
**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): October 6, 2017

KALVISTA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36830
(Commission
File Number)

20-0915291
(IRS Employer
Identification No.)

One Kendall Square
Bld 200, Ste 2203
Cambridge, MA 02139
(Address of Principal Executive Offices) (Zip Code)

(857) 999-0075
(Registrant's telephone number, including area code)

(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))

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 October 6, 2017, KalVista Pharmaceuticals Limited (“KalVista Limited”), a wholly-owned subsidiary of KalVista Pharmaceuticals, Inc. (the “Company”), and Merck Sharp & Dohme Corp. (“Merck”) entered into an option agreement (the “Option Agreement”) and the Company and Merck entered into a stock purchase agreement and a voting agreement (the “Stock Purchase Agreement” and “Voting Agreement”, respectively, and collectively with the Option Agreement, the “Agreements”). The Company is the guarantor of KalVista Limited’s obligations under the Option Agreement. Together the Company and KalVista Limited are referred to herein as “KalVista”.

Option Agreement

Under the terms of the Option Agreement, KalVista Limited has granted to Merck certain rights including an option to acquire KVD001 through a period following completion of the Phase 2 proof-of-concept trial that KalVista intends to commence later this year. KalVista Limited also has granted to Merck a similar option to acquire investigational orally delivered molecules for DME that KalVista will continue to develop as part of its ongoing research and development activities. KalVista also granted non-exclusive rights to use the compounds solely for research purposes, and agreed to use its diligent efforts to develop the two compounds. KalVista will fund and retain control over the planned Phase 2 clinical trial of KVD001 as well as development of the investigational oral DME compounds through Phase 2, unless Merck determines to exercise its options earlier.

Under the terms of the Option Agreement, KalVista will receive \$37 million in a non-refundable upfront fee from Merck. Assuming the exercise of both options and achievement of each of the milestones set forth in the Option Agreement, KalVista could receive up to an additional \$715 million in option exercise payments and clinical, regulatory and commercialization milestone payments, as well as tiered royalties ranging from mid-single digits to low-teens on any global net sales (which, in the case of KVD001, only apply to sales over a certain threshold).

Merck may terminate the Option Agreement at any time upon written notice to KalVista. KalVista may terminate the Option Agreement in the event of Merck’s material breach of the Option Agreement, subject to cure.

Stock Purchase Agreement

Under the terms of the Stock Purchase Agreement, Merck has paid approximately \$9.1 million to purchase 1,070,589 new shares of the Company’s common stock at a price of \$8.50 per share. Under the terms of the Stock Purchase Agreement, the Company has provided Merck with certain rights to have such purchased shares registered for sale under the Securities Act of 1933, as amended (“1933 Act”). Merck has also agreed that it will hold the shares for a specified period of time and, pursuant to the Voting Agreement, vote the shares in accordance with the recommendations of the Board (other than with respect to extraordinary transactions), and provide the Company, through its representatives, with an irrevocably proxy for such matters, in each case, subject to the terms and conditions of the Stock Purchase Agreement and Voting Agreement. In addition, Merck has agreed that for a certain period of time, neither it nor its affiliates will undertake certain actions related to the potential acquisition of additional equity interests in the Company, subject to the terms and conditions of the Stock Purchase Agreement.

The foregoing description of the material terms of the Agreements is qualified in its entirety by the terms of the Agreements, which the Company intends to file as exhibits to its Quarterly Report on Form 10-Q for the quarter ended October 31, 2017.

Item 3.02. Unregistered Sales of Equity Securities.

The description of the Stock Purchase Agreement above is incorporated herein by reference. The issuance of the shares is exempt from registration under the 1933 Act in reliance on Section 4(a)(2) thereunder.

Item 8.01. Other Events.

On October 10, 2017, the Company issued a press release with respect to the execution of the Agreements, as described under Item 1.01 of this Current Report on Form 8-K. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

**Exhibit
Number**

Description

99.1

[Press release dated October 10, 2017.](#)

SIGNATURE

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.

KALVISTA PHARMACEUTICALS, INC.

Date: October 10, 2017

By: /s/ T. Andrew Crockett

T. Andrew Crockett

Chief Executive Officer



KalVista Pharmaceuticals Announces Collaboration with Merck

- Covers Development of Investigational Plasma Kallikrein Inhibitors for Treatment of Diabetic Macular Edema –***
- \$37 Million Upfront Fee Plus Potential Milestone Payments and Sales Royalties –***
- Merck Acquires 9.9% Stake in KalVista in Private Placement –***
- Investigational Intravitreal DME Candidate KVD001 Phase 2 Clinical Trial Still Planned to Initiate in 2017 –***

Cambridge, MA, October 10, 2017 – KalVista Pharmaceuticals, Inc. (NASDAQ: KALV), a clinical stage pharmaceutical company focused on the discovery, development, and commercialization of small molecule protease inhibitors, today announced that it has entered into a collaboration agreement with Merck, known as MSD outside the United States and Canada, through a subsidiary, for KVD001, the Company’s investigational intravitreal (IVT) injection candidate currently in development for potential treatment of diabetic macular edema (DME), as well as future oral DME compounds based upon plasma kallikrein inhibition.

