

**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 10, 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 December 10, 2020, KalVista Pharmaceuticals, Inc. (the “Company”) reported its financial results for the fiscal quarter ended October 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

<b><u>Exhibit Number</u></b>	<b><u>Description</u></b>
99.1	<a href="#">Press release dated December 10, 2020</a>

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**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.**

Date: December 10, 2020

By: /s/ Benjamin L. Palleiko

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Benjamin L. Palleiko  
Chief Business Officer and Chief Financial Officer

**KalVista Pharmaceuticals Reports Second Fiscal Quarter Results**

– *KVD900 Phase 2 Clinical Trial Patient Treatment Completed; Data Expected Q1 2021* –

**Cambridge, MA and Salisbury, England, December 10, 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 second fiscal quarter ended October 31, 2020.

“We have completed the patient treatment phase of our KVD900 Phase 2 trial and are in the process of wrapping up that study. Data from this trial evaluating KVD900 as an oral on-demand treatment for hereditary angioedema is expected in the first quarter of 2021,” said Andrew Crockett, Chief Executive Officer of KalVista. “The formulation data recently shared for KVD824, our oral prophylactic treatment candidate for HAE, showed concentrations that we believe can lead to efficacy levels competitive with approved injectable therapies. We expect to submit an Investigational New Drug Application to the FDA for a Phase 2 clinical trial of KVD824 as a potential twice-daily oral treatment in the prevention of HAE attacks in the first quarter of 2021.”

**Second Fiscal Quarter and Recent Business Highlights:**

- Completed treatment of the planned target of 50 patients in a Phase 2 clinical trial intended to evaluate the safety and efficacy of KVD900 as an oral on-demand treatment of hereditary angioedema (HAE) attacks. This trial is expected to provide data in the first quarter of 2021. A Pediatric Investigational Plan (PIP) has also been approved by the European Medicines Agency (EMA) for KVD900.
- Provided data on KVD824 as a twice-daily oral candidate for prophylactic treatment of HAE. Work to optimize the exposure profile of KVD824 yielded a formulation that maintains the plasma concentrations KalVista believes are required to compete with approved injectable therapies, while showing an encouraging safety and tolerability profile in up to 14 days of dosing. An Investigational New Drug Application (IND) submission to the U.S. Food and Drug Administration (FDA) for a Phase 2 clinical trial is expected in the first quarter of 2021.
- Announced a novel oral Factor XIIa inhibitor program as the next area of development focus. KalVista’s internal research team has discovered multiple series of oral Factor XIIa inhibitors, initially being advanced with the potential to provide the next generation of HAE therapeutics. IND-enabling studies for potential oral Factor XIIa inhibitor candidates are expected in 2021.

**Second Fiscal Quarter Financial Results:**

- Revenue: No revenue was recognized for the three months ended October 31, 2020, compared to \$3.9 million for the same period in the prior fiscal year. The decrease of \$3.9 million was due to the expiration of the Merck Option Agreement in February 2020. No future revenue remains to be recognized under this agreement.
  - R&D Expenses: Research and development expenses were \$9.1 million for the three months ended October 31, 2020, compared to \$9.8 million for the same period in the prior fiscal year. The decrease in expenses during the quarter primarily reflects a decrease in spending on KVD001, which concluded a Phase 2 clinical trial in December 2019, a decrease in spending on KVD900, and a decrease in spending on preclinical activities. These decreases were somewhat offset by increased spending related to the development of KVD824.
  - G&A Expenses: General and administrative expenses were \$3.6 million for the three months ended October 31, 2020, compared to \$3.4 million for the same period in the prior fiscal year. The \$0.2 million increase in expenses reflects an increase in employee related expenses.
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- Net Loss: Net loss was \$10.4 million, or \$(0.58) per weighted average basic and diluted share, for the three months ended October 31, 2020, compared to net loss of \$5.9 million, or \$(0.33) 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 October 31, 2020 compared to the same period in the prior fiscal year was primarily due to the decrease in revenue in the three months ended October 31, 2020.
- Cash: Cash, cash equivalents and marketable securities were \$55.9 million as of October 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. KalVista has developed a proprietary portfolio of novel, small molecule plasma kallikrein inhibitors initially targeting hereditary angioedema (HAE) and diabetic macular edema (DME). KalVista is developing KVD900 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 first quarter of 2021. KVD824 is in development for prophylactic treatment of HAE with an expected IND filing for a phase 2 clinical trial in the first quarter of 2021. KalVista's recently announced oral Factor XIIa inhibitor program represents a new generation of therapies that may further improve the treatment of HAE for patients. 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](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, 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, our expectations about safety and efficacy of our product candidates and timing of clinical trials and its results, our ability to commence or complete clinical studies and to obtain regulatory approvals for KVD900, KVD824 and other candidates in development, the ability of KVD900, KVD824 and other candidates in development to treat HAE or DME, the future progress and potential success of our oral Factor XIIa program, 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 financial results are detailed in our annual report on Form 10-K filed on July 1, 2020, our quarterly reports on Form 10-Q, 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.**

