

**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): September 9, 2019

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.)

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)

(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 | 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 2.02. Results of Operations and Financial Condition.

On September 9, 2019, KalVista Pharmaceuticals, Inc. (the “Company”) reported its financial results for the fiscal quarter ended July 31, 2019. A copy of the press release issued by the Company is furnished as Exhibit 99.1 to this report.

The information furnished with Item 2.02 of this report, 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 into any other filing under the Exchange Act or under 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.

| <u>Exhibit Number</u> | <u>Description</u> |
|-----------------------|--|
| 99.1 | Press release September 9, 2019. |

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: September 9, 2019

By: /s/ Benjamin L. Palleiko
Benjamin L. Palleiko
Chief Business Officer and Chief Financial Officer

KalVista Pharmaceuticals Reports Fiscal First Quarter Results

– Phase 2 Clinical Trial of KVD900 for On-Demand Oral Treatment of Hereditary Angioedema (HAE) Attacks Expected to Complete in Late 2019 –

– KVD001 Phase 2 Clinical Trial for Patients with Diabetic Macular Edema (DME) Data Expected in Q4 2019 –

Cambridge, MA and Salisbury, England September 9, 2019– KalVista Pharmaceuticals, Inc. (NASDAQ: KALV), a clinical stage pharmaceutical company focused on the discovery, development, and commercialization of small molecule protease inhibitors, today provided an operational update and released financial results for the fiscal first quarter ended July 31, 2019.

“With enrollment complete in our Phase 2 trial for KVD001, we expect data in the fourth quarter of 2019,” said Andrew Crockett, Chief Executive Officer of KalVista. “Our second ongoing Phase 2 trial, with KVD900 for on-demand treatment of hereditary angioedema attacks is currently enrolling, and we continue to expect to complete that trial late this year. On the research side, our team continues to work on our earlier stage programs including KVD824, for which we expect to announce further development plans in the first half of 2020.”

First Quarter and Recent Business Highlights:

- Opened an Investigational New Drug (IND) Application for KVD900 with the U.S. Food and Drug Administration (FDA) to enable clinical development in the United States.

Fiscal First Quarter Financial Results:

- **Revenue:** Revenue was \$3.4 million for the three months ended July 31, 2019, compared to \$3.7 million for the same period in 2018. Revenue in the three months ended July 31, 2019 consisted of the recognition of a portion of the upfront payment from Merck related to the agreement signed in October 2017.
- **R&D Expenses:** Research and development expenses were \$9.7 million for the three months ended July 31, 2019, compared to \$8.4 million for the same period in 2018. The increase in R&D expense primarily reflects the ongoing clinical trial for KVD900 and an increase in preclinical activities. These increases in expense were somewhat offset by a decrease in expense related to KVD001 as it heads toward completion of a Phase 2 clinical trial later this year.
- **G&A Expenses:** General and administrative expenses were \$3.2 million for the three months ended July 31, 2019, compared to \$2.4 million for the same period in 2018. The increase was primarily due to an increase in compensation related expenses and professional fees in the three months ended July 31, 2019 compared to those incurred in the same period in 2018.
- **Net Loss:** Net loss was \$7.3 million, or \$(0.42) per basic and diluted share for the three months ended July 31, 2019, compared to a net loss of \$5.0 million, or \$(0.47) per basic and diluted share, for the same period in 2018.
- **Cash:** Cash, cash equivalents and marketable securities were \$100.4 million as of July 31, 2019.

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 and is advancing multiple drug candidates for HAE as well as DME. The Company has selected KVD900 as its program to be advanced as an on-demand therapy for acute HAE attacks and commenced a Phase 2 proof-of-concept study in HAE patients in late 2018. In DME, KalVista's most advanced program, an intravitreally administered plasma kallikrein inhibitor known as KVD001, began a Phase 2 clinical trial in 2017 that is anticipated to report data in the fourth quarter of 2019.

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, our cash runway, potential 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 16, 2019 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.

