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 9, 2023

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 Capital Market

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

Emerging growth company ☐

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

Item 7.01 Regulation FD Disclosure.

Spokespersons of Akebia Therapeutics, Inc. (the "Company") plan to present the information in the presentation attached hereto as Exhibit 99.1 (the "Presentation") at various meetings beginning on January 9, 2023, including investor and analyst meetings that coincide with the J.P. Morgan Healthcare Conference.

A copy of the presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Current Report on Form 8-K (including Item 7.01 and Exhibit 99.1) 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 of that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing.

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

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Akebia Therapeutics, Inc. Presentation January 2023
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 9, 2023

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

Exhibit 99.

Akebia® THERAPEUTICS

John P. Butler, CEO
David A. Spellman, CFO
Mercedes Carrasco, IR & Corp Comm

January 2023

Commercial Depth.
Operational Excellence.
A Commitment to Advance Innovation to Address Unmet Needs.

CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS

Statements in this presentation regarding Akebia Therapeutics, Inc.'s ("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: Akebia's plans, strategies and prospects for its business, including with respect to Akebia's Formal Dispute Resolution Request, or FDRR, that Akebia submitted with the U.S. Food and Drug Administration, or FDA, to appeal the Complete Response Letter that it received in March 2022 and its expectations regarding the timing of a potential response from the FDA to the FDRR; Akebia's ability to implement its main objectives, including its cash management strategy, support of vadadustat, investment in a pipeline of internal assets and assessing other strategic growth opportunities when appropriate; the timing of, or likelihood of, regulatory approval of vadadustat by the FDA or European Medicines Agency, or EMA, including with respect to labeling or other restrictions; expectations with respect to Akebia's pipeline, including Akebia's ability to execute on its development plans, including expectations of the timing and outcome of the study in acute respiratory distress syndrome, or ARDS, and Akebia's early hypoxia inducible factor, or HIF, research; Akebia's revenue guidance for Auryxia in 2022 and expectations and assumptions related thereto; Akebia's goals, objectives and expectations with respect to its operating plan and cash resources, including its belief that its existing cash resources and revenues from Auryxia will be sufficient to fund its current operating plan for at least the next twelve months; the potential therapeutic benefits, safety profile, and effectiveness of vadadustat for anemia due to chronic kidney disease, or CKD, or for ARDS; Akebia's outlook as it relates to future opportunities for vadadustat in the U.S., Europe, and other territories, including the potential demand and market opportunity for vadadustat, if approved, and the size of eligible patient populations and Akebia's ability to secure a new commercial partner for vadadustat in Europe and other territories; and the potential therapeutic applications of the HIF pathway.

The terms "believe," "plan," "potential," "estimate," "expect," "future," "advance," "will," "continue," 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: the potential demand and market potential and acceptance of, as well as coverage and reimbursement related to, Auryxia, including estimates regarding the potential market opportunity; Akebia's ability to implement cost avoidance measures and reduce overhead costs, including its ability to reduce operating expenses; decisions made by health authorities, such as the FDA and the EMA, with respect to regulatory filings, including the New Drug Application and the FDRR for vadadustat; the potential therapeutic benefits, safety profile, and effectiveness of vadadustat; manufacturing, supply chain and quality matters and any recalls, write-downs, impairments or other related consequences or potential consequences; the risk that future clinical trials of product candidates may be unsuccessful, including that vadadustat may not be found to be an effective treatment for ARDS; Akebia's intellectual property position, including its ability to obtain, maintain and enforce patent and other intellectual property protection for Akebia's commercial product, Auryxia, vadadustat and any other product candidates; and early termination of any of Akebia's collaborations. 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, 2022, 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 press release, 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.

Akebia

Akebia

A Commitment to Address Patients' Unmet Needs

Maximize Value and Advance Innovation

Akebia

1 Revenue + Cash Management

- Auryxia® (ferric citrate) net product revenue up 27% in the first three quarters of 2022 vs first three quarters of 2021
- R&D and SG&A expenses down 17% in the first three quarters of 2022 vs first three quarters of 2021*

2 Support Vadadustat Globally

- Vafseo™ in market in Japan
- Vadadustat under review in EU; CHMP opinion expected in Q1 2023
- Vadadustat under review in US; Interim response to its Formal Dispute Resolution Request (FDRR) received in December 2022; Akebia expects to submit requested information in January 2023