Leah Monteiro

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

	<u>October 31,</u> <u>2020</u>	<u>April 30,</u> <u>2020</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 16,174	\$ 15,789
Marketable securities	39,700	51,925
Research and development tax credit receivable	14,685	16,527
Prepaid expenses and other current assets	<u>1,517</u>	<u>4,455</u>
<b>Total current assets</b>	72,076	88,696
Property and equipment, net	1,889	2,043
Right of use assets	1,305	1,612
Other assets	178	178
<b>Total assets</b>	<u><u>\$ 75,448</u></u>	<u><u>\$ 92,529</u></u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 2,173	\$ 1,677
Accrued expenses	6,941	5,455
Lease liability - current portion	<u>422</u>	<u>588</u>
<b>Total current liabilities</b>	9,536	7,720
Long-term liabilities:		
Lease liability - net of current portion	<u>932</u>	<u>1,057</u>
<b>Total long-term liabilities</b>	932	1,057
Stockholders' equity:		
Common stock, \$0.001 par value	18	18
Additional paid-in capital	209,750	207,208
Accumulated deficit	(142,832)	(121,592)
Accumulated other comprehensive loss	<u>(1,956)</u>	<u>(1,882)</u>
<b>Total stockholders' equity</b>	64,980	83,752
<b>Total liabilities and stockholders' equity</b>	<u><u>\$ 75,448</u></u>	<u><u>\$ 92,529</u></u>

**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,	
	2020	2019	2020	2019
<b>Revenue</b>	\$ —	\$ 3,920	\$ —	\$ 7,289
<b>Operating expenses:</b>				
Research and development	9,148	9,789	20,313	19,476
General and administrative	3,633	3,420	6,912	6,665
<b>Total operating expenses</b>	<u>12,781</u>	<u>13,209</u>	<u>27,225</u>	<u>26,141</u>
<b>Operating loss</b>	<u>(12,781)</u>	<u>(9,289)</u>	<u>(27,225)</u>	<u>(18,852)</u>
<b>Other income:</b>				
Interest income	193	505	451	1,095
Foreign currency exchange rate gain (loss)	(24)	560	414	108
Other income	2,186	2,321	5,119	4,408
<b>Total other income</b>	<u>2,355</u>	<u>3,386</u>	<u>5,984</u>	<u>5,611</u>
<b>Net loss</b>	<u>\$ (10,426)</u>	<u>\$ (5,903)</u>	<u>\$ (21,241)</u>	<u>\$ (13,241)</u>
Net loss per share, basic and diluted	\$ (0.58)	\$ (0.33)	\$ (1.19)	\$ (0.75)
Weighted average common shares outstanding, basic and diluted	17,907,393	17,823,302	17,877,988	17,656,150

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

	Six Months Ended October 31,	
	2020	2019
<b>Cash flows from operating activities</b>		
Net loss	\$ (21,241)	\$ (13,241)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	261	248
Stock-based compensation expense	2,436	2,236
Realized gain from sale of marketable securities	(116)	(129)
Non-cash operating lease expense	17	2
Amortization of premium on marketable securities	137	79
Foreign currency exchange (gain) loss	(168)	(81)
Changes in operating assets and liabilities:		
Research and development tax credit receivable	2,322	(577)
Prepaid expenses and other current assets	3,031	785
Accounts payable	446	(558)
Accrued expenses	1,335	(564)
Deferred revenue	—	(7,289)
Net cash used in operating activities	<u>(11,540)</u>	<u>(19,089)</u>
<b>Cash flows from investing activities</b>		
Purchases of marketable securities	(19,342)	(42,561)
Sales and maturities of marketable securities	31,261	39,729
Acquisition of property and equipment	(35)	(212)
Net cash provided by (used in) investing activities	<u>11,884</u>	<u>(3,044)</u>
<b>Cash flows from financing activities</b>		
Issuance of common stock, net of offering expenses	—	11,422
Issuance of common stock from equity incentive plans	106	170
Finance lease principal payments	—	(54)
Net cash provided by financing activities	<u>106</u>	<u>11,538</u>
Effect of exchange rate changes on cash and cash equivalents	<u>(65)</u>	<u>308</u>
Net increase (decrease) in cash and cash equivalents	385	(10,287)
Cash and cash equivalents at beginning of period	15,789	32,006
Cash and cash equivalents at end of period	<u>\$ 16,174</u>	<u>\$ 21,719</u>

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