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): February 18, 2022

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 1.01 Entry into a Material Definitive Agreement

Second Amended and Restated License Agreement with Vifor Pharma (International) Ltd.

On February 18, 2022, Akebia Therapeutics, Inc. ("Akebia") and Vifor (International) Ltd. ("Vifor Pharma") entered into a Second Amended and Restated License Agreement (the "Amended Agreement"), which amends and restates the Amended and Restated License Agreement, dated April 8, 2019 (as amended and restated, the "Prior Agreement"). Pursuant to the Amended Agreement, Akebia granted Vifor Pharma an exclusive license to sell vadadustat to Fresenius Medical Care North America and its affiliates, including Fresenius Kidney Care Group LLC, to certain third party dialysis organizations approved by Akebia, to independent dialysis organizations that are members of certain group purchasing organizations, and to certain non-retail specialty pharmacies (collectively, the "Supply Group") in the United States (the "Territory"). Vadadustat is Akebia's investigational oral hypoxia-inducible factor ("HIF") prolyl hydroxylase inhibitor for the treatment of anemia due to chronic kidney disease ("CKD"), for which Akebia has filed a new drug application with the U.S. Food and Drug Administration ("FDA").

Like the Prior Agreement, the Amended Agreement is structured as a profit share arrangement between Akebia and Vifor Pharma in which Akebia will receive approximately 66% of the profit, net of certain pre-specified costs. Under the Amended Agreement, Vifor Pharma will make an upfront payment to Akebia of $25 million in lieu of the previously disclosed milestone payment of $25 million that Vifor Pharma was to pay to Akebia following approval of vadadustat by the FDA. In addition, Vifor Pharma agreed to make an equity investment in Akebia as further described below under "*Investment Agreement*." Akebia currently retains rights to commercialize vadadustat for use in the non-dialysis dependent CKD market and to sell to dialysis organizations outside of the Supply Group. As under the Prior Agreement, during the term of the Amended Agreement, Vifor Pharma is not permitted to sell any HIF product that competes with vadadustat in the Territory to the Supply Group.

As under the Prior Agreement, the Amended Agreement provides that Akebia and Vifor Pharma will enter into a commercial supply agreement for vadadustat pursuant to which Akebia will supply all of Vifor Pharma's requirements for vadadustat in the Territory. Under the Amended Agreement, Vifor Pharma will contribute $40 million to a working capital facility (the "Working Capital Fund") to partially fund Akebia's costs of purchasing vadadustat from its contract manufacturers, which amount of funding will fluctuate, and which funding Akebia will repay to Vifor Pharma over time.

Like the Prior Agreement, unless earlier terminated, the Amended Agreement will expire upon the later of the expiration of all patents that claim or cover vadadustat or the expiration of marketing or regulatory exclusivity for vadadustat in the Territory. Vifor Pharma may terminate the Amended Agreement in its entirety upon 30 months' prior written notice after the first anniversary of the receipt of regulatory approval, if approved, from the FDA for vadadustat for dialysis-dependent CKD patients. Akebia may terminate the Amended Agreement in its entirety for convenience, following the earlier of a certain period of time elapsing or following certain specified regulatory events, and upon 6 months' prior written notice. If Akebia so terminates for convenience, subject to a specified exception, Akebia will pay a termination fee to Vifor Pharma. In addition, either party may, subject to a cure period, terminate the Amended Agreement in the event of the other party's uncured material breach or bankruptcy. Akebia may also terminate the Amended Agreement upon the occurrence of certain other events. The Amended Agreement also continues to include a standstill provision and customary representations and warranties.

The foregoing description of the Amended Agreement does not purport to be complete, and is qualified in its entirety by reference to the Amended Agreement, a copy of which Akebia expects to file with its Annual Report on Form 10-K for the year ended December 31, 2021.