3 Pipeline & Strategic Growth

- Acute Respiratory Distress Syndrome (ARDS) study with UT Health expected to commence this year
  - High unmet need with ~46% mortality with severe ARDS[1]
- Progress early HIF research for IND in 2024 in an acute indication

CHMP is The Committee for Medicinal Products for Human Use. HIF is hypoxia-inducible factor. *When excluding one-time restructuring charge of ~$14.7M in 2022 [1]https://pubmed.ncbi.nlm.nih.gov/26903337/

Akebia® THERAPEUTICS

Strategic Pillar: Revenue and Cash Management

Auryxia® (ferric citrate)

Auryxia®

FDA approved in two indications:

- Hyperphosphatemia in patients with CKD on dialysis (2014)
- Iron deficiency anemia in patients with CKD not on dialysis (2017)

Serving the Renal Market

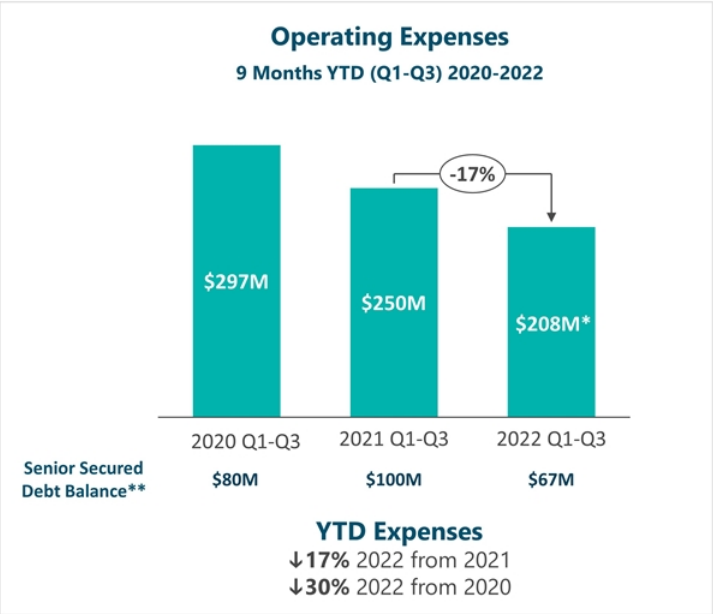
Compelling product profile with favorable MoA efficacy and tolerability

Akebia Cares: Ensures Auryxia access for eligible patients

Year Over Year Revenue Growth to Fund Current Operations

- **$142M** net product revenue in FY2021
- **$127M** net product revenue through Q3 YTD 2022
  - Expect to achieve upper end of previously disclosed revenue guidance of $170-$175M.

Cost Management Principles In Place



Expense Management - Q3 2022

- R&D: $27.4M; Down from $40.5M in Q3 2021
- SG&A: 30.9M; Down from $46.4 in Q3 2021

Strong Balance Sheet

- Year End Debt Balance of $67M
  - Retired a portion of debt facility with Pharmakon; Saving ~34% of cash interest on loan for remainder of term

* When excluding one-time restructuring charge of ~$14.7M in 2022
**Debt as of September 30 in each year. Year End 2020 was $100M, following $20M drawdown in Q4 2020

Akebia® THERAPEUTICS

Strategic Pillar:
Support Vadadustat Globally

Unmet Need in Treatment of Anemia due to CKD

Anemia may be associated with adverse clinical outcomes in patients with chronic kidney disease (CKD)

Dialysis-Dependent (DD) Patients

- Anemia due to CKD is well recognized, but not always well controlled
- Despite available options, a percentage of patients still do not achieve Hb levels within the target range[1]

Non-Dialysis Dependent (NDD) Patients

- Anemia due to CKD not well recognized and many patients not under care of nephrologist
- Patients less often treated, influenced by route of administration and safety concerns

Shortcomings of the Current Standard of Care (ESAs)

- Inconvenient injectable administration, mostly performed in office/center
- Associated with frequent hemoglobin overshoots, supra physiologic elevations of EPO

Hb is Hemoglobin. ESA is erythropoietin stimulating agent. EPO is erythropoietin.
[1]DOPPS: https://www.dopps.org/DPM-HD/DPMSlideBrowser.aspx?type=Topic&id=1

