3] United States Renal Data System. 2017 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2018.

Akebia THERAPEUTICS

Dr. Geoff Block et al presented results from an investigator-sponsored study of ferric citrate at ERA-EDTA 2018

NON-DIALYSIS

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]

Publication planned

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."

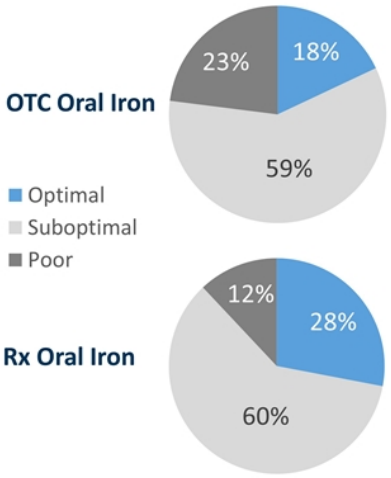
*Keryx Biopharmaceuticals, Inc. (now a wholly owned subsidiary of Akebia) provided funding and study medication for this investigator initiated study.; SOURCE [1] Geoffrey Block, Martha Block, Gerard Smits, Laura Kooienga, Rupal Mehta, Tamara Isakova, Myles Wolf, Glenn Chertow. Randomized trial of the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

Akebia THERAPEUTICS

Major commercial opportunity in IDA for non-dialysis patients, driven by limited efficacy of traditional oral iron combined with preference to avoid IV iron

NON-DIALYSIS

Nephs believe oral iron achieves optimal response in only ~25% of patients[1]



Nephs currently prescribe oral iron first line, despite limited satisfaction with patient results[2]…

50% Always treat CKD NDD* patients with oral iron before IV iron

But only…

28% Believe their CKD NDD patients get decent results when prescribed oral iron

And…

57% Believe an oral iron product with improved tolerability would offset IV iron in NDD CKD patients

…and believe there is a need for an effective, well-tolerated oral option[3]

65%

Strongly agree they would prefer effective, well-tolerated oral iron over IV iron

58%

Strongly agree there is a ***clinical*** unmet need for more effective, better tolerated oral iron

*Non-dialysis-dependent

SOURCES: [1] Spherix RealWorld Dynamix Renal Anemia, Feb 2018 (n = 172 nephrologists, 1059 patients records).; [2] Spherix RealTime Dynamix Renal Anemia, Q4 2018 (n=202 nephrologists).; [3] Auryxia ATU market research survey Q4 2018 (n=104 nephrologists).

Akebia THERAPEUTICS

Nephrologists believe Auryxia has strong potential in IDA

NON-DIALYSIS

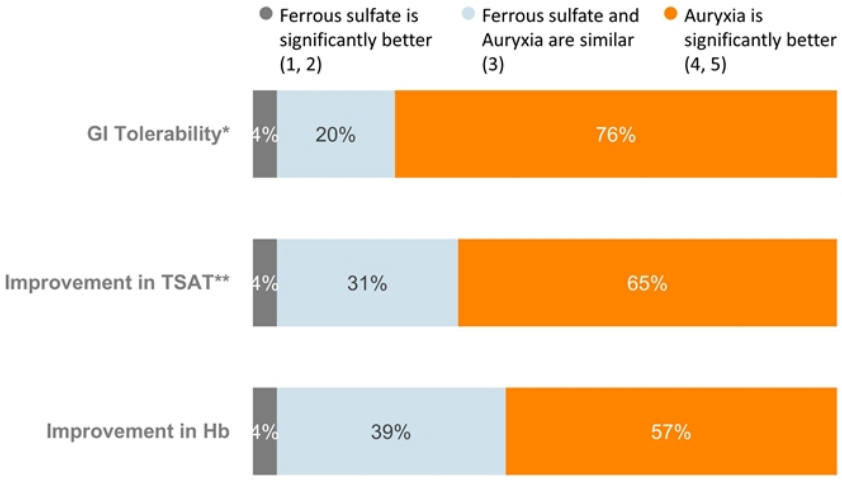
Nephrologist perspective on Auryxia to Potentially Address the Unmet Need[1]

48% ***Very likely*** to use after traditional oral iron failure

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

41% ***Very likely*** to use in place of IV 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.