Investment Agreement

In connection with entering into the Amended Agreement, on February 18, 2022, Akebia and Vifor Pharma entered into an investment agreement (the "Investment Agreement") pursuant to which Akebia agreed to sell an aggregate of 4,000,000 shares of its common stock, par value $0.00001 per share (the "Shares"), to Vifor Pharma for a total of $20 million. The issuance of the Shares is expected to take place on or about February 23, 2022.

Vifor Pharma has agreed to a lock-up restriction to not sell or otherwise dispose of the Shares for a period of time following the effective date of the Investment Agreement as well as a customary standstill agreement. In addition, the Investment Agreement contains voting agreements made by Vifor Pharma with respect to the Shares. The Shares will be issued and sold in reliance upon the exemption from registration contained in Section 4(a)(2) of the Securities Act of 1933, as amended (the "Act"), and/or Rule 506 promulgated thereunder, as the transaction will not involve any public offering within the meaning of Section 4(a)(2) of the Act.

The foregoing description of the Investment Agreement does not purport to be complete, and is qualified in its entirety by reference to the Investment Agreement, a copy of which Akebia expects to file with its Annual Report on Form 10-K for the year ended December 31, 2021.

First Amendment and Waiver to Loan Agreement with Pharmakon

On February 18, 2022, in connection with entering into the Amended Agreement, Akebia, BioPharma Credit PLC (the "Collateral Agent"), BPCR Limited Partnership (as a "Lender") and BioPharma Credit Investments V (Master) LP (as a "Lender") entered into the First Amendment and Waiver (the "First Amendment and Waiver"), which amends and waives certain provisions of the Loan Agreement, dated November 11, 2019, between the parties (as amended, the "Loan Agreement").

Pursuant to the First Amendment and Waiver, the Collateral Agent and the Lenders agreed to (1) add the Working Capital Fund to the definition of Permitted Indebtedness under the Loan Agreement, as such term is defined in the Loan Agreement, subject to certain rights of notice and acceleration of the loans under the Loan Agreement granted to the Collateral Agent and Lenders in connection with Akebia's repayment of the Working Capital Fund to Vifor Pharma, and (2) provide Akebia with a waiver with respect to a financial statement covenant included in the Loan Agreement.

The foregoing description of the First Amendment and Waiver does not purport to be complete, and is qualified in its entirety by reference to the First Amendment and Waiver, a copy of which Akebia expects to file with its Annual Report on Form 10-K for the year ended December 31, 2021.

Item 3.02 Unregistered Sales of Equity Securities

The information regarding the Investment Agreement set forth in Item 1.01 is incorporated herein by reference.

Item 7.01 Regulation FD Disclosure

On February 22, 2022, Akebia issued a press release announcing certain of the agreements described in Items 1.01 and 3.02 of this Current Report on Form 8-K. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1.

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, nor shall it be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Exhibit Description
99.1	Press release of Akebia Therapeutics, Inc. dated February 22, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

Forward-Looking Statements

This Current Report on Form 8-K includes forward-looking statements. Such forward-looking statements include those about Akebia's relationship with Vifor Pharma, including statements regarding the anticipated profit sharing payments from Vifor Pharma, creation of a working capital facility and future entry into a commercial supply agreement pursuant to the Amended Agreement and the potential commercialization of vadadustat if approved by the FDA, issuance of the Shares, and repayment of the Working Capital Fund and related acceleration of the loans under the Loan Agreement. The words "anticipate," "believe," "expect," "intend," "may," "plan," "target," "potential," "will," "would," "could," "should," "continue," 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, but not limited to: interactions with the FDA regarding vadadustat, including reviews and inspections, the timing related thereto and the outcome thereof and any related approvals; the potential termination of the Amended Agreement by Akebia or Vifor Pharma; Akebia's and Vifor Pharma's ability to satisfy their respective obligations under the Amended Agreement; the potential therapeutic benefits, safety profile and effectiveness of vadadustat; the direct or indirect impact of the COVID-19 pandemic on Akebia's or Vifor Pharma's businesses, operations, and the markets and communities in which Akebia, Vifor Pharma and the Supply Group operate; the timing and content of advice given and decisions made by health authorities, including approval and labeling decisions; the potential indications, demand and market potential and acceptance of, as well as coverage and reimbursement related to, vadadustat, if approved, including the size of eligible patient populations; manufacturing, supply and quality risks, and any recalls, write-downs, impairments or other related consequences or potential consequences; the actual funding required to develop and commercialize and to operate Akebia; the risks associated with potential generic entrants for vadadustat, if approved; the competitive landscape for vadadustat, if approved; the scope, timing, and outcome of any legal, regulatory and administrative proceedings; changes in the economic and financial conditions of the businesses of Akebia, Vifor Pharma and the Supply Group; expected reliance on third parties, including with respect to the development, manufacturing, supply or commercialization of Akebia's product and product candidates; Akebia's expectations, projections and estimates regarding its capital requirements; and Akebia's intellectual property position, including its ability to obtain, maintain and enforce patent and other intellectual property protection for vadadustat. 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, 2021, and other filings that Akebia may make with the Securities and Exchange Commission in the future. Except as required by law, Akebia does not undertake, and specifically disclaims, any obligation to update any forward-looking statements contained in this Current Report on Form 8-K.

