

**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): March 14, 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))

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 pursuant to Section 13(a) of the Exchange Act. ☒

**Item 2.02. Results of Operations and Financial Condition.**

On March 14, 2019, KalVista Pharmaceuticals, Inc. (the “Company”) reported its financial results for the three months ended January 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<br/>Number</u> | <u>Description</u>   |
|---------------------------|--|
| 99.1                      | <a href="#"><u>Press release dated March 14, 2019.</u></a> |

**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: March 14, 2019

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

**KalVista Pharmaceuticals Reports Fiscal Third Quarter Results**

*– Oral Hereditary Angioedema (HAE) Candidate KVD900 Phase 2 Trial Progressing –*

*– Intravitreal Diabetic Macular Edema (DME) Candidate KVD001 Phase 2 Trial Completion Expected H2 2019 –*

*– Oral Plasma Kallikrein Inhibitor Candidate KVD824 Dosing in First-in-Human Trial –*

**Cambridge, MA and Salisbury, England, March 14, 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 third quarter ended January 31, 2019.

“We are pleased with the progress of the Phase 2 trial of KVD900 as we move through the regulatory and site set-up process,” said Andrew Crockett, Chief Executive Officer of KalVista. “KVD900 is our most advanced candidate for oral treatment of HAE and we continue to expect data late this year. Our latest oral plasma kallikrein inhibitor candidate, KVD824, has begun dosing in a first-in-human trial and we expect to provide an update on this around mid-year. In other ongoing clinical activity, enrollment is on track for our Phase 2 trial of KVD001, our intravitreal DME candidate.”

**Third Quarter and Recent Business Highlights:**

- Provided a clinical update on oral plasma kallikrein inhibitors currently in the clinic. KVD900 was advanced into a Phase 2 clinical trial as a potential oral on-demand therapy, which will investigate efficacy in at least 50 type 1 and type 2 HAE patients. The trial will be conducted at 10-15 sites in the UK, Germany and other European countries. This two-part study will evaluate the pharmacodynamic and pharmacokinetic properties of KVD900 as well as the efficacy of the drug versus placebo. KVD824 was named as the next oral plasma kallikrein inhibitor candidate and has commenced dosing in a first-in-human trial. The Company expects to give an update on KVD824 around mid-2019.
  - Appointed Brian J. G. Pereira to Board of Directors. Brian is a veteran biopharmaceutical and healthcare leader with experience in financing and growing companies. He has been President and CEO of Visterra, Inc. since 2013 and previously served as President and CEO of AMAG Pharmaceuticals. Dr. Pereira’s experience in medical matters, clinical development and commercial infrastructure will be of great value to KalVista as we approach late stage development for our programs.
  - Announced data from a poster presentation given at the American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting. The Company provided additional data from a Phase 1 single ascending dose study of KVD900, evaluating the efficacy and safety of tablet and capsule formulations of the drug in healthy adult males, with a food-effect crossover study. The data showed that a single 600 mg dose of KVD900 provided >90% inhibition of plasma kallikrein within 30 minutes of dosing and protected against high molecular weight kininogen cleavage for at least 10 hours. No significant food effect was observed on the pharmacodynamic profile of the 600 mg KVD900 tablet in fed and fasted states.
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**Upcoming Events:**

- Presenting during a poster session at the Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting, April 28 – May 2, 2019, in Vancouver, Canada:

**Presentation Date:** Monday, April 29, 2019

**Presentation Time:** 4.00pm-5.45pm EST

**Abstract Title:** Novel oral plasma kallikrein (PKa) inhibitors KV998052 and KV998054 ameliorate VEGF-induced retinal thickening in a murine model of retina edema.

**Session:** 289

**Session Title:** Retinal Vascular Diseases II

**Fiscal Third Quarter Financial Results:**

- Revenue: Revenue was \$3.9 million for the three months ended January 31, 2019, compared to \$2.3 million for the same period in 2018. Revenue in the three months ended January 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 \$7.7 million for the three months ended January 31, 2019, compared to \$4.5 million for the same period in 2018. The increase in R&D expense primarily reflects the ongoing clinical trials for KVD001 and KVD900 and preparation for KVD824 to enter the clinic.
- G&A Expenses: General and administrative expenses were \$2.9 million for the three months ended January 31, 2019, compared to \$2.1 million for the same period in 2018.
- Net Loss: Net loss was \$4.0 million, or \$(0.23) per basic and diluted share for the three months ended January 31, 2019, compared to a net loss of \$5.2 million, or \$(0.49) per basic and diluted share, for the same period in 2018.
- Cash: Cash, cash equivalents and investments were \$111.1 million as of January 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 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, is enrolling a Phase 2 clinical trial that is anticipated to complete in the second half of 2019.

For more information, please visit [www.kalvista.com](http://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 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 30, 2018 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:****KalVista Pharmaceuticals, Inc.**

