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): April 8, 2025

KALVISTA PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-36830**	**20-0915291**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

55 Cambridge Parkway
Suite 901E
Cambridge, Massachusetts **02142**
(Address of principal executive offices) **(Zip Code)**

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

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, $0.001 par value per share	KALV	The Nasdaq Stock Market LLC

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.

License Supply and Distribution Agreement

On April 8, 2025, KalVista Pharmaceuticals, Ltd., a wholly owned subsidiary of KalVista Pharmaceuticals, Inc. (the "Company") entered into a License, Supply, and Distribution Agreement (the "License Agreement") with Kaken Pharmaceutical Co., Ltd ("Kaken"), pursuant to which the Company has licensed commercialization rights in Japan to Kaken for sebetralstat (the "Licensed Product"), an investigational, oral on-demand treatment for hereditary angioedema ("HAE").

Under the terms of the License Agreement, Kaken will pay the Company, within 30 days of the date of the License Agreement, an upfront payment of $11.0 million (the "Initial Amount") and is obligated to make additional payments to the Company totaling up to approximately $13.0 million upon the achievement of certain regulatory and sales milestones. In addition, effective royalty payments in the mid-twenties shall be payable for each unit of Licensed Product that the Company supplies as a percentage of the Japanese National Health Insurance price of the Licensed Product.

The License Agreement will remain in effect on a Licensed Product-by-Licensed Product basis and will expire upon the expiration of the Royalty Term for the final Licensed Product; however, it will automatically renew for two-year periods following the expiration of the initial term, unless otherwise terminated. The "Royalty Term" means the period beginning on the date of the first commercial sale of the Licensed Product in Japan and ends on the latest of (i) the expiration of the last valid claim of the royalty patents covering such Licensed Product in Japan, (ii) the expiration of regulatory exclusivity for such Licensed Product in Japan, or (iii) ten (10) years after the first commercial sale of such Licensed Product in Japan. The License Agreement may be terminated by either party for material breach, upon a party's insolvency or bankruptcy or upon a challenge by one party of any patents of the other party, and Kaken may terminate in specified situations, including for a safety concern or clinical failure, or at its convenience following the second anniversary of the first commercial sale of a Licensed Product in Japan, with 12 months' notice.

Pursuant to the License Agreement, the parties agreed to develop a joint steering committee to provide strategic oversight of the parties' activities under the Agreement.

The above description of the License Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the License Agreement. A copy of the License Agreement will be filed as an exhibit to the Company's Annual Report on Form 10-K for the annual period ending April 30, 2025.

Item 7.01. Regulation FD.

On April 8, 2025, the Company issued a press release announcing its entry into the License Agreement, a copy of which is attached hereto as Exhibit 99.1. The information contained in this Item 7.01, including Exhibit 99.1, is being furnished to the Securities and Exchange Commission and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or incorporated by reference in any filing under the Securities Act of 1933, as amended.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release issued April 8, 2025.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

Forward-Looking Statements

This filing contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, the timing and potential amount of milestones and royalty payments to be received under the License Agreement. Statements including words such as "may," "will," "to be," or "expect" and statements in the future tense are forward-looking statements. These forward-looking statements involve risks and uncertainties, as well as assumptions, which, if they do not fully

materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. Forward-looking statements are subject to risks and uncertainties that may cause the company's actual activities or results to differ significantly from those expressed in any forward-looking statement, including the risk that sebetralstat may not be approved by the FDA or other regulatory authorities for the treatment of HAE, and risks and uncertainties described under the heading "Risk Factors" in documents the company files from time to time with the SEC. These forward-looking statements speak only as of the date of this report, and the company undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof.