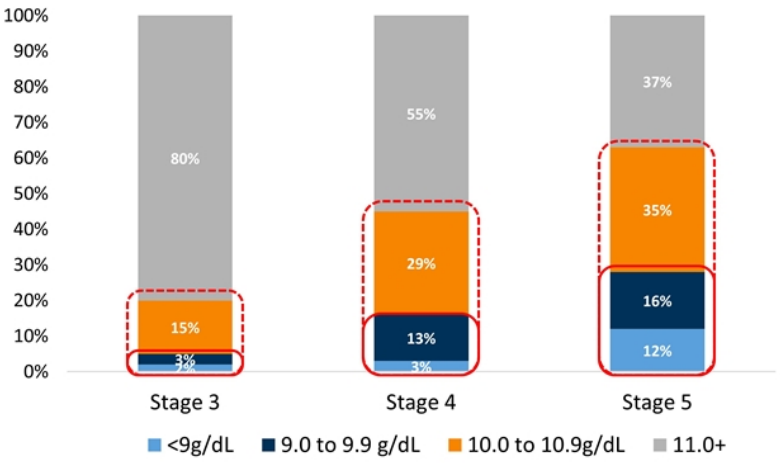
Akebia THERAPEUTICS

In anemia due to CKD market, ESA treatment has decreased dramatically driven primarily by CV risk, leaving many patients with low hemoglobin untreated

NON-DIALYSIS

High proportion of patients with low Hb are not treated

Hemoglobin Levels in patients NOT treated with ESA by CKD Stage[1]



Unmet needs in anemia due to CKD for non-dialysis patients

- Lower risk of **CV events**
- Less variability in **hemoglobin levels**
- Lower risk of **hypertension**
- More **convenient dosing**

SOURCE: [1] Spherix RealWorld Dynamix Renal Anemia market research survey and chart review, Feb 2018 (172 nephrologists, 1059 patient records).

Akebia THERAPEUTICS

Global Phase 3 program for vadadustat designed to assess efficacy, safety and cardiovascular outcomes, with additional data to support potential for new oral SoC in anemia due to CKD

NON-DIALYSIS

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

PRO$_2$TECT CORRECTION	N ≈ 3,700	PRO$_2$TECT CONVERSION
Not ESA Treated		ESA Treated
Vadadustat vs Darbepoetin Alfa		Vadadustat vs Darbepoetin Alfa

Primary Efficacy Endpoint: Change in hemoglobin (Hb) from baseline
Primary Safety Endpoint: Major Adverse Cardiovascular Events (MACE)

Additional Non-Primary Endpoints

- Individual MACE components
- Chronic Heart Failure
- Thrombotic Events
- Hospitalizations
- Hb excursions
- Time in range (Hb)
- IV iron use
- CKD Progression

Strong financial position

Approximately **117 million** shares outstanding at December 31, 2018

$431 million cash position[1]

