

**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): July 15, 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 July 15, 2019, KalVista Pharmaceuticals, Inc. (the “Company”) reported its financial results for the fiscal year ended April 30, 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 dated July 15, 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: July 16, 2019

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

KalVista Pharmaceuticals Provides Operational Update and Fiscal Year Financial Results

– KVD900 Enrolling Phase 2 Clinical Trial for Oral Treatment of Hereditary Angioedema (HAE) with Data Expected in Late 2019 –

– Enrollment Complete in KVD001 Phase 2 Clinical Trial for Patients with Diabetic Macular Edema (DME) with Data Expected in H2 2019 –

– Operations Funded into 2021 –

Cambridge, MA and Salisbury, England, July 15, 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 year ended April 30, 2019.

“This fiscal year has been busy as we prepare for data in two Phase 2 clinical trials before the end of 2019,” said Andrew Crockett, Chief Executive Officer of KalVista. “We believe the use of KVD900 has the potential to be a compelling option for patients in search of an oral on-demand therapy for HAE because of its rapid and high exposure levels and favorable tolerability to date. We believe equally that KVD001 could represent an important therapeutic alternative for DME patients, especially for those patients whose disease is inadequately treated with anti-VEGF.”

In addition to KVD900 and KVD001, KalVista’s next clinical stage oral plasma kallikrein inhibitor, KVD824, has now completed dosing in a first-in-human study. Preliminary data show high exposure levels and no concerning tolerability signals in single ascending dose, multiple ascending dose, and food effect cohorts. KVD824 also demonstrated significant effects in relevant pharmacology models of HAE and DME which support progression of the compound in either indication. The Company is conducting additional formulation work to optimize the exposure profile of the drug before deciding which indication to pursue. This additional work is expected to be completed in 2019 and KalVista is currently planning to initiate a Phase 2 clinical trial in the chosen indication in the first half of 2020.

Fiscal 2019 and Recent Business Highlights:

- Closed a public offering of common stock and full exercise of the underwriters’ over-allotment option to purchase additional shares for gross proceeds of over \$78 million.
 - Initiated a robust Phase 2 trial for KVD900.
 - Named KVD824 the next oral plasma kallikrein inhibitor and initiated a first-in-human clinical trial.
 - Enrolled the Phase 2 clinical trial for KVD001.
 - Appointed Brian J. G. Pereira, Daniel B. Soland, and Martin Edwards to the Board of Directors.
 - 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
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observed on the pharmacodynamic profile of the 600 mg KVD900 tablet in fed and fasted states.

- Promoted Benjamin L. Palleiko to Chief Business Officer in addition to his role as Chief Financial Officer.
- Presented data at the Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting 2019. The data demonstrated that novel oral plasma kallikrein inhibitors KV998052 and KV998054 demonstrated the ability to prevent and reverse VEGF-induced retinal edema in mice.
- Announced data at C1-Inhibitor Deficiency and Angioedema Workshop and European Academy of Allergy and Clinical Immunology (EAACI) Congress. KVD900 Phase 1 data showed rapid and nearly complete suppression of plasma kallikrein activity and was well tolerated for potential use as an on-demand treatment for HAE.
- Accepted for publication in *Ophthalmology Retina*: Open-Label Phase 1B Study of Intravitreal KVD001, a Plasma Kallikrein Inhibitor, in Patients with Center Involved Diabetic Macular Edema and Reduced Vision. A total of 14 patients were each given a single intravitreal dose (1µg, 3µg or 10µg) of KVD001 the study eye. No dose-limiting toxicities or serious adverse events were reported. Although this was not an efficacy study, improvement of retinal edema and vision occurred to some extent in most study eyes.

Fourth Quarter and Full Year Financial Results:

- Revenue: Revenue was \$2.9 million for the three months ended April 30, 2019, compared to \$4.8 million for the same period in the prior year. Revenue was \$16.1 million for the fiscal year ended April 30, 2019, compared to \$8.4 million in the prior fiscal year. Revenue in 2019 reflected recognition of the upfront payment from Merck related to the agreement signed in October 2017.
- R&D Expenses: Research and development expenses were \$11.1 million for the three months ended April 30, 2019, compared to \$5.9 million for the same period in the prior year. Research and development expenses were \$35.0 million for the fiscal year ended April 30, 2019, compared to \$18.2 million in the prior fiscal year. The increase in spending primarily reflects increased costs related to the ongoing clinical trial for KVD001 and the commencement of the phase 2 clinical trial for KVD900 and the commencement of the phase 1 clinical trial for KVD824 as well as increased expenses on earlier stage programs.
- G&A Expenses: General and administrative expenses were \$3.0 million for the three months ended April 30, 2019, compared to \$2.0 million for the same period in the prior year. General and administrative expenses were \$10.9 million for the fiscal year ended April 30, 2018, compared to \$8.9 million in the prior year. The increase in G&A expenses was primarily due to increased compensation and related expenses and to a lesser extent, increases in professional fees.
- Net Loss: Net loss was \$8.5 million, or \$(0.49) per weighted average basic and diluted share, for the three months ended April 30, 2019, compared to net loss of \$0.7 million, or \$(0.06) per weighted average basic and diluted share for the same period in the prior year. Net loss was \$20.8 million, or \$(1.38) per weighted average basic and diluted share for the fiscal year ended April 30, 2019, compared to a net loss of \$15.8 million, or \$(1.53) per weighted average basic and diluted share in the prior year. The increase in net loss and net loss per share in both the three months and year ended April 30, 2019 was primarily related to the ramp up of research and development expenses in the current year compared to the prior year.
- Cash Position: Cash, cash equivalents and investments were \$100.8 million as of April 30, 2019, compared to \$51.1 million as of April 30, 2018. The increase in the net cash position is

primarily the result of the \$78 million of gross proceeds raised in the public offering in September 2018.