Vadadustat

Investigational oral HIF-prolyl hydroxylase inhibitor for anemia due to CKD

	Status	Market Potential

Europe and Other Territories	▪ MAA for DD and NDD patients submitted to European Medicines Agency in October 2021; CHMP opinion expected Q1 2023
	▪ Akebia seeking commercial partner in Europe following potential approval by EMA
	▪ Also, under review in UK, Switzerland, Australia, Korea and Taiwan
		▪ Full rights in Europe and certain other territories*
		▪ Potential multi-billion € opportunity in EU5 alone:
		  ▪ ~203k dialysis dependent patients treated with ESA[1]
		  ▪ At least 300k non-dialysis dependent patients treated with ESA[1]

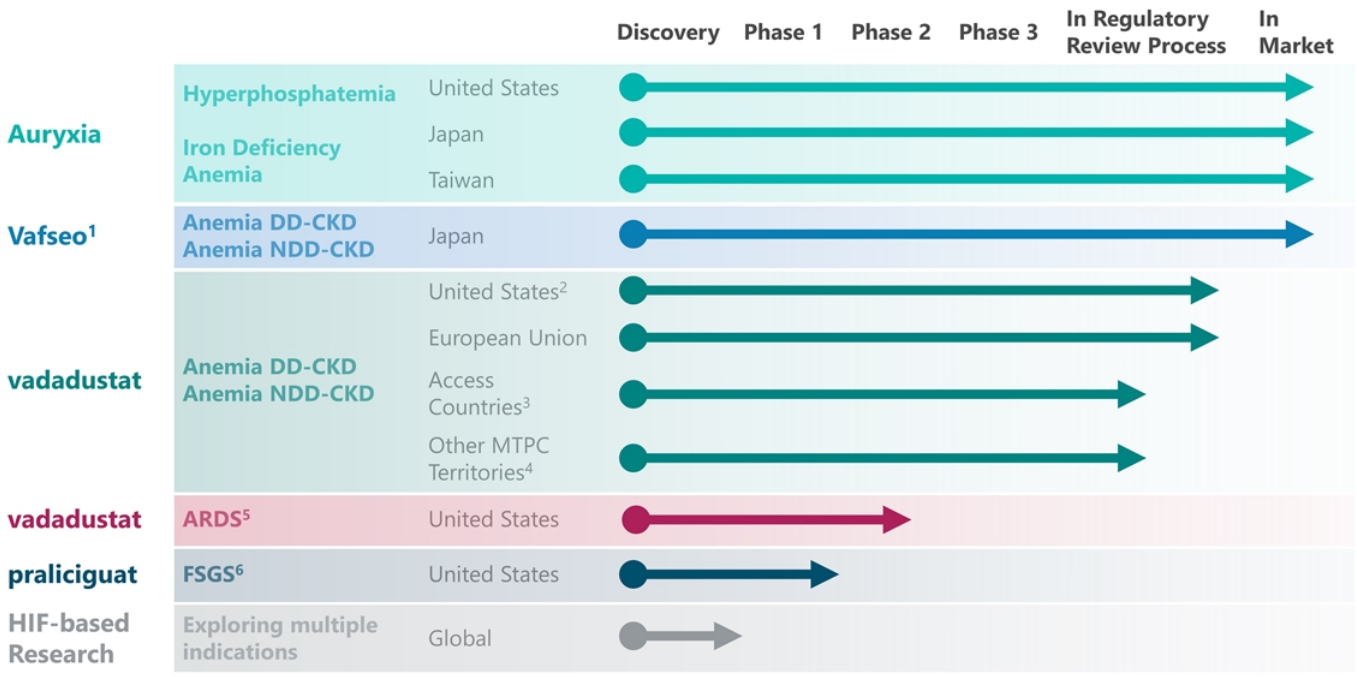
United States	▪ Received interim response from FDA to formal dispute resolution request for vadadustat in DD patient population regarding Complete Response Letter received in March 2022 ▪ Akebia expects to submit requested information in January 2023 and expects to receive a response to its appeal 30 days post submission	▪ U.S. rights subject to license agreement with CSL Vifor that leverages their exclusive distribution into certain dialysis organizations, representing ~60%[2] of the dialysis market. ▪ $2B estimated U.S. dialysis market potential[3]

MAA is marketing authorisation application. EU5 is France, Germany, Italy, Spain, UK
*Australia, China, Canada, Latin America, Middle East and Russia
[1] EU5 for dialysis dependent and non-dialysis dependent patient populations; CVRG CKD (2016-2025) & DRG (2018); Spherix RealWorld Dynamix, 2022 [2] Vifor Pharma Ltd./Annual Report 2019 [3] 2020 USRDS Annual Data Report: https://adr.usrds.org/2020/reference-tables. Based on internal estimates and industry reports estimating ESA pricing.