KalVista Pharmaceuticals Inc.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share amounts)
(Unaudited)

| | <u>July 31, 2019</u> | <u>April 30, 2019</u> |
|---|--------------------------|---------------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 30,107 | \$ 32,006 |
| Marketable securities | 70,259 | 68,805 |
| Research and development tax credit receivable | 12,625 | 11,315 |
| Prepaid expenses and other current assets | 2,728 | 3,420 |
| Total current assets | 115,719 | 115,546 |
| Right of use assets | 1,737 | — |
| Property and equipment, net | 2,255 | 2,413 |
| Other assets | 173 | 173 |
| Total assets | \$ 119,884 | \$ 118,132 |
| Liabilities and Stockholders' Equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 3,103 | \$ 2,860 |
| Accrued expenses | 4,261 | 5,647 |
| Deferred revenue - current portion | 6,023 | 9,545 |
| Lease liability - current portion | 580 | — |
| Total current liabilities | 13,967 | 18,052 |
| Long-term liabilities: | | |
| Deferred revenue - net of current portion | 2,873 | 3,342 |
| Lease liability - net of current portion | 1,177 | — |
| Total long-term liabilities | 4,050 | 3,342 |
| Stockholders' equity: | | |
| Common stock, \$0.001 par value | 18 | 17 |
| Additional paid-in capital | 203,650 | 191,123 |
| Accumulated deficit | (99,814) | (92,476) |
| Accumulated other comprehensive loss | (1,987) | (1,926) |
| Total stockholders' equity | 101,867 | 96,738 |
| Total liabilities and stockholders' equity | \$ 119,884 | \$ 118,132 |

KalVista Pharmaceuticals Inc.
Condensed Consolidated Statement of Operations
(in thousands, except share and per share amounts)
(Unaudited)

| | Three Months Ended July 31, | |
|---|--------------------------------|------------|
| | 2019 | 2018 |
| Revenue | \$ 3,369 | \$ 3,718 |
| Operating expenses: | | |
| Research and development | 9,686 | 8,356 |
| General and administrative | 3,247 | 2,371 |
| Total operating expenses | 12,933 | 10,727 |
| Operating loss | (9,564) | (7,009) |
| Other income: | | |
| Interest income | 590 | 89 |
| Foreign currency exchange gain (loss) | (453) | 67 |
| Other income | 2,089 | 1,823 |
| Total other income | 2,226 | 1,979 |
| Net loss | \$ (7,338) | \$ (5,030) |
| Net loss per share, basic and diluted | \$ (0.42) | \$ (0.47) |
| Weighted average common shares outstanding, basic and diluted | 17,488,997 | 10,799,895 |

KalVista Pharmaceuticals Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands, unaudited)

| | Three Months Ended July 31, | |
|--|--------------------------------|------------|
| | 2019 | 2018 |
| Cash Flows from Operating Activities | | |
| Net loss | \$ (7,338) | \$ (5,030) |
| Adjustments to reconcile net loss to net cash used in operating activities | | |
| Depreciation and amortization | 121 | 50 |
| Stock-based compensation expense | 1,074 | 347 |
| Realized (gain) loss from available for sale securities | (29) | — |
| Amortization of right of use assets | 138 | — |
| Amortization of discount/premium on available for sale securities | 35 | — |
| Foreign currency remeasurement loss | 454 | 6 |
| Changes in operating assets and liabilities: | | |
| Research and development tax credit receivable | (2,060) | 919 |
| Prepaid expenses and other current assets | 561 | (69) |
| Other assets | — | — |
| Accounts payable | 392 | 1,126 |
| Accrued expenses | (1,117) | 157 |
| Lease obligations | (137) | — |
| Deferred revenue | (3,369) | (3,718) |
| Net cash used in operating activities | (11,275) | (6,212) |
| Cash Flows from Investing Activities | | |
| Acquisition of property and equipment | (98) | (565) |
| Purchases of available for sale securities | (19,646) | — |
| Sales and maturities of available for sale securities | 18,214 | — |
| Net cash used in investing activities | (1,530) | (565) |
| Cash Flows from Financing Activities | | |
| Capital lease principal payments | (54) | (52) |
| Proceeds from issuance of common stock from equity incentive plans | 32 | — |
| Proceeds from issuance of common stock, net of \$123 of offering expenses | 11,422 | 5,000 |
| Net cash provided by financing activities | 11,400 | 4,948 |
| Effect of exchange rate changes on cash and cash equivalents | (494) | (1,156) |
| Net decrease in cash and cash equivalents | (1,899) | (2,985) |
| Cash and cash equivalents, beginning of period | 32,006 | 51,055 |
| Cash and cash equivalents, end of period | \$ 30,107 | \$ 48,070 |

Contact:

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