Akebia Therapeutics, Inc. Form 8-K February 13, 2017

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 9, 2017

AKEBIA THERAPEUTICS, INC.

(Exact name of registrant as specified in charter)

Delaware (State or Other Jurisdiction 001-36352 (Commission 20-8756903 (I.R.S. Employer

of Incorporation)

File Number)

Identification No.)

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245 First Street, Suite 1100, Cambridge, Massachusetts 02142

(Address of Principal Executive Offices, including Zip Code)

(617) 871-2098

(Registrant s telephone number, including area code)

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))

Item 1.01 Entry into a Material Definitive Agreement

Research and License Agreement

On February 9, 2017, Akebia Therapeutics, Inc. (Akebia) entered into a Research and License Agreement (the Agreement) with Janssen Pharmaceutica NV, one of the Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen), pursuant to which Janssen granted Akebia an exclusive license under certain intellectual property rights to develop and commercialize worldwide certain hypoxia-inducible factor (HIF) prolyl hydroxylase-targeted compounds.

Under the terms of the Agreement, Janssen granted to Akebia a license for a three-year research term to conduct research on the HIF compound portfolio, unless Akebia elects to extend such research term for up to two additional one-year periods upon payment of an extension fee. During the research term, Akebia may designate one or more compounds as candidates for development and commercialization. Once a compound is designated for development and commercialization, Akebia will be solely responsible for the development and commercialization of the compound worldwide at its own cost and expense. The Agreement includes a license to develop and commercialize JNJ5169, a preclinical compound in development as an oral treatment for inflammatory bowel disease.

Under the terms of the Agreement, Akebia will pay an upfront payment of \$1 million to Janssen within 30 days of execution of the Agreement. In addition, Janssen could be eligible to receive up to an aggregate of \$16.5 million from Akebia in specified development milestone payments on a product-by-product basis. Janssen will also be eligible to receive up to \$215 million from Akebia in specified commercial milestones as well as tiered, escalating royalties ranging from a low to mid-single digit percentage of net sales, on a product-by-product basis.

Unless earlier terminated, the Agreement will expire on a product-by-product and country-by-country basis upon the expiration of the last royalty term, which ends upon the longer of the expiry of the patents licensed under the Agreement, the expiry of regulatory exclusivity for such product, or 10 years from first commercial sale of such product. Akebia may terminate the Agreement in its entirety or only with respect to a particular licensed compound or product upon 180 days prior written notice to Janssen. The parties also have customary termination rights, subject to a cure period, in the event of the other party s material breach of the Agreement or in the event of certain additional circumstances.

The foregoing description of the Agreement does purport to be complete, and is qualified in its entirety by reference to the Agreement, a copy of which we expect to file with our Quarterly Report on Form 10-Q for the quarter ended March 31, 2017.

Warrant

In connection with its entry into the Agreement, on February 9, 2017, Akebia issued a Common Stock Purchase Warrant (the Warrant) to Johnson & Johnson Innovation JJDC, Inc. (JJDC), an affiliate of Janssen, for 509,611 shares of Akebia s common stock at an exercise price of \$9.81 per share. The Warrant is exercisable by JJDC, in whole or in part, at any time prior to the fifth anniversary of the date of issuance.

The Warrant and the shares issuable upon exercise of the Warrant will be sold and issued without registration under the Securities Act of 1933 (the Securities Act) in reliance on the exemptions provided by Section 4(a)(2) of the Securities Act as transactions not involving a public offering and Rule 506 promulgated under the Securities Act as sales to accredited investors, and in reliance on similar exemptions under applicable state laws.

The foregoing description of the Warrant does purport to be complete, and is qualified in its entirety by reference to the Warrant, a copy of which we expect to file with our Quarterly Report on Form 10-Q for the quarter ended

March 31, 2017.

Item 2.03 Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registration.

The information set forth under Item 1.01 with respect to the Research and License Agreement is incorporated by reference into this Item 2.03.

Item 3.02 Unregistered Sales of Equity Securities.

The information set forth under Item 1.01 with respect to the Warrant is incorporated by reference into this Item 3.02.

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.

By: /s/ John P. Butler John P. Butler

President and Chief Executive Officer

Date: February 13, 2017