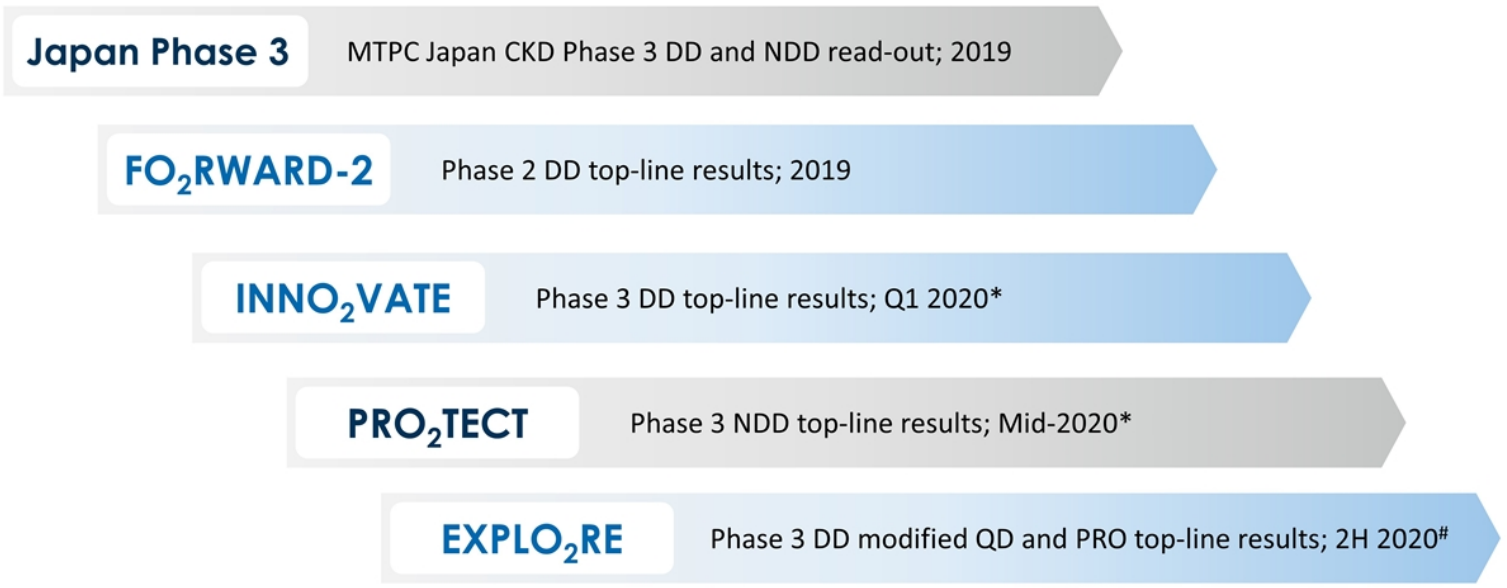
Expect existing cash resources[2] and estimated product revenue to fund operations into **Q3 2020**

Growing revenue stream expected, driven by Auryxia sales and collaboration revenue[3]

[1] Cash, cash equivalents and available for sale securities, pro forma, unaudited, as of 9/30/2018.
[2] Includes prepaid quarterly committed cost share funding from Akebia's collaborators.
[3] Otsuka R&D cost reimbursement to increase from 52.5% to 80% in 2019.

