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 9, 2021

KALVISTA PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-36830**	**20-0915291**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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 September 9, 2021, KalVista Pharmaceuticals, Inc. (the "Company") reported its financial results for the fiscal quarter ended July 31, 2021. 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 Number	Description
99.1	Press release dated September 9, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: September 9, 2021

By: /s/ Benjamin L. Palleiko

Benjamin L. Palleiko
Chief Business Officer and Chief Financial Officer

Exhibit 99.1

KalVista Pharmaceuticals Reports First Fiscal Quarter Results

– FDA End-of-Phase 2 Meeting for KVD900 Oral HAE Phase 3 Program Scheduled for This Month –
– KVD824 Phase 2 KOMPLETE Clinical Trial Enrolling –

Cambridge, MA and Salisbury, England, September 9, 2021 – 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, 2021.

"We have made excellent progress in the rollout of our Phase 2 KOMPLETE clinical trial for KVD824," said Andrew Crockett, Chief Executive Officer of KalVista. "Site initiations are underway, and patients are being enrolled in the trial to evaluate KVD824 as a potential oral prophylactic treatment for HAE. We will be having an end-of-Phase 2 meeting with the FDA later this month regarding KVD900, our oral on-demand candidate for treatment of HAE attacks and are ready to initiate the Phase 3 study quickly afterwards. We look forward to advancing both of these compounds as we continue with our strategy of bringing a full spectrum of oral treatment options to HAE patients."

First Fiscal Quarter and Recent Business Highlights:

- Presented Phase 2 data for KVD900 in late-breaking session at European Academy of Allergy and Clinical Immunology (EAACI) Congress. The data showed that a single on-demand treatment with orally administered KVD900 significantly slows progression and accelerates resolution of attacks in patients with hereditary angioedema (HAE). KalVista also presented four other posters at EAACI related to the HAE clinical landscape and unmet needs, as well as preclinical data from other oral molecules.
- Scheduled an end-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) to review the proposed development plans for KVD900, KalVista's oral on-demand candidate for treatment of HAE attacks, expected to take place in September 2021. KVD900 also received Orphan Drug Designation from the FDA.
- Presented data at the International Society on Thrombosis and Haemostasis (ISTH) Virtual Congress showcasing small molecule Factor XIIa inhibitor research.
- Provided a progress update on the KVD824 Phase 2 KOMPLETE Clinical Trial. KVD824 is in development for oral prophylactic treatment of HAE. Regulatory submissions have been approved in Canada, Australia, and the UK with patient enrollment now underway. KalVista also submitted a response to the clinical hold related to the U.S. Investigational New Drug (IND) filing for KVD824 and is prepared to initiate the study in the U.S. upon clearance from the FDA.
- Presented KVD001 data at American Chemical Society (ACS) Meeting.

First Fiscal Quarter Financial Results:

- Revenue: No revenue was recognized for the three months ended July 31, 2021 or July 31, 2020.

- R&D Expenses: Research and development expenses were $13.7 million for the three months ended July 31, 2021, compared to $11.2 million for the same period in the prior fiscal year. The increase in R&D expenses during the quarter primarily reflects increased preclinical spending and the ongoing clinical trial for KVD824, offset by a decrease in spending on KVD900 and KVD001 due to their concluded Phase 2 clinical trials in February 2021 and December 2019, respectively.
- G&A Expenses: General and administrative expenses were $5.9 million for the three months ended July 31, 2021, compared to $3.3 million for the same period in 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 other administrative costs.
- Net Loss: Net loss was $16.1 million, or $(0.66) per weighted average basic and diluted share, for the three months ended July 31, 2021, compared to net loss of $10.8 million, or $(0.61) 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 primarily resulted from the increase in operating expenses, primarily research and development.
- Cash Position: Cash, cash equivalents and marketable securities were $230.6 million as of July 31, 2021, compared to $248.9 million as of April 30, 2021. The decrease in the net cash position was due to increased operating expenses.

