# 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 14, 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  $\Box$ 

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.  $\Box$ 

#### Item 2.02 Results of Operations and Financial Condition

On September 14, 2020, KalVista Pharmaceuticals, Inc. (the "Company") reported its financial results for the fiscal quarter ended July 31, 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

Exhibit	
<u>Number</u>	<b>Description</b>
99.1	Press release dated September 14, 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.

# KALVISTA PHARMACEUTICALS, INC.

By: /s/ Benjamin L. Palleiko

Benjamin L. Palleiko Chief Business Officer and Chief Financial Officer

Date: September 14, 2020

# KalVista Pharmaceuticals Reports First Fiscal Quarter Results

# - KVD900 On-Demand Data Expected Q4 2020 -

**Cambridge, MA and Salisbury, England, September 14, 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 first fiscal quarter ended July 31, 2020.

"We are pleased that our KVD900 Phase 2 trial has met its enrollment target and data is expected before the end of this year. We believe KVD900 can bring the first effective and well-tolerated oral on-demand treatment option to patients suffering from hereditary angioedema attacks," said Andrew Crockett, Chief Executive Officer of KalVista. "Our portfolio of oral options intended to treat HAE also includes prophylactic treatment candidate KVD824, for which we are completing our formulation studies which include dosing in subjects. We look forward to providing additional pharmacokinetic and pharmacodynamic data for KVD824 later this year in advance of starting a Phase 2 clinical trial. Similar to KVD900, our goal with KVD824 is to conduct a robust Phase 2 trial to provide proof-of-concept and potentially an expedited development pathway. We will provide further details on our plans as we prepare to initiate the trial."

# First Fiscal Quarter and Recent Business Highlights:

- Met enrollment target for the Phase 2 clinical trial intended to evaluate the safety and efficacy of KVD900 compared to placebo in the treatment of HAE attacks. This trial is expected to provide data in the fourth quarter of 2020.
- Submitted a Pediatric Investigational Plan (PIP) to the European Medicines Agency (EMA) for KVD900.

## **First Fiscal Quarter Financial Results:**

- Revenue: No revenue was recognized for the three months ended July 31, 2020, compared to \$3.4 million for the same period in the prior fiscal year. The decrease of \$3.4 million was due to the expiration of the Merck Option Agreement in February 2020. No future revenue remains under this agreement.
- R&D Expenses: Research and development expenses were \$11.2 million for the three months ended July 31, 2020, compared to \$9.7 million for the same period in the prior fiscal year. The increase in spending during the quarter primarily reflects increased costs related to the ongoing clinical trial for KVD900 as well as increased expenses in relation to the development of KVD824, primarily offset by a decrease in spending on KVD001 which concluded a Phase 2 clinical trial in December 2019, and a decrease in spending on preclinical activities.
- G&A Expenses: General and administrative expenses were \$3.3 million for the three months ended July 31, 2020, compared to \$3.2 million for the same period in the prior fiscal year.

- Net Loss: Net loss was \$10.8 million, or \$(0.61) per weighted average basic and diluted share, for the three months ended July 31, 2020, compared to net loss of \$7.3 million, or \$(0.42) per weighted average basic and diluted share, for the same period in the prior fiscal year. The increase in net loss and net loss per share in the three months ended July 31, 2020 as compared to the same period in the prior fiscal year primarily due to the decrease in revenue and increase in research and development expenses in the three months ended July 31, 2020.
- Cash: Cash, cash equivalents and marketable securities were \$64.3 million as of July 31, 2020, compared to \$67.7 million as of April 30, 2020. The decrease in net cash position was due to increased spending, primarily on research and development activities.

