

**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): December 3, 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 December 3, 2019, KalVista Pharmaceuticals, Inc. (the “Company”) reported its financial results for the fiscal quarter ended October 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 December 3, 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: December 3, 2019

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

KalVista Pharmaceuticals Reports Fiscal Second Quarter Results

– KVD900 Phase 2 Trial Data for On-Demand Treatment of HAE Expected in 2020 –

– KVD001 Phase 2 Clinical Trial for Patients with Diabetic Macular Edema (DME) Data Expected This Month –

– KVD900 Receives FDA Fast Track Designation –

Cambridge, MA and Salisbury, England, December 3, 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 second quarter ended October 31, 2019.

“We recently received Fast Track designation for KVD900, illustrating the high level of unmet need in the HAE community for efficacious and safe, orally-delivered therapies,” said Andrew Crockett, Chief Executive Officer of KalVista. “Our Phase 2 clinical trial for KVD900 continues, and we expect to have data from that trial in 2020. The Phase 2 clinical trial of KVD001 in DME will provide data this month.”

Second Quarter and Recent Business Highlights:

- Presented at The International Symposium on Ocular Pharmacology and Therapeutics (ISOPT). KalVista’s Chief Scientific Officer, Edward P. Feener, PhD, spoke on “Kallikrein-Kinin System in Diabetic Retinopathy – Novel Target.”
- Announced that the Phase 2 trial of KVD900 as an on-demand therapy for HAE is anticipated to complete enrollment in 2019 with data expected in 2020. The trial is being conducted in approximately 20 sites in Europe and the U.S.
- Received Fast Track designation for KVD900 from the U.S. FDA, supporting the Company’s belief in the high level of unmet need in HAE and providing a potentially expedited path to drug approval.

Fiscal Second Quarter Financial Results:

- Revenue: Revenue was \$3.9 million for the three months ended October 31, 2019, compared to \$5.6 million for the same period in 2018. Revenue in the three months ended October 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 \$9.8 million for the three months ended October 31, 2019, compared to \$7.9 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 expense related to preclinical activities.
 - G&A Expenses: General and administrative expenses were \$3.4 million for the three months ended October 31, 2019, compared to \$2.6 million for the same period in 2018.
 - Net Loss: Net loss was \$5.9 million, or \$(0.33) per basic and diluted share for the three months ended October 31, 2019, compared to a net loss of \$3.3 million, or \$(0.22) per basic and diluted share, for the same period in 2018.
 - Cash: Cash, cash equivalents and marketable securities were \$93.5 million as of October 31, 2019.
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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 Company's 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 is conducting a Phase 2 proof-of-concept study in HAE patients that is expected to provide data in 2020. In DME, KalVista's most advanced program, an intravitreally administered plasma kallikrein inhibitor known as KVD001, is anticipated to report data from a Phase 2 clinical trial 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 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 15, 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>October 31,</u> <u>2019</u>	<u>April 30,</u> <u>2019</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 21,719	\$ 32,006
Marketable securities	71,742	68,805
Research and development tax credit receivable	11,814	11,315
Prepaid expenses and other current assets	2,617	3,420
Total current assets	107,892	115,546
Right of use assets	1,634	—
Property and equipment, net	2,365	2,413
Other assets	173	173
Total assets	\$ 112,064	\$ 118,132
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,238	\$ 2,860
Accrued expenses	5,029	5,647
Deferred revenue - current portion	2,601	9,545
Lease liability - current portion	602	—
Total current liabilities	10,470	18,052
Long-term liabilities:		
Deferred revenue - net of current portion	2,754	3,342
Lease liability - net of current portion	1,053	—
Total long-term liabilities	3,807	3,342
Stockholders' equity:		
Common stock, \$0.001 par value	18	17
Additional paid-in capital	204,950	191,123
Accumulated deficit	(105,717)	(92,476)
Accumulated other comprehensive loss	(1,464)	(1,926)
Total stockholders' equity	97,787	96,738
Total liabilities and stockholders' equity	\$ 112,064	\$ 118,132

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

	Three Months Ended October 31,		Six Months Ended October 31,	
	2019	2018	2019	2018
Revenue	\$ 3,920	\$ 5,592	\$ 7,289	\$ 9,311
Operating expenses:				
Research and development	9,789	7,876	19,476	16,232
General and administrative	3,420	2,609	6,665	4,979
Total operating expenses	<u>13,209</u>	<u>10,485</u>	<u>26,141</u>	<u>21,211</u>
Operating loss	<u>(9,289)</u>	<u>(4,893)</u>	<u>(18,852)</u>	<u>(11,900)</u>
Other income:				
Interest income	505	204	1,095	293
Foreign currency exchange gain (loss)	560	(231)	108	(165)
Other income	2,321	1,616	4,408	3,438
Total other income	<u>3,386</u>	<u>1,589</u>	<u>5,611</u>	<u>3,566</u>
Net loss	<u>\$ (5,903)</u>	<u>\$ (3,304)</u>	<u>\$ (13,241)</u>	<u>\$ (8,334)</u>
 Net loss per share, basic and diluted	 \$ (0.33)	 \$ (0.22)	 \$ (0.75)	 \$ (0.64)
 Weighted average common shares outstanding, basic and diluted	 17,823,302	 15,108,272	 17,656,150	 12,954,083

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

	Six Months Ended October 31,	
	2019	2018
Cash Flows from Operating Activities		
Net loss	\$ (13,241)	\$ (8,334)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	248	153
Stock-based compensation expense	2,236	1,323
Realized (gain) loss from available for sale securities	(129)	—
Amortization of right of use assets	273	—
Amortization of discount/premium on available for sale securities	79	—
Foreign currency remeasurement (gain) loss	(81)	226
Changes in operating assets and liabilities:		
Research and development tax credit receivable	(577)	(692)
Prepaid expenses and other current assets	785	(517)
Accounts payable	(558)	2,088
Accrued expenses	(564)	66
Lease obligations	(271)	—
Deferred revenue	(7,289)	(9,311)
Net cash used in operating activities	(19,089)	(14,998)
Cash Flows from Investing Activities		
Acquisition of property and equipment	(212)	(786)
Purchases of available for sale securities	(42,561)	—
Sales and maturities of available for sale securities	39,729	—
Net cash used in investing activities	(3,044)	(786)
Cash Flows from Financing Activities		
Capital lease principal payments	(54)	(104)
Proceeds from issuance of common stock from equity incentive plans	170	25
Proceeds from issuance of common stock, net of \$123 of offering expenses	11,422	87,811
Net cash provided by financing activities	11,538	87,732
Effect of exchange rate changes on cash and cash equivalents	308	(1,887)
Net (decrease) increase in cash and cash equivalents	(10,287)	70,061
Cash and cash equivalents, beginning of period	32,006	51,055
Cash and cash equivalents, end of period	\$ 21,719	\$ 121,116

Contact:

KalVista Pharmaceuticals, Inc.

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