“We are pleased to collaborate with Merck for the continuing development of KVD001 and future oral programs for patients with DME,” said Andrew Crockett, Chief Executive Officer of KalVista. “Plasma kallikrein inhibition is a novel approach to the treatment of DME that we believe may offer benefit to a significant number of patients, and an oral therapy particularly would represent a groundbreaking advance for treatment of this indication. We have always believed that development and commercialization of our DME therapies would require the resources of a large pharmaceutical company, and we believe Merck has the wherewithal and resources to help us advance development of our DME drug candidates. Importantly for KalVista, this collaboration also meets our strategic objectives of maintaining control of our oral HAE portfolio that we plan to develop independently. We look forward to providing more details about the Phase 2 trial for KVD001 in DME patients as the trial commences.”

Under the terms of the agreement, KalVista has granted to Merck certain rights including an option to acquire KVD001 through a period following completion of the Phase 2 proof-of-concept trial that KalVista intends to commence later this year. KalVista also has granted to Merck a similar option to acquire investigational orally delivered molecules for DME that KalVista will continue to develop as part of its ongoing research and development activities. As consideration for the agreement, Merck will pay to KalVista a \$37 million non-refundable upfront fee. KalVista is further eligible to receive payments associated with the exercise of the options by Merck and the achievement of milestones for each program that potentially total up to \$715 million. KalVista also will receive tiered royalties on net sales for therapeutic candidates commercialized under this agreement. KalVista will fund and retain control over the planned Phase 2 clinical trial of KVD001 as well as development of the investigational oral DME compounds through Phase 2, unless Merck exercises its options earlier.

In addition to the collaboration, KalVista has entered into a separate \$9.1 million private placement transaction with Merck under which Merck has acquired 1,070,589 shares of KalVista, representing a 9.9% ownership stake, at a price of \$8.50 per share. This private placement closed concurrent with execution of the Option Agreement.

“The KalVista team has already made important progress in advancing this candidate into the clinic. At Merck, we look forward to the opportunity to apply our expertise and resources upon the achievement of proof of concept for KVD001,” said Ben Thorner, senior vice president and Head of Business Development & Licensing Merck Research Laboratories. “Merck is seeking to collaborate on the development of candidates that we believe have the potential to transform practice in areas where there is a clear need for new and improved therapeutic options.”

The agreement with Merck covers only the investigational IVT and oral plasma kallikrein inhibitor programs for DME. KalVista retains full rights to its oral hereditary angioedema (HAE) portfolio, and will have the opportunity to select and develop future oral HAE compounds. KalVista intends to continue to aggressively pursue its efforts to develop a best-in-class oral therapy for HAE, as well as additional programs focused on other proteases.

About KalVista Pharmaceuticals, Inc.

KalVista Pharmaceuticals, Inc. is a pharmaceutical company focused on the discovery, development, and commercialization of small molecule protease inhibitors for diseases with significant unmet need. The initial focus is on inhibitors of plasma kallikrein, which is an important component of the body’s inflammatory response and which, in excess, can lead to increased vascular permeability, edema and inflammation. KalVista has developed a proprietary portfolio of novel, small molecule plasma kallikrein inhibitors initially targeting hereditary angioedema (HAE) and diabetic macular edema (DME). The Company has created a structurally diverse portfolio of oral plasma kallikrein inhibitors from which it plans to select multiple drug candidates to advance into clinical trials for HAE. The first candidate of this planned portfolio, KVD818, is currently in a first-in-human study and additional program candidates are in preclinical development. KalVista’s most advanced program, an intravitreally administered plasma kallikrein inhibitor known as KVD001, has successfully completed its first-in-human study in patients with DME and is being prepared for Phase 2 studies in 2017.

For more information, please visit www.kalvista.com.

Forward-Looking Statements

This press release contains “forward-looking” statements within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: “anticipate,” “intend,” “plan,” “goal,” “seek,” “believe,” “project,” “estimate,” “expect,” “strategy,” “future,” “likely,” “may,” “should,” “will” and similar references to future periods. These statements are subject to numerous risks and uncertainties that could cause actual results to differ materially from what we expect. Examples of forward-looking statements include, among others, available funding and future clinical trial timing and results. Further information on potential risk factors that could affect our business and its financial results are detailed in the annual report on Form 10-K filed on July 27, 2017, our most recent Quarterly Report on Form 10-Q, and other reports as filed from time to time with the Securities and Exchange Commission. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

Contact:

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