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: February 22, 2022

By: /s/ John P. Butler

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

Exhibit 99.1

Akebia Therapeutics Announces Amendment of License Agreement with Vifor Pharma in Preparation for Potential Vadadustat Launch

Agreement Leverages Vifor Pharma's Exclusive Distribution Arrangement with Certain Dialysis Organizations

Agreement Defines Profit Share Economics of Potential Vadadustat Revenue if Approved

- Vifor Pharma to make equity purchase of $20 million
- $40 million refundable working capital investment to partially fund launch supply
- $25 million upfront payment

CAMBRIDGE, Mass. – February 22, 2022 – Akebia Therapeutics, Inc. (Nasdaq: AKBA), a biopharmaceutical company with the purpose to better the lives of people impacted by kidney disease, and Vifor Pharma Group (Vifor Pharma), today announced that the companies have amended and restated the terms of their license agreement, pursuant to which Akebia Therapeutics, Inc. (Akebia) granted Vifor Pharma an exclusive license to sell vadadustat, Akebia's investigational oral therapeutic for the treatment of anemia due to chronic kidney disease (CKD), to Fresenius Medical Care North America and its affiliates (including Fresenius Kidney Care Group LLC) and other entities in the United States, subject to vadadustat's approval by the U.S. Food and Drug Administration (FDA). Vadadustat's Prescription Drug User Fee Act (PDUFA) date is March 29, 2022.

The new agreement further supports Akebia's commercialization strategy ahead of a potential first-in-class U.S. launch for vadadustat which, as previously noted, provides access to up to 60% of U.S. dialysis patients through existing Vifor Pharma relationships. Previous agreements between the companies granted Vifor Pharma an exclusive license to sell vadadustat, if approved by the FDA, to Fresenius Kidney Care Group for use solely within its dialysis facilities and certain other third-party dialysis facilities in the U.S. The new agreement further expands this license to also include additional independent dialysis organizations.

"Vifor Pharma shares our commitment to bring innovative treatments to people living with kidney disease, which has been a cornerstone of our longstanding relationship," said John P. Butler, Chief Executive Officer of Akebia. "As we approach vadadustat's PDUFA date and potential launch, we are thrilled to clarify the agreement, which we believe will enable our companies to get vadadustat to dialysis patients more quickly."

In consideration for the extension of Vifor Pharma's customer group, Vifor Pharma agreed to an additional equity purchase of $20 million. Further, Vifor Pharma will contribute $40 million for use as working capital to partially fund Akebia's costs of manufacturing vadadustat to support commercialization in the U.S. following FDA approval; such working capital to be refundable over time.

Under the terms of the amended and restated agreement, Vifor Pharma will accelerate payment of the previously agreed upon $25 million milestone to Akebia. Akebia will retain approximately 66% of the profit, net of certain pre-specified costs. Akebia will share the profit with Otsuka pursuant to the License and Collaboration Agreement between Akebia and Otsuka in the U.S.