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: April 8, 2025

By: /s/ Brian Piekos
Brian Piekos
Chief Financial Officer

Exhibit 99.1

KalVista Pharmaceuticals Enters into Licensing Agreement with Kaken Pharmaceutical to Commercialize Sebetralstat for HAE in Japan

-Up to $24 million in upfront and milestone payments, plus royalties-

-Sebetralstat has potential to become first, oral on-demand treatment of HAE in Japan, underscoring commercial opportunity-

-Kaken brings regional expertise and proven track record in commercializing innovative therapies-

CAMBRIDGE, Mass. & SALISBURY, England – (BUSINESS WIRE) – April 8, 2025 – KalVista Pharmaceuticals, Inc. (Nasdaq: KALV) today announced that its wholly-owned subsidiary, KalVista Pharmaceuticals, Ltd., has licensed commercialization rights in Japan to Kaken Pharmaceutical, Co., Ltd. (JPX: 4521.T) for sebetralstat, an investigational, oral on-demand treatment for hereditary angioedema (HAE). KalVista will receive an upfront payment of $11 million, with an additional payment of up to $11 million upon achievement of a regulatory milestone anticipated in early 2026. Beyond these payments, the Company is also eligible for commercial milestone payments, plus royalties based on the Japan National Health Insurance (NHI) price, with the royalty rate as a percentage of sales approximately in the mid-twenties.

“We are pleased to partner with Kaken, whose expertise and demonstrated success in the region make them well-suited to work alongside our exceptional team to bring sebetralstat to the HAE community in Japan,” said Ben Palleiko, CEO of KalVista. “This collaboration is an important part of our strategy to expand the global reach of sebetralstat as we prepare for several commercial launches starting this year. Our focus remains on delivering a safe and effective oral on-demand therapy that we believe will make a meaningful difference for people living with HAE worldwide.”

As previously announced, KalVista received Orphan Drug Designation for sebetralstat from Japan’s Ministry of Health, Labour and Welfare (MHLW) and the Company has submitted a New Drug Application (NDA) for sebetralstat in Japan. If approved, sebetralstat would be the first oral on-demand treatment for HAE in the country.

About KalVista Pharmaceuticals, Inc.

KalVista Pharmaceuticals, Inc., is a global biopharmaceutical company dedicated to developing and delivering life-changing oral therapies for individuals affected by rare diseases with significant unmet needs. The Company’s lead investigational product is sebetralstat, a novel, oral, on-demand treatment for hereditary angioedema (HAE). Sebetralstat is under regulatory review by the U.S. FDA, with a PDUFA goal date of June 17, 2025. In addition, KalVista has completed Marketing Authorization Applications for sebetralstat to the European Medicines Agency, the Pharmaceuticals and Medical Devices Agency, and multiple other global regulatory authorities. For more information about KalVista, please visit www.kalvista.com.

About Sebetralstat

Sebetralstat is an investigational, novel oral plasma kallikrein inhibitor for the treatment of hereditary angioedema (HAE). We have filed multiple regulatory applications seeking approval of sebetralstat as the first oral, on-demand treatment for HAE in individuals aged 12 and older, and are investigating its use in children aged 2 to 11. If approved, sebetralstat has the potential to become the foundational therapy for HAE management worldwide.

About Kaken Pharmaceutical, Co., Ltd.

Kaken Pharmaceutical is a specialty pharmaceutical company in Japan with strong experience in developing and commercializing novel pharmaceuticals in the fields of orthopedics and dermatology. Kaken concentrates its R&D resources in areas such as immune system, nervous system, infectious diseases and rare diseases with unmet medical needs. Kaken, in its philosophy, strives to improve the quality of life of patients through the development and distribution of superior pharmaceuticals. For further information, visit www.kaken.co.jp/english.

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, timings or outcomes of communications with the FDA, our expectations about safety and efficacy of our product candidates and timing of clinical trials and its results, our ability to commence clinical studies or complete ongoing clinical studies, including our KONFIDENT-S and KONFIDENT-KID trials, and to obtain regulatory approvals for sebetralstat and other candidates in development, the success of any efforts to commercialize sebetralstat, the ability of sebetralstat and other candidates in development to treat HAE or other diseases, and the future progress and potential success of our oral Factor XIIa program. Further information on potential risk factors that could affect our business and financial results are detailed in our filings with the Securities and Exchange Commission, including in our annual report on form 10-K for the year ended April 30, 2024, our quarterly reports on Form 10-Q, and our other reports that we make 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.

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