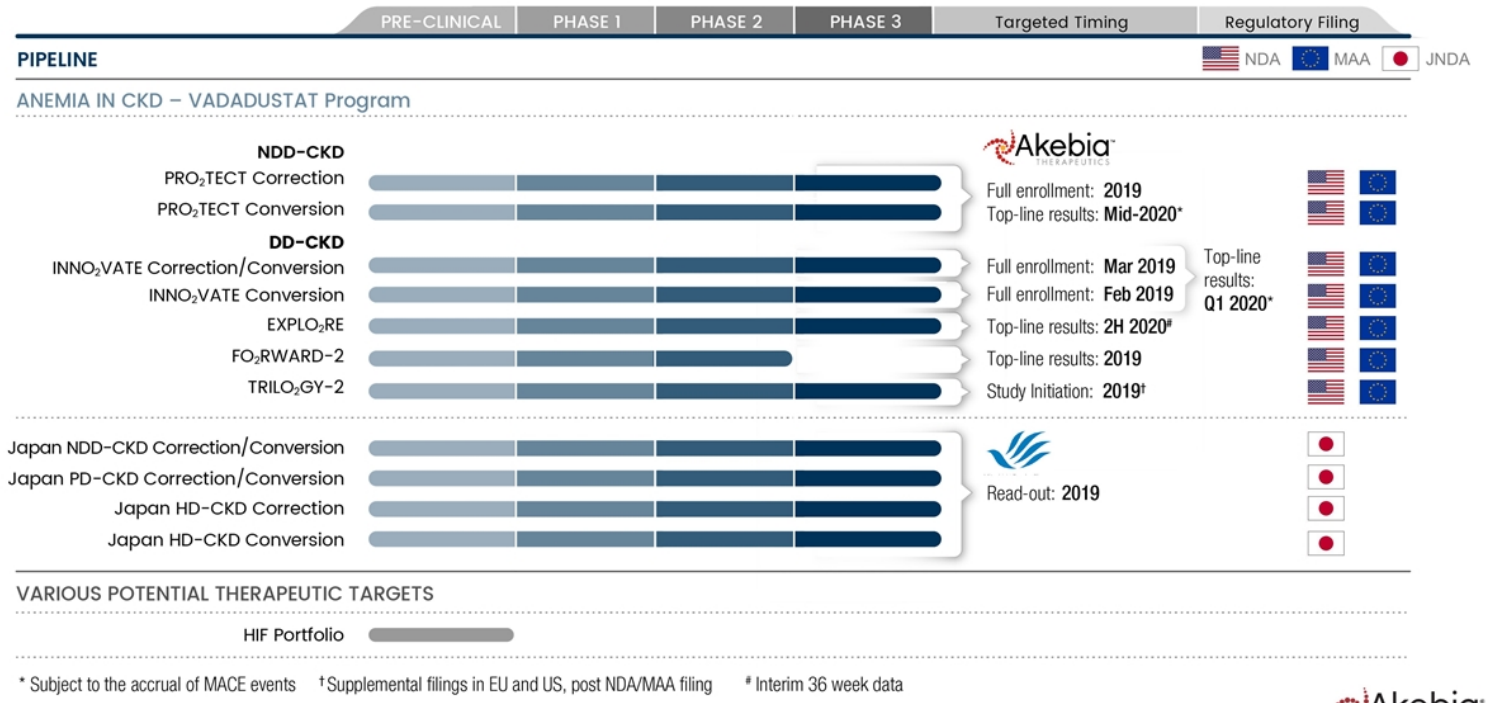
Akebia THERAPEUTICS

Expected near-term clinical catalysts for vadadustat starting in 2019 through mid-2020



*Subject to accrual of MACE events.
Interim 36 week data.

Pipeline



* Subject to the accrual of MACE events † Supplemental filings in EU and US, post NDA/MAA filing # Interim 36 week data

Note: NDD-CKD denotes non-dialysis-dependent chronic kidney disease and DD-CKD denotes dialysis-dependent chronic kidney disease.

Akebia THERAPEUTICS

What's next? Strong value creation through portfolio maximization and pipeline growth, driven by our mission to advance care for patients with kidney disease

Full integration & Financial strength

- Research, Development, Commercial
- Financial strength with $431 million cash position[1], product sales and collaboration revenue

Strong portfolio synergies

- Leveraging Auryxia relationships for vadadustat launch, subject to FDA approval
- Explore co-development potential for vadadustat and Auryxia

Pipeline and Growth

- HIF compounds portfolio
- Positioned to be partner of choice for innovation in renal

[1] Cash, cash equivalents and available for sale securities, pro forma, unaudited, as of 9/30/2018.

Akebia: Fully integrated biotech company focused on kidney disease with complementary portfolio and financial strength

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

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

Expect existing cash resources[1] and estimated product revenue to fund operations into Q3 2020

Financial strength with $431 million cash position[2], product sales and collaboration revenue

[1] Includes prepaid quarterly committed cost share funding from Akebia's collaborators.
[2] Cash, cash equivalents and available for sale securities, pro forma, unaudited, as of 9/30/2018.

Akebia THERAPEUTICS