

**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 1, 2020

KALVISTA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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 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 2.02 Results of Operations and Financial Condition

On July 1, 2020, KalVista Pharmaceuticals, Inc. (the “Company”) reported its financial results for the fiscal year ended April 30, 2020. 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 and 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.

(d) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press release dated July 1, 2020

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: July 1, 2020

KALVISTA PHARMACEUTICALS, INC.

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 Phase 2 Clinical Trial for Oral Treatment of Hereditary Angioedema (HAE) Data Expected in 2H 2020 –

– Oral HAE Prophylactic Candidate KVD824 Phase 2 Clinical Trial Planned to Commence in 2H 2020 –

– Operations Funded into 2022 –

Cambridge, MA and Salisbury, England, July 1, 2020 – 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, 2020.

“We have two oral candidates in clinical trials that have the potential to provide HAE patients with a complete set of options to treat their disease,” said Andrew Crockett, Chief Executive Officer of KalVista. “We are pleased with our progress with the formulation work for KVD824 to deliver a twice-daily treatment for prevention of HAE attacks. Subjects have begun dosing with these new formulations to obtain additional pharmacokinetic and pharmacodynamic data, and we look forward to providing these data later this year in advance of starting a Phase 2 clinical trial. Patients also continue to be treated in our Phase 2 clinical trial for KVD900 as an on-demand therapy, and we expect data from that trial in the second half of this year.”

Fiscal 2020 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.
 - 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.”
 - Received Fast Track designation for KVD900 from the FDA, supporting KalVista’s belief in the high level of unmet need in HAE for oral therapy and providing a potentially expedited path to drug approval.
 - Announced results of the Phase 2 trial of KVD001, an intravitreal candidate for treatment of diabetic macular edema (DME). KVD001 did not meet its primary endpoint in the overall study population, but it did demonstrate a protection against vision loss and a pre-specified subgroup analysis showed a clinical benefit on vision. The trial was designed to evaluate patients who were poor responders to previous treatment with anti-VEGF therapy. KVD001 was generally safe and well tolerated with no drug-related serious adverse events. Both KVD001 and future oral DME molecules were subject to an option agreement with Merck, which subsequently expired in February.
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- Selected KVD824 for development as a twice-daily oral prophylactic treatment for HAE. KVD824 is a highly potent and selective plasma kallikrein inhibitor which achieved high exposures and a favorable safety and tolerability profile in a first-in-human study. Additional formulation work on KVD824 is ongoing, and the Company expects to provide this and other data before initiating a Phase 2 clinical trial, which is anticipated to be in the second half of 2020.
- Adjusted expectations for KVD900 data to the second half of 2020 due to the impact of COVID-19, and revised financial guidance that activities are funded into at least early 2022.

Fourth Quarter and Full Year Financial Results:

- **Revenue:** Revenue was \$3.8 million for the three months ended April 30, 2020, compared to \$2.9 million for the same period in the prior fiscal year. Revenue was \$12.7 million for the fiscal year ended April 30, 2020, compared to \$16.1 million for the prior fiscal year. All of the revenue recognized in the fiscal year ended April 30, 2020 was recognized from deferred revenue that existed at the beginning of the period. No future revenue exists under the Merck Option Agreement.
- **R&D Expenses:** Research and development expenses were \$9.5 million for the three months ended April 30, 2020, compared to \$11.1 million for the same period in the prior fiscal year. The decrease in spending during the quarter was primarily due to the conclusion of the Phase 2 clinical trial for KVD001 in the previous quarter. Research and development expenses were \$40.2 million for the fiscal year ended April 30, 2020, compared to \$35.0 million for the prior fiscal year. The increase in spending in the fiscal year ended April 30, 2020 primarily reflects increased costs related to the ongoing clinical trial for KVD900 as well as increased expenses on preclinical activities.
- **G&A Expenses:** General and administrative expenses were \$3.3 million for the three months ended April 30, 2020, compared to \$3.0 million for the same period in the prior fiscal year. General and administrative expenses were \$13.0 million for the fiscal year ended April 30, 2020, compared to \$10.9 million for the prior fiscal year. The increase in G&A expenses was primarily due to an increase in compensation related expenses and to a lesser extent, increases in commercial planning expenses, professional fees, and insurance costs.
- **Net Loss:** Net loss was \$6.6 million, or \$(0.37) per weighted average basic and diluted share, for the three months ended April 30, 2020, compared to net loss of \$8.5 million, or \$(0.49) per weighted average basic and diluted share for the same period in the prior fiscal year. Net loss was \$29.1 million, or \$(1.64) per weighted average basic and diluted share for the fiscal year ended April 30, 2020, compared to net loss of \$20.8 million, or \$(1.38) per weighted average basic and diluted share in the prior fiscal year. The decrease in net loss and net loss per share in the three months ended April 30, 2020 as compared to the same period in the prior fiscal year primarily resulted from decreased research and development spending due to the completion of the Phase 2 clinical trial for KVD001 in the previous quarter. The increase in net loss and net loss per share in year ended April 30, 2020 was primarily

- related to the ramp up of research and development activities in the current year compared to the prior fiscal year.
- Cash Position: Cash, cash equivalents and marketable securities were \$67.7 million as of April 30, 2020, compared to \$100.8 million as of April 30, 2019. The decrease in the net cash position was due to increased spending, primarily on research and development activities during the year ended April 30, 2020 compared to the prior fiscal year.

