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 09, 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)**

Registrant's Telephone Number, Including Area Code: 857 999-0075

(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 9, 2021, KalVista Pharmaceuticals, Inc. (the "Company") reported its financial results for the fiscal quarter ended October 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 December 9, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

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 thereunto duly authorized.

KALVISTA PHARMACEUTICALS, INC.

Date: December 9, 2021

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

Exhibit 99.1

KalVista Pharmaceuticals Reports Second Fiscal Quarter Results

– Preparing for Initiation of KVD900 Phase 3 Clinical Trial–

– KVD824 Phase 2 KOMPLETE Clinical Trial Enrolling –

– Funded Beyond Data on Both HAE Trials –

Cambridge, MA and Salisbury, England, December 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 second fiscal quarter ended October 31, 2021.

“This quarter we made great strides in advancing the two distinct compounds in our oral hereditary angioedema franchise into later stage trials. We are very pleased with the Phase 3 trial design for KVD900, our candidate for on-demand HAE therapy, where we believe the primary endpoint is both meaningful to patients and was successful in our Phase 2 trial. The KVD824 KOMPLETE Phase 2 protocol for prophylactic treatment of HAE has regulatory approvals in 12 of the 13 countries where the trial will be conducted,” said Andrew Crockett, Chief Executive Officer of KalVista. “Importantly, we are funded into at least early 2024, beyond both the KVD900 Phase 3 and KVD824 Phase 2 clinical trial data sets.”

Second Fiscal Quarter and Recent Business Highlights:

- Initiated KOMPLETE, the Phase 2 clinical trial of KVD824 that is currently enrolling patients.
- Presented Phase 2 data for KVD900 at American College of Allergy, Asthma & Immunology (ACAAI) Annual Scientific Meeting. Data presentations included an oral presentation and poster presentation on Phase 2 clinical trial data. The data showed that KVD900 was rapidly absorbed which was associated with a significantly shorter median time to initial symptom relief with KVD900 than with placebo. Patient reported outcomes captured in the phase 2 trial suggested that attack symptom improvement with use of KVD900 was clinically meaningful from the patients’ perspective.
- Completed an End-of-Phase 2 meeting with the FDA which confirmed that KalVista’s Phase 3 trial design, similar to the successful Phase 2 trial, is expected to be appropriate to support an NDA submission. The primary endpoint of this Phase 3 trial is time to beginning of symptom relief using the PGI-C scale that was one of the endpoints in the Phase 2 study. The trial is expected to be conducted at more than 50 sites worldwide and recruit approximately 100 patients, consistent with late stage trials of approved on-demand treatments for HAE. The trial is intended to evaluate all HAE attacks, including laryngeal attacks and breakthrough attacks for patients using prophylaxis. Similar to the

Phase 2 trial for KVD900, patients will administer treatment as soon as they recognize the onset of an attack. Patients are expected to begin dosing in the trial during the first quarter of calendar year 2022.

Second Fiscal Quarter Financial Results:

- Revenue: No revenue was recognized for the three months ended October 31, 2021 or October 31, 2020.
- R&D Expenses: Research and development expenses were $17.5 million for the three months ended October 31, 2021, compared to $9.1 million for the same period in the prior fiscal year. The increase in R&D expenses during the quarter primarily reflects increased preclinical spending, the ongoing Phase 2 KOMPLETE clinical trial for KVD824, and the ongoing preparation for the Phase 3 clinical trial for KVD900.
- G&A Expenses: General and administrative expenses were $6.1 million for the three months ended October 31, 2021, compared to $3.6 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 facility expenses, commercial planning expenses, and other administrative costs.
- Net Loss: Net loss was $19.7 million, or $(0.80) per weighted average basic and diluted share, for the three months ended October 31, 2021, compared to net loss of $10.4 million, or $(0.58) 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 $209.8 million as of October 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 the KOMPLETE Clinical Trial

KOMPLETE is the worldwide Phase 2 clinical trial of KVD824 as a potential oral prophylactic therapy for HAE. The trial is a randomized, double-blind, parallel group design evaluating twice-daily dosing of 300 mg, 600 mg, and 900 mg KVD824 against placebo for 12 weeks. KOMPLETE is intended to enroll 48 HAE patients randomized into four equal arms after they report experiencing a minimum of three attacks in an eight-week run-in period. The primary endpoint of the trial is the rate of investigator confirmed HAE attacks during the treatment period. Secondary endpoints include the proportion of participants without investigator confirmed HAE attacks and the rate of investigator confirmed HAE attacks that require conventional treatment. KOMPLETE will be conducted at more than 30 sites in 13 countries.

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

	October 31, 2021	April 30, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 46,491	$ 50,592
Marketable securities	163,322	198,337
Research and development tax credit receivable	17,399	10,418
Prepaid expenses and other current assets	7,266	4,917
Total current assets	234,478	264,264
Property and equipment, net	2,180	1,791
Right of use assets	6,959	5,758
Other assets	193	200
Total assets	**$ 243,810**	**$ 272,013**
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,159	$ 1,981
Accrued expenses	6,025	6,930
Lease liability - current portion	930	863
Total current liabilities	10,114	9,774
Long-term liabilities:		
Lease liability - net of current portion	6,224	5,046
Total long-term liabilities	6,224	5,046
Stockholders’ equity:		
Common stock, $0.001 par value	24	24
Additional paid-in capital	432,763	426,437
Accumulated deficit	(203,595)	(167,836)
Accumulated other comprehensive loss	(1,720)	(1,432)
Total stockholders’ equity	227,472	257,193
Total liabilities and stockholders' equity	**$ 243,810**	**$ 272,013**

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,	
	2021	**2020**	**2021**	**2020**
Revenue	**$—**	**$—**	**$—**	**$—**
Operating expenses:				
Research and development	17,546	9,148	31,215	20,313
General and administrative	6,057	3,633	11,903	6,912
Total operating expenses	23,603	12,781	43,118	27,225
Operating loss	**(23,603)**	**(12,781)**	**(43,118)**	**(27,225)**
Other income:				
Interest income	290	193	564	451
Foreign currency exchange rate (loss) gain	(280)	(24)	(331)	414
Other income	3,943	2,186	7,127	5,119
Total other income	**3,953**	**2,355**	**7,360**	**5,984**
Net loss	**$(19,650)**	**$(10,426)**	**$(35,758)**	**$(21,241)**
Net loss per share, basic and diluted	**$(0.80)**	**$(0.58)**	**$(1.46)**	**$(1.19)**
Weighted average common shares outstanding, basic and diluted	24,439,623	17,907,393	24,434,852	17,877,988

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

	Six Months Ended October 31,	
	2021	**2020**
Cash flows from operating activities		
Net loss	$ (35,758)	$ (