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, began a Phase 2 clinical trial in 2017 that is anticipated to complete in the second half 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>April 30,</u> <u>2019</u>	<u>April 30,</u> <u>2018</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 32,006	\$ 51,055
Marketable securities	68,805	—
Research and development tax credit receivable	11,315	6,834
Prepaid expenses and other current assets	3,420	1,491
Total current assets	<u>115,546</u>	<u>59,380</u>
Other assets	173	173
Property and equipment, net	2,413	1,836
Total assets	<u><u>\$ 118,132</u></u>	<u><u>\$ 61,389</u></u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,860	\$ 1,433
Accrued expenses	5,593	3,087
Deferred revenue - current portion	9,545	18,475
Capital lease liability - current portion	54	221
Total current liabilities	<u>18,052</u>	<u>23,216</u>
Long-term liabilities:		
Deferred revenue - net of current portion	3,342	10,862
Capital lease liability - net of current portion	—	58
Total long-term liabilities	<u>3,342</u>	<u>10,920</u>
Stockholders' equity:		
Common stock, \$0.001 par value	17	11
Additional paid-in capital	191,123	100,011
Accumulated deficit	(92,476)	(71,660)
Accumulated other comprehensive loss	(1,926)	(1,109)
Total stockholders' equity	<u>96,738</u>	<u>27,253</u>
Total liabilities and stockholders' equity	<u><u>\$ 118,132</u></u>	<u><u>\$ 61,389</u></u>

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

	Three Months Ended April 30,		Years Ended April 30,	
	2019	2018	2019	2018
Revenue	\$ 2,926	\$ 4,840	\$ 16,127	\$ 8,394
Operating expenses:				
Research and development	11,139	5,852	35,021	18,237
General and administrative	3,047	1,957	10,926	8,862
Total operating expenses	<u>14,186</u>	<u>7,809</u>	<u>45,947</u>	<u>27,099</u>
Operating loss	<u>(11,260)</u>	<u>(2,969)</u>	<u>(29,820)</u>	<u>(18,705)</u>
Other income:				
Interest income	381	65	1,397	82
Foreign currency exchange rate gain (loss)	(34)	262	49	(1,574)
Other income	2,511	1,985	7,682	4,392
Total other income	<u>2,858</u>	<u>2,312</u>	<u>9,128</u>	<u>2,900</u>
Loss before income taxes	<u>(8,402)</u>	<u>(657)</u>	<u>(20,692)</u>	<u>(15,805)</u>
Income tax expense	124	—	124	—
Net loss	<u>\$ (8,526)</u>	<u>\$ (657)</u>	<u>\$ (20,816)</u>	<u>\$ (15,805)</u>
Net loss per share, basic and diluted	\$ (0.49)	\$ (0.06)	\$ (1.38)	\$ (1.53)
Weighted average common shares outstanding, basic and diluted	17,253,938	10,797,055	15,080,863	10,321,780

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

	Years Ended April 30	
	2019	2018
Cash Flows from Operating Activities		
Net loss	\$ (20,816)	\$ (15,805)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities		
Depreciation and amortization	378	180
Stock-based compensation expense	2,966	1,060
Realized (gain) loss from available for sale securities	(23)	—
Foreign currency remeasurement gain	(80)	(651)
Changes in operating assets and liabilities:		
Research and development tax credit receivable	(4,883)	(4,256)
Grants and other receivables	—	319
Prepaid expenses and other current assets	(1,979)	(746)
Other assets	—	(123)
Accounts payable	1,534	217
Accrued expenses	2,665	1,132
Deferred revenue	(16,127)	29,231
Net cash (used in) provided by operating activities	(36,365)	10,558
Cash Flows from Investing Activities		
Purchases of available for sale securities	(79,889)	—
Sales and maturities of available for sale securities	11,548	—
Acquisition of property and equipment	(1,081)	(1,427)
Net cash used in investing activities	(69,422)	(1,427)
Cash Flows from Financing Activities		
Proceeds from issuance of common stock, net of issuance costs	87,910	9,137
Proceeds from issuance of common stock from exercise of stock options	242	—
Capital lease principal payments	(209)	(151)
Net cash provided by financing activities	87,943	8,986
Effect of exchange rate changes on cash and cash equivalents	(1,205)	1,988
Net (decrease) increase in cash and cash equivalents	(19,049)	20,105
Cash and cash equivalents, beginning of year	51,055	30,950
Cash and cash equivalents, end of year	\$ 32,006	\$ 51,055

Contact:

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