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. KalVista has selected KVD900 as its program to be advanced as an on-demand therapy for acute HAE attacks and is conducting a Phase 2 proof-of-concept study in HAE patients with data expected in the second half of 2020. KVD824 is in development for prophylactic treatment of HAE and is expected to enter a Phase 2 clinical trial in the second half of 2020. In DME, an intravitreally administered plasma kallikrein inhibitor known as KVD001, completed a Phase 2 clinical trial in 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, potential benefits of our product candidates, and the impact of COVID-19. Further information on potential risk factors that could affect our business and its 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, 2020 once filed, and our other reports that we may file 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.

Leah Monteiro
Senior Director, Corporate Communications & Investor Relations
857-999-0808
leah.monteiro@kalvista.com

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

	<u>April 30,</u> <u>2020</u>	<u>April 30,</u> <u>2019</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 15,789	\$ 32,006
Marketable securities	51,925	68,805
Research and development tax credit receivable	16,527	11,315
Prepaid expenses and other current assets	4,455	3,420
Total current assets	<u>88,696</u>	<u>115,546</u>
Property and equipment, net	2,043	2,413
Right of use assets	1,612	—
Other assets	178	173
Total assets	<u><u>\$ 92,529</u></u>	<u><u>\$ 118,132</u></u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,677	\$ 2,860
Accrued expenses	5,455	5,647
Deferred revenue - current portion	—	9,545
Lease liability - current portion	588	—
Total current liabilities	<u>7,720</u>	<u>18,052</u>
Long-term liabilities:		
Deferred revenue - net of current portion	—	3,342
Lease liability - net of current portion	1,057	—
Total long-term liabilities	<u>1,057</u>	<u>3,342</u>
Stockholders' equity:		
Common stock, \$0.001 par value	18	17
Additional paid-in capital	207,208	191,123
Accumulated deficit	(121,592)	(92,476)
Accumulated other comprehensive loss	(1,882)	(1,926)
Total stockholders' equity	<u>83,752</u>	<u>96,738</u>
Total liabilities and stockholders' equity	<u><u>\$ 92,529</u></u>	<u><u>\$ 118,132</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,	
	2020	2019	2020	2019
Revenue	\$ 3,824	\$ 2,926	\$ 12,690	\$ 16,127
Operating expenses:				
Research and development	9,485	11,139	40,194	35,021
General and administrative	3,296	3,047	13,029	10,926
Total operating expenses	<u>12,781</u>	<u>14,186</u>	<u>53,223</u>	<u>45,947</u>
Operating loss	<u>(8,957)</u>	<u>(11,260)</u>	<u>(40,533)</u>	<u>(29,820)</u>
Other income:				
Interest income	363	381	1,830	1,397
Foreign currency exchange rate gain (loss)	(613)	(34)	(367)	49
Other income	2,498	2,511	9,830	7,682
Total other income	<u>2,248</u>	<u>2,858</u>	<u>11,293</u>	<u>9,128</u>
Loss before income taxes	(6,709)	(8,402)	(29,240)	(20,692)
Income tax (benefit) expense	(124)	124	(124)	124
Net loss	<u>\$ (6,585)</u>	<u>\$ (8,526)</u>	<u>\$ (29,116)</u>	<u>\$ (20,816)</u>
Net loss per share, basic and diluted	\$ (0.37)	\$ (0.49)	\$ (1.64)	\$ (1.38)
Weighted average common shares outstanding, basic and diluted	17,845,599	17,253,938	17,748,666	15,080,863

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

	Years Ended April 30,	
	2020	2019
Cash flows from operating activities		
Net loss	\$ (29,116)	\$ (20,816)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	512	378
Stock-based compensation expense	4,448	2,966
Realized (gain) from sale of marketable securities	(300)	(23)
Non-cash operating lease expense	13	—
Amortization of premium on available for sale securities	193	—
Foreign currency exchange (gain) loss	74	(80)
Changes in operating assets and liabilities:		
Research and development tax credit receivable	(5,781)	(4,883)
Prepaid expenses and other current assets	(1,112)	(1,979)
Other assets	(5)	—
Accounts payable	(1,004)	1,534
Accrued expenses	(48)	2,665
Deferred revenue	(12,690)	(16,127)
Net cash used in operating activities	(44,816)	(36,365)
Cash flows from investing activities		
Purchases of available for sale securities	(49,797)	(79,889)
Sales and maturities of available for sale securities	66,770	11,548
Acquisition of property and equipment	(220)	(1,081)
Net cash provided by (used in) investing activities	16,753	(69,422)
Cash flows from financing activities		
Issuance of common stock, net of offering expenses	11,422	87,910
Issuance of common stock from equity incentive plans	216	242
Finance lease principal payments	(54)	(209)
Net cash provided by financing activities	11,584	87,943
Effect of exchange rate changes on cash and cash equivalents	262	(1,205)
Net decrease in cash and cash equivalents	(16,217)	(19,049)
Cash and cash equivalents, beginning of year	32,006	51,055
Cash and cash equivalents, end of year	\$ 15,789	\$ 32,006

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