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): **May 24, 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 1.01 Entry into a Material Definitive Agreement.

On May 24, 2023 (the "Effective Date"), Akebia Therapeutics, Inc. (the "Company") and MEDICE Arzneimittel Pütter GmbH & Co. KG ("Medice") entered into a License Agreement (the "License Agreement") pursuant to which the Company granted to Medice an exclusive license to develop and commercialize vadadustat (the "Licensed Product") for the treatment of anemia in patients with chronic kidney disease in the European Economic Area, the United Kingdom, Switzerland and Australia (the "Territory").

Under the License Agreement, the Company is entitled to receive the following payments: (i) an up-front payment of $10 million, (ii) commercial milestone payments up to an aggregate of $100 million, and (iii) tiered royalties ranging from 10% to 30% of Medice's annual net sales of the Licensed Product in the Territory, subject to reduction in certain circumstances. The royalties will expire on a country-by-country basis upon the latest to occur of (a) the date of expiration of the last-to-expire valid claim of any Company, Medice, or joint patent that covers the Licensed Product in such country in the Territory, (b) the date of expiration of data or regulatory exclusivity for the Licensed Product in such country in the Territory, and (c) the date that is 12 years from first commercial sale of the Licensed Product in such country in the Territory.

Under the License Agreement, the Company retains the right to develop the Licensed Product for non-dialysis patients with anemia due to chronic kidney disease in the Territory. If the Company develops the Licensed Product for non-dialysis patients and such Licensed Product receives marketing approval in the Territory, Medice will commercialize the Licensed Product for both indications in the Territory. In this instance, the Company would receive 70% of the net product margin of any sales of the Licensed Product in the non-dialysis patient population, unless Medice requests to share the cost of the development necessary to gain approval to market the Licensed Product for non-dialysis patients in the Territory and the parties agree on alternative financial terms.

The Company and Medice will establish a joint steering committee to oversee the development and commercialization of the Licensed Product in the Territory.

The License Agreement expires on the date of expiration of all payment obligations due thereunder with respect to the Licensed Product in the last country in the Territory, unless earlier terminated in accordance with the terms of the License Agreement. Either party may, subject to a cure period, terminate the License Agreement in the event of the other party's uncured material breach. Medice has the right to terminate the License Agreement in its entirety for convenience upon 12 months' prior written notice delivered on or after the date that is 12 months after the Effective Date. The License Agreement includes customary terms relating to, among others, indemnification, confidentiality, remedies, and representations and warranties. The License Agreement provides that the Company and Medice will enter into a supply agreement pursuant to which the Company will supply the Licensed Product to Medice for commercial use in the Territory.

The foregoing description of the License Agreement does not purport to be complete and is qualified in its entirety by reference to the License Agreement, a copy of which the Company expects to file as an exhibit to its Quarterly Report on Form 10-Q for the quarter ending June 30, 2023.

Item 7.01 Regulation FD Disclosure.

On May 25, 2023, the Company issued the press release furnished as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

The information in this Item 7.01 (including 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated May 25, 2023, issued by Akebia Therapeutics, Inc.
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: May 25, 2023

By: /s/ John P. Butler

Name: John P. Butler

Title: President and Chief Executive Officer

Exhibit 99.1

Akebia Therapeutics Enters into License Agreement with Medice Arzneimittel Pütter GmbH&Co.KG for the Commercialization of Vafseo® for the Treatment of Anemia associated with CKD in Europe and Australia

- Medice brings extensive expertise in nephrology and an established European dialysis business
- Akebia to receive a $10 million upfront payment, potential for up to $100 million in commercial milestone payments, and tiered royalties up to 30% of net sales in dialysis
- Akebia retains majority of economics in non-dialysis indication if approved by EMA and retains rights to all other indications

CAMBRIDGE, Mass.—May 25, 2023—Akebia Therapeutics®, Inc. (Nasdaq: AKBA), a biopharmaceutical company with the purpose to better the lives of people impacted by kidney disease, today announced an agreement with MEDICE Arzneimittel Pütter GmbH&Co.KG (Medice – The Health Family), for Medice to market Vafseo® (vadadustat), an oral hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor developed by Akebia to treat anemia due to chronic kidney disease (CKD), in Europe. Akebia is retaining the rights to develop and commercialize in Europe for all other indications. The exclusive license agreement grants Medice the rights to market and sell Vafseo in the European Economic Area in addition to the United Kingdom, Switzerland and Australia. Akebia will receive an upfront payment of $10 million, commercial milestone payments up to $100 million, and tiered royalty payments up to 30% of net sales.