Akebia® THERAPEUTICS

Strategic Pillar: Pipeline and Strategic Growth

Current In-Market Therapies and Development Plans



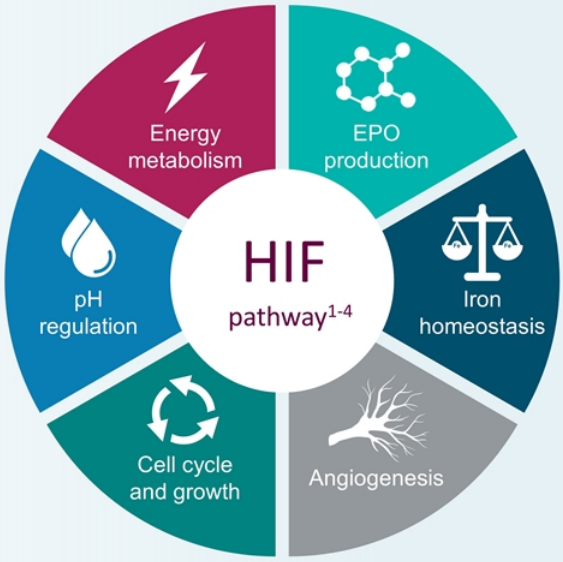
[1]Marketed by MTPC [2]Appeal filed for dialysis dependent patient population [3]United Kingdom, Switzerland, Australia [4]Korea, Taiwan [5]Clinical study conducted by UTHealth Houston [6]Further CMC development for clinical trial materials ongoing

Strategic Investment to Advance Pipeline

Expertise in HIF Science and Renal Defines Focus

The discovery of HIF has laid the foundation to help understand the central role of oxygen sensing in many diseases.

Utilizing Akebia's investigations into the HIF mechanism of action in anemia due to CKD to other hypoxic conditions, such as acute respiratory distress syndrome.



[1]Maxwell PH, Eckardt KU. Nat Rev Nephrol. 2016;12(3):157-168. [2]Kumar H, Choi DK. Mediators Inflamm. 2015;2015:584758. [3]Pergola PE, et al. Kidne Int. 2016;90(5):1115-1122. [4]Sanghani NS, Haase VH. Adv Chronic Kidney Dis. 2019;26(4):253-266

Acute Respiratory Distress Syndrome (ARDS)

Life-threatening acute form of lung disease characterized by acute bilateral pulmonary edema, severe hypoxia

Usually requires intubation and mechanical ventilation[1]

Directly caused by pneumonia, aspiration, trauma; Sepsis is the most common indirect cause[2]

Prevents other organs from getting the oxygen they need to function

The HIF Pathway in ARDS[3]

When stabilized, HIF triggers wide-ranging adaptive, protective responses during hypoxic or ischemic conditions. HIF target genes have the potential to address the pathophysiology of ARDS.

- Upregulate extracellular adenosine signaling
- Increases in glycolytic capacity of alveolar epithelia
- Anti-inflammatory signaling that resolves mucosal inflammation
- Stimulate EPO and VEGF production to increase oxygen delivery to hypoxic tissue

[1]https://www.uptodate.com/contents/ventilator-management-strategies-for-adults-with-acute-respiratory-distress-syndrome.
[2]https://www.nhs.uk/conditions/acute-respiratory-distress-syndrome/
[3]Chowdhury R, et al. Chem Soc Rev. 2008 Jul;37(7):1308-19.; Colgan SP, et al. Annu Rev Immunol 38, 341-363.; Koivunen P, et al. Trends Mol Med. 2018 Dec;24(12):1021-1035.; Pugh CW, et al. Nat Med. 2003 Jun;9(6):677-84.; Ecklet T, et al. J Immunol . 2014 Feb 1;192(3):1249-56.