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

|   | January 31,<br>2019 | April 30,<br>2018 |
|---|---------------------|-------------------|
| <b>Assets</b>                                     |                     |                   |
| Current assets:                                   |                     |                   |
| Cash and cash equivalents                         | \$ 56,345           | \$ 51,055         |
| Investments                                       | 54,802              | —                 |
| Research and development tax credit receivable    | 8,970               | 6,834             |
| Prepaid expenses and other current assets         | 3,946               | 1,491             |
| <b>Total current assets</b>                       | <b>124,063</b>      | <b>59,380</b>     |
| Other assets                                      | 173                 | 173               |
| Property and equipment, net                       | 2,289               | 1,836             |
| <b>Total assets</b>                               | <b>\$ 126,525</b>   | <b>\$ 61,389</b>  |
| <b>Liabilities and Stockholders' Equity</b>       |                     |                   |
| Current liabilities:                              |                     |                   |
| Accounts payable                                  | \$ 2,998            | \$ 1,433          |
| Accrued expenses                                  | 3,408               | 3,087             |
| Deferred revenue - current portion                | 12,311              | 18,475            |
| Capital lease liability - current portion         | 109                 | 221               |
| <b>Total current liabilities</b>                  | <b>18,826</b>       | <b>23,216</b>     |
| Long-term liabilities:                            |                     |                   |
| Deferred revenue - net of current portion         | 3,666               | 10,862            |
| Capital lease liability - net of current portion  | —                   | 58                |
| <b>Total long-term liabilities</b>                | <b>3,666</b>        | <b>10,920</b>     |
| Stockholders' equity:                             |                     |                   |
| Common stock, \$0.001 par value                   | 17                  | 11                |
| Additional paid-in capital                        | 190,067             | 100,011           |
| Accumulated deficit                               | (83,950 )           | (71,660)          |
| Accumulated other comprehensive loss              | (2,101 )            | (1,109)           |
| <b>Total stockholders' equity</b>                 | <b>104,033</b>      | <b>27,253</b>     |
| <b>Total liabilities and stockholders' equity</b> | <b>\$ 126,525</b>   | <b>\$ 61,389</b>  |

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

|   | Three Months Ended<br>January 31, |                    | Nine Months Ended<br>January 31, |                     |
|---|-----------------------------------|--------------------|----------------------------------|---------------------|
|   | 2019                              | 2018               | 2019                             | 2018                |
| <b>Revenue</b>  | \$ 3,890                          | \$ 2,331           | \$ 13,201                        | \$ 3,554            |
| <b>Operating expenses:</b>                                    |                                   |                    |                                  |                     |
| Research and development                                      | 7,650                             | 4,548              | 23,882                           | 12,385              |
| General and administrative                                    | 2,900                             | 2,129              | 7,879                            | 6,905               |
| <b>Total operating expenses</b>                               | 10,550                            | 6,677              | 31,761                           | 19,290              |
| <b>Operating loss</b>   | <b>(6,660 )</b>                   | <b>(4,346 )</b>    | <b>(18,560 )</b>                 | <b>(15,736 )</b>    |
| <b>Other income:</b>  |                                   |                    |                                  |                     |
| Interest income   | 723                               | 14                 | 1,016                            | 17                  |
| Foreign currency exchange rate gain (loss)                    | 248                               | (1,887 )           | 83                               | (1,836 )            |
| Other income  | 1,733                             | 985                | 5,171                            | 2,407               |
| <b>Total other income</b>                                     | 2,704                             | (888 )             | 6,270                            | 588                 |
| <b>Net loss</b>   | <b>\$ (3,956 )</b>                | <b>\$ (5,234 )</b> | <b>\$ (12,290 )</b>              | <b>\$ (15,148 )</b> |
| Net loss per share to common stockholders, basic and diluted  | \$ (0.23 )                        | \$ (0.49 )         | \$ (0.85 )                       | \$ (1.49 )          |
| Weighted average common shares outstanding, basic and diluted | 17,231,449                        | 10,788,556         | 14,379,872                       | 10,168,520          |



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

|  | <b>Nine Months Ended<br/>January 31</b> |                         |
|--|---|-------------------------|
|  | <b>2019</b>                             | <b>2018</b>             |
| <b>Cash Flows from Operating Activities</b>                                |   |                         |
| Net loss   | \$ (12,290)                             | \$ (15,148)             |
| Adjustments to reconcile net loss to net cash used in operating activities |   |                         |
| Depreciation and amortization  | 256                                     | 129                     |
| Stock-based compensation expense   | 2,120                                   | 779                     |
| Foreign currency remeasurement loss  | (20)                                    | (500)                   |
| Changes in operating assets and liabilities:                               |   |                         |
| Research and development tax credit receivable                             | (2,409)                                 | (2,383)                 |
| Prepaid expenses and other current assets                                  | (2,475)                                 | (1,206)                 |
| Grants and other receivables   | —                                       | 281                     |
| Other Assets   | —                                       | (123)                   |
| Accounts payable   | 1,748                                   | 548                     |
| Accrued expenses   | 417                                     | 332                     |
| Deferred revenue   | (13,201)                                | 33,804                  |
| Net cash used in operating activities                                      | <u>(25,854)</u>                         | <u>16,513</u>           |
| <b>Cash Flows from Investing Activities</b>                                |   |                         |
| Acquisition of property and equipment                                      | (806)                                   | (343)                   |
| Purchases of available for sale securities                                 | (55,419)                                | —                       |
| Sales of available for sale securities                                     | 850                                     | —                       |
| Net cash used in investing activities                                      | <u>(55,375)</u>                         | <u>(343)</u>            |
| <b>Cash Flows from Financing Activities</b>                                |   |                         |
| Capital lease principal payments   | (155)                                   | (101)                   |
| Issuance of common stock from stock option exercises                       | 132                                     | —                       |
| Issuance of common stock, net of offering expenses                         | 87,811                                  | 9,100                   |
| Net cash provided by financing activities                                  | <u>87,788</u>                           | <u>8,999</u>            |
| Effect of exchange rate changes on cash and cash equivalents               | (1,269)                                 | 2,559                   |
| Net decrease in cash and cash equivalents                                  | 5,290                                   | 27,728                  |
| Cash and cash equivalents, beginning of period                             | 51,055                                  | 30,950                  |
| Cash and cash equivalents, end of period                                   | <u><u>\$ 56,345</u></u>                 | <u><u>\$ 58,678</u></u> |