“We are thrilled to partner with Medice to bring Vafseo to market in Europe this year,” said John P. Butler, Chief Executive Officer of Akebia. “Medice specializes in renal and anemia care and has deep commercial expertise gained by building a successful portfolio in the dialysis space. We believe Vafseo has the potential to be a centerpiece of Medice’s portfolio of products for dialysis patients. Our collaboration also provides the flexibility to pursue additional indications to maximize value for Akebia while potentially serving many more patients.”

“We’re eager to bring Vafseo to market in Europe as we believe dialysis patients with anemia due to CKD could benefit from additional therapeutic options,” said Dr. Richard Ammer, Chief Executive Officer of Medice. “We look forward to working closely with Akebia as we prepare for a commercial launch in dialysis this year.”
Anemia associated with CKD, common in patients on dialysis, is a debilitating condition which may be associated with many adverse clinical outcomes. Throughout Europe, we estimate that more than 325,000 dialysis patients are currently treated for anemia associated with CKD.

Under the terms of the agreement, in addition to the $10 million upfront payment and commercial milestones of up to $100 million, Akebia will receive tiered royalties from 10% to 30% of net sales. Vafseo is currently approved in Europe and the United Kingdom for the treatment of symptomatic anemia associated with CKD in adults on chronic maintenance dialysis. Under the agreement, Akebia has the right to develop Vafseo for use as a treatment of anemia due to CKD in adults not on dialysis. If Akebia exercises this right, Medice will commercialize Vafseo for both indications in the defined territory and Akebia would retain 70% of the net profit margin generated by use in the non-dialysis population, or alternative equivalent financial terms to be negotiated by the parties.

Akebia retains rights to vadadustat for all other indications. If Akebia chooses to develop vadadustat for any other indication and seeks a collaboration partner in the territory, Medice has a right of first offer to collaborate on the development and commercialization of Vafseo in such defined territory.

Vadadustat is approved in 33 countries and regulatory opinions are expected in Switzerland and Australia later this year.

Important Safety Information
For safety information, view the European Summary of Product Characteristics (SPC/SmPC) for Vafseo™ (vadadustat) at https://ec.europa.eu/health/documents/community-register/2023/20230424158854/anx_158854_en.pdf.

The full Summary of Product Characteristics (SPC/SmPC) for Vafseo® (vadadustat) will be available on the UK MHRA website at https://products.mhra.gov.uk/.

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. The Company 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 an 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. Vadadustat is not approved by the U.S. Food and Drug Administration. In April 2023 and May 2023 respectively, the European Commission and United Kingdom Medicines and Healthcare products Regulatory Agency granted marketing authorization for vadadustat for the treatment of symptomatic anemia associated with chronic kidney disease in adults on chronic maintenance dialysis. In Japan, vadadustat is approved as a treatment for anemia due to CKD in both dialysis-dependent and non-dialysis dependent adult patients.

About Medice
MEDICE Arzneimittel Pütter GmbH&Co.KG, founded in 1949 and headquartered in Iserlohn (Germany), is a fully integrated pharmaceutical company with own GxP capabilities in development, manufacturing and pan-European and international distribution of pharmaceuticals and medical devices. It is the core of “MEDICE – The Health Family” aiming to improve patient management by offering high quality innovative drugs, non-pharmacological interventions and value adding services. For more information, please visit www.medice.eu, which does not form a part of this release.

Forward Looking Statement

Statements in this press release 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 and expectations with respect to commercializing Vafseo in Europe, including the timing thereof; Akebia's expectations on the timing for certain regulatory decisions for vadadustat by regulatory authorities in Switzerland and Australia; statements regarding the potential market opportunity of vadadustat and beliefs about the benefits that vadadustat could provide to dialysis patients; statements about Akebia’s ability to serve more patients while pursuing additional indications for vadadustat and maximizing value; and beliefs about Vafseo becoming the centerpiece of Medice’s portfolio of products for dialysis patients. The terms "expect," "intend," "believe," "plan," "goal," "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: the potential demand and market potential and acceptance of, as well as coverage and reimbursement related to, vadadustat; decisions made by health authorities, such as the FDA, with respect to regulatory filings; the results of preclinical and clinical research; the potential therapeutic benefits, safety profile, and effectiveness of vadadustat; 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; and 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 quarter ended March 31, 2023, 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 press release.

Akebia Therapeutics Contact
Mercedes Carrasco
mcarrasco@akebia.com