Limitations of Standard of Care

- Current standard of care is non-specific and focused on minimizing mechanical ventilation
- Extended use of mechanical ventilation may lead to long term pulmonary damage due to ventilator induced lung injury and subsequent fibrosis
- **Despite improvement in treatment strategies, a study indicated high hospital mortality rates for patients with ARDS admitted to participating ICUs:[1]**
  - **Mild: 34.9%**
  - **Moderate: 40.3%**
  - **Severe: 46.1%**

No approved or widely accepted drug therapy to treat, prevent, or improve outcomes of ARDS

[1] https://pubmed.ncbi.nlm.nih.gov/26903337

Initial Findings Evaluating Vadadustat for ARDS

Investigator-sponsored clinical study by UTHealth

Scientific Hypothesis[1,2]

- HIF stabilization may lead to
  - Upregulation of protective genes involved in vascular function and acute inflammation
  - Restoration of endothelial and epithelial barriers
    - Dysregulation of cellular barriers is a common link in multi-organ inflammation in severe COVID-19

Pre-Clinical Evidence[3]

- Mouse model used to evaluate effect of vadadustat when administered 8 hours after lipopolysaccharide-induced lung inflammation and assessed at 24 hours
- Compared to control, vadadustat-treated mice had:
  - Significantly lower bronchoalveolar lavage cell, neutrophil, and macrophage counts
  - Significant changes in cytokines

Investigator-Sponsored Clinical Study - UTHealth

- 449 adult subjects at 5 hospitals; randomized 1:1 to vadadustat 900 mg or placebo 1x per day orally for up to 14 days while hospitalized; measured on NIAID-OS* at Day 7 and Day 14 (primary)
- Vadadustat demonstrated 94% probability of conferring benefit on the NIAID-OS at Day 14, but failed to meet the primary superiority threshold of >95% probability. In a pre-specified analysis at Day 7, there was a 97% probability that vadadustat was superior to placebo.
- The incidence of treatment emergent adverse events was 78.6% in the vadadustat group vs 76.2% in the placebo group

[1]Marchetti M. Ann Hematol. 2020;99(8):1701-1707
[2]Watts ER, Sarah R Walmsley SR. Trends Mol Med. 2019 Jan;25(1:33-46.
[3]Data on File. Akebia Therapeutics, Inc.
*National Institute of Allergy and Infectious Disease Ordinal Scale

Akebia

Integrated Biotechnology Company

Experienced Leadership Team and Board of Directors

U.S. Field Team Supporting Nephrology Market

- Auryxia® (ferric citrate) in market
  - Experienced Account Managers targeting key accounts
- Medical Science Liaison Team with significant renal experience
- Manufacturing capability supporting two global supply chains

Innovative Research & Development Team

- Two approved medicines: Auryxia and Vafseo*
- Breadth of scientific experience
- Leveraged Nobel Prize-winning science – the HIF mechanism
- Expertise in leading discovery and development programs
- Designed, actively managed global Phase 3 trials of 7,000+ patients

Existing cash resources and product revenue expected to be sufficient to fund current operating plan through at least 12 months**

*Vafseo approved in Japan and commercialized by MTPC
**Assumes that Auryxia revenues continue to grow, and Akebia is successful implementing cost reduction measures.

Akebia's Leadership Team

Industry veterans with strong clinical development and commercialization experience across multiple therapeutic areas

Corporate Officers

Chief Executive Officer
John Butler

Chief Financial Officer
David Spellman

Chief Medical Officer
Steven K. Burke, M.D.

Chief Operating Officer
Michel Dahan

Chief Legal Officer
Nikki Hadas

Leadership

SVP, Manufacturing
Thierry Bilbault

SVP, Quality
Kimberly Garko

SVP, Commercial
Bennett Smith

VP, Program Executive
Tracey Vetterick

SVP, People
Meredith Bowman

SVP, General Counsel
Carolyn Rucci

2023
A Defining Year

Building on Our Strategic Pillars

1 Revenue + Cash Management

- Continue Year over Year Revenue Growth of Auryxia
- Decrease Year over Year Operating Expenses (R&D + SG&A)

2 Support Vadadustat

- Potential European approval of vadadustat
- Secure EU partnership and support partner launch
- Continue appeal process with FDA to identify potential path for approval of vadadustat for adult patients on dialysis

3 Pipeline & Strategic Growth

- Advance ARDS program via trial with UTHealth Houston
- Thoughtfully invest in HIF-based research

Maximize Value and Advance Innovation in Area of Unmet Patient Needs


Akebia®
THERAPEUTICS