# **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

SCHEDULE 14A

Proxy Statement Pursuant to Section 14(a) of the Securities Exchange Act of 1934
(Amendment No.)

Filed by the Registrant ⊠	
Filed by a Party other than the Registrant □	
Check the appropriate box:	
	Preliminary Proxy Statement
	Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))
	Definitive Proxy Statement
$\boxtimes$	Definitive Additional Materials
	Soliciting Material under §240.14a-12
AKEBIA THERAPEUTICS, INC. (Name of Registrant as Specified In Its Charter)	
	n/a (Name of Person(s) Filing Proxy Statement, if other than the Registrant)
Payment of Filing Fee (Check all boxes that apply):	
$\boxtimes$	No fee required
	Fee paid previously with preliminary materials
	Fee computed on table in exhibit required by Item 25(b) per Exchange Act Rules 14a-6(i)(1) and 0-11

Commencing on or about March 27, 2023, Akebia Therapeutics, Inc. plans to provide the materials contained in this Schedule 14A in communications to certain of its stockholders.

Dear [Stockholder],

Thank you for your time and ongoing interest in Akebia.

As a follow up, we thought it would be helpful to share an Update to Stockholders, which summarizes recent business highlights aligned to three strategic pillars and potential upcoming milestones and pipeline progress.

The presentation is available via the Investors section of Akebia's website at: https://ir.akebia.com.

Thank you for your continued support of Akebia.

Best,

Mercedes Carrasco



**Update for Stockholders March 2023** 

#### 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 expectations on the timing for certain regulatory decisions for vadadustat by the FDA and regulatory authorities in the U.K., Switzerland and Australia; the timing of, or likelihood of, regulatory approval of vadadustat by the FDA or European Medicines Agency, or EMA; expectations with respect to Akebia's pieline, 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 goals, objectives and expectations with respect to its operating plan and cash resources, including its belief that its existing cash resources and revenues from Aurnyai(R) will be sufficient to fund its current operating plan for at least the next twelve months; Akebia's expectations with respect to the future principal balance of its outstanding debt; Akebia's expectations with respect to the leverage the surrent operating plan for at least the next twelve months; Akebia's expectations with respect to the future principal balance of its outstanding debt; Akebia's expectations with respect to the future principal balance of its outstanding debt; Akebia's expectations with respect to the future principal balance of its outstanding debt; Akebia's expect

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; the competitive landscape for Auryxia, including potential generic entrants; the ability of Akebia to attract and retain qualified personnel; Akebia's ability to

implement cost avoidance measures and 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; Akebia's ability to partner for vadadustat in Europe in a timely manner, on acceptable terms, or at all; the potential therapeutic benefits, safety profile, and effectiveness of vadadustat; the results of preclinical and clinical research; 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, Aurysia, 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 Annual Report on Form 10-K for the year ended December 31, 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 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.

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A
Commitment
to Address
Patients'
Unmet Needs



Maximize
Value and
Advance
Innovation



### **Revenue + Cash Management**

- Auryxia® (ferric citrate) net product revenue \$177.1M for 2022 up 24.5% over 2021
- Operating expense reduced year-over-year; reduction of excess purchase commitment liability of \$67.6M
- Cash to fund operating plan expected for at least 12 months from Form 10-K filing date; cleared going concern
- Reduced debt principal balance by nearly half since June 30, 2022; expected to be \$51M by March 31, 2023

# **Support Vadadustat Globally**

- Vafseo™ in market in Japan; Vadanem Tablet (vadadustat) approved in Korea
- Positive CHMP opinion recommending European Commission approve vadadustat for dialysis dependent patients; expect Marketing Authorization in May 2023
  - With EMA approval, vadadustat would be approved in 31 countries globally
- Vadadustat FDA appeal in process; interim response received in February 2023

# **Pipeline & Strategic Growth**

- Acute respiratory distress syndrome (ARDS) study with UT Health expected to commence this year
- Progress early HIF research for potential IND in 2024 in an acute indication

CHMP is The Committee for Medicinal Products for Human Use. HIF is hypoxia-inducible factor, IND is Investigational New Dr

# 2023 A Defining Year

#### **Potential 2023 Milestones**

- European Commission approval for vadadustat for dialysis dependent patients (May 2023)
- European vadadustat partnership
- Receive regulatory decision for vadadustat for U.K., Switzerland and Australia
- Receive decision on appeal process with FDA related to CRL for vadadustat
- Present data from the FOCUS study on three times weekly dosing for vadadustat in dialysis patients
- Present data from the IMPACT investigatorsponsored study evaluating the effect of Auryxia as a phosphate binder on utilization of IV iron and erythropoiesis-stimulating agents (ESAs) on dialysis patients

### **Potential 2023 Pipeline Progress**

- Initiate our next ARDS study with UT Health in a non-covid ARDS population
- Assess potential regulatory path for indications for vadadustat in acute settings
- Potential to leverage our infrastructure to build out our development or commercial portfolio with new external assets
- Maturation of our preclinical HIF programs with the potential for multiple INDs over the coming years