# 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). KalVista 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 fourth quarter of 2020. KVD824 is in development for prophylactic treatment of HAE with a Phase 2 clinical trial planned to commence in late 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, including the potential impact of COVID-19, that could cause actual results to differ materially from what we expect. Examples of forward-looking statements include, among others, KalVista's expectations about future clinical trial timing and results, its ability to commence or complete clinical studies and to obtain regulatory approvals for KVD824, the ability of KVD900 and KVD824 to treat HAE, and the sufficiency of our cash, cash equivalents and investments to fund our operations. Further information on potential risk factors that could affect our business and its financial results are detailed in our annual report on Form 10-K filed on July 1, 2020, our quarterly report on Form 10-Q for the three months ended July 31, 2020, when filed, and other filings we may make 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)

	July 31, 2020		April 30, 2020	
Assets				
Current assets:				
Cash and cash equivalents	\$ 18,014	\$	15,789	
Marketable securities	46,317		51,925	
Research and development tax credit receivable	12,638		16,527	
Prepaid expenses and other current assets	 3,256		4,455	
Total current assets	80,225		88,696	
Property and equipment, net	2,019		2,043	
Right of use assets	1,480		1,612	
Other assets	 178		178	
Total assets	\$ 83,902	\$	92,529	
Liabilities and stockholders' equity	 			
Current liabilities:				
Accounts payable	\$ 1,774	\$	1,677	
Accrued expenses	6,170		5,455	
Lease liability - current portion	513		588	
Total current liabilities	8,457		7,720	
Long-term liabilities:				
Lease liability - net of current portion	1,010		1,057	
Total long-term liabilities	1,010		1,057	
Stockholders' equity:				
Common stock, \$0.001 par value	18		18	
Additional paid-in capital	208,442		207,208	
Accumulated deficit	(132,406)		(121,592)	
Accumulated other comprehensive loss	(1,619)		(1,882)	
Total stockholders' equity	 74,435		83,752	
Total liabilities and stockholders' equity	\$ 83,902	\$	92,529	

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

	Three Months Ended July 31,			
	2020		2019	
Revenue	\$		\$	3,369
Operating expenses:				
Research and development		11,165		9,686
General and administrative		3,278		3,247
Total operating expenses		14,443		12,933
Operating loss		(14,443)		(9,564)
Other income:				
Interest income		259		590
Foreign currency exchange rate gain (loss)		438		(453)
Other income		2,932		2,089
Total other income		3,629		2,226
Net loss	<u>\$</u>	(10,814)	\$	(7,338)
Net loss per share, basic and diluted	\$	(0.61)	\$	(0.42)
Weighted average common shares outstanding, basic and diluted		17,848,583		17,488,997

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

	Three Months Ended July 31,				
		2020		2019	
Cash flows from operating activities					
Net loss	\$	(10,814)	\$	(7,338)	
Adjustments to reconcile net loss to net cash used in operating activities:					
Depreciation and amortization		128		121	
Stock-based compensation expense		1,188		1,074	
Realized gain from sale of marketable securities		(70)		(29)	
Non-cash operating lease expense		8		1	
Amortization of premium on marketable securities		68		35	
Foreign currency exchange (gain) loss		(432)		454	
Changes in operating assets and liabilities:					
Research and development tax credit receivable		4,462		(2,060)	
Prepaid expenses and other current assets		1,301		561	
Accounts payable		35		392	
Accrued expenses		538		(1,117)	
Deferred revenue		—		(3,369)	
Net cash used in operating activities		(3,588)		(11,275)	
Cash flows from investing activities					
Purchases of marketable securities		(9,807)		(19,646)	
Sales and maturities of marketable securities		15,342		18,214	
Acquisition of property and equipment		(22)		(98)	
Net cash provided by (used in) investing activities		5,513		(1,530)	
Cash flows from financing activities					
Issuance of common stock, net of offering expenses		_		11,422	
Issuance of common stock from equity incentive plans		46		32	
Finance lease principal payments		_		(54)	
Net cash provided by financing activities		46		11,400	
Effect of exchange rate changes on cash and cash equivalents		254		(494)	
Net increase (decrease) in cash and cash equivalents		2,225		(1,899)	
Cash and cash equivalents at beginning of period		15,789		32,006	
Cash and cash equivalents at end of period	\$	18,014	\$	30,107	

# Contact: KalVista Pharmaceuticals, Inc.

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