Akebia has retained all rights to commercialize vadadustat, in collaboration with Otsuka, in the non-dialysis dependent market and to the remaining dialysis organizations representing approximately 40% of the U.S. dialysis market, following FDA approval.

About Akebia Therapeutics

Akebia Therapeutics, Inc. is a fully integrated biopharmaceutical company with the purpose to better the lives of people impacted by kidney disease. Akebia was founded in 2007 and is headquartered in Cambridge, Massachusetts. For more information, please visit our website at www.akebia.com, which does not form a part of this release.

About Vadadustat

Vadadustat is a potential first-in-class oral hypoxia-inducible factor prolyl hydroxylase inhibitor designed to mimic the physiologic effect of altitude on oxygen availability. At higher altitudes, the body responds to lower oxygen availability with stabilization of hypoxia-inducible factor, which can lead to increased red blood cell production and improved oxygen delivery to tissues. The New Drug Application for vadadustat for the treatment of anemia due to chronic kidney disease (CKD) is under review by the U.S. Food and Drug Administration (FDA). Vadadustat is an investigational new drug and is not approved by the FDA or any regulatory authority with the exception of Japan's Ministry of Health, Labour and Welfare. In Japan, vadadustat is approved as a treatment for anemia due to CKD in both dialysis-dependent and non-dialysis dependent adult patients.

About Anemia due to Chronic Kidney Disease (CKD)

Anemia is a condition in which a person lacks enough healthy red blood cells to carry adequate oxygen to the body's tissues. It commonly occurs in people with CKD because their kidneys do not produce enough erythropoietin (EPO), a hormone that helps regulate production of red blood cells. Anemia due to CKD can have a profound impact on a person's quality of life as it can cause fatigue, dizziness, shortness of breath and cognitive dysfunction. Left untreated, anemia leads to deterioration in health and is associated with increased morbidity and mortality in people with CKD.

Forward-Looking Statement

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: vadadustat's potential to be a first-in-class HIF-PH inhibitor for the treatment of anemia due to chronic

kidney disease in the U.S. and the anticipated scheduled PDUFA date for vadadustat; the access to dialysis patients and the dialysis market that is provided as a result of Vifor Pharma's relationships; the impact that clarifying the license agreement will have on Akebia's ability to get vadadustat to dialysis patients more quickly; The terms "believe," "expect," "potential," "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: decisions made by health authorities, such as the FDA and the European Medicines Agency, with respect to regulatory filings and approvals, including labeling or other restrictions, for vadadustat and Akebia's outlook related thereto; any delays in the FDA review of, and potential approval related to, Akebia's New Drug Application (NDA) submission for any reason; the potential therapeutic benefits, safety profile, and effectiveness of vadadustat; the potential indications, demand, potential and acceptance of, and Akebia's estimates regarding the potential market opportunity for Akebia's product candidate, vadadustat, if approved, or any other products or product candidates and the size of eligible patient populations; the direct or indirect impact of the COVID-19 pandemic on regulators and Akebia's business, operations, and the markets and communities in which Akebia and its partners, collaborators, vendors and customers operate; manufacturing, supply chain and quality matters and any recalls, write-downs, impairments or other related consequences or potential consequences; early termination of any of Akebia's collaborations, including the amended and restated license agreement; and Akebia's and Vifor Pharma's ability to satisfy their obligations under the amended and restated license agreement; the competitive landscape for vadadustat, if approved. Other risks and uncertainties include those identified under the heading "Risk Factors" in Akebia's Quarterly Report on Form 10-Q for the period ended September 30, 2021, and other filings that Akebia may make with the U.S. Securities and Exchange Commission in the future. These forward-looking statements (except as otherwise noted) speak only as of the date of this presentation, and, except as required by law, Akebia does not undertake, and specifically disclaims, any obligation to update any forward-looking statements contained in this presentation.

Akebia Therapeutics
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