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 oral on-demand therapy for acute HAE attacks, which completed a Phase 2 efficacy trial in February 2021, demonstrating statistical and clinical significance across all endpoints. KVD824 is in development for prophylactic treatment of HAE with the Phase 2 KOMPLETE clinical trial underway. In addition, KalVista's 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, called KVD001, has completed a Phase 2 clinical trial.

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, 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, including our Phase 2 KOMPLETE clinical trial, and to obtain regulatory approvals for KVD900, KVD824 and other candidates in development, our ability to resolve a clinical hold with regards to KVD824,

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 filings with the Securities and Exchange Commission, including in our annual report on Form 10-K for the year ended April 30, 2021, our quarterly reports on Form 10-Q, and our other reports that 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@kalvista.com

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

	July 31, 2021	April 30, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 48,343	$ 50,592
Marketable securities	182,288	198,337
Research and development tax credit receivable	13,613	10,418
Prepaid expenses and other current assets	5,538	4,917
Total current assets	249,782	264,264
Property and equipment, net	1,944	1,791
Right of use assets	7,207	5,758
Other assets	200	200
Total assets	**$ 259,133**	**$ 272,013**
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,448	$ 1,981
Accrued expenses	5,876	6,930
Lease liability - current portion	905	863
Total current liabilities	8,229	9,774
Long-term liabilities:		
Lease liability - net of current portion	6,474	5,046
Total long-term liabilities	6,474	5,046
Stockholders’ equity:		
Common stock, $0.001 par value	24	24
Additional paid-in capital	429,840	426,437
Accumulated deficit	(183,945)	(167,836)
Accumulated other comprehensive loss	(1,489)	(1,432)
Total stockholders’ equity	244,430	257,193
Total liabilities and stockholders' equity	**$ 259,133**	**$ 272,013**

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

	Three Months Ended July 31,	
	2021	**2020**
Revenue	**$ —**	**$ —**
Operating expenses:		
Research and development	13,669	11,165
General and administrative	5,847	3,278
Total operating expenses	19,516	14,443
Operating loss	**(19,516)**	**(14,443)**
Other income:		
Interest income	274	259
Foreign currency exchange rate (loss) gain	(51)	438
Other income	3,184	2,932
Total other income	**3,407**	**3,629**
Net loss	**$ (16,109)**	**$ (10,814)**
Net loss per share, basic and diluted	**$ (0.66)**	**$ (0.61)**
Weighted average common shares outstanding, basic and diluted	24,429,919	17,848,583

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

	Three Months Ended July 31,	
	2021	**2020**
Cash flows from operating activities		
Net loss	$ (16,109)	$ (10,814)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	132	128
Stock-based compensation expense	2,795	1,188
Realized loss (gain) from sale of marketable securities	23	(70)
Non-cash operating lease expense	22	8
Amortization of premium on marketable securities	753	68
Foreign currency exchange loss (gain)	14	(432)
Changes in operating assets and liabilities:		
Research and development tax credit receivable	(3,211)	4,462
Prepaid expenses and other current assets	(625)	1,301
Accounts payable	(528)	35
Accrued expenses	(1,001)	538
Net cash used in operating activities	(17,735)	(3,588)
Cash flows from investing activities		
Purchases of marketable securities	(19,036)	(9,807)
Sales and maturities of marketable securities	34,204	15,342
Acquisition of property and equipment	(287)	(22)
Net cash provided by investing activities	14,881	5,513
Cash flows from financing activities		
Issuance of common stock from equity incentive plans	608	46
Net cash provided by financing activities	608	46
Effect of exchange rate changes on cash and cash equivalents	(3)	254
Net (decrease) increase in cash and cash equivalents	(2,249)	2,225
Cash and cash equivalents at beginning of period	50,592	15,789
Cash and cash equivalents at end of period	$ 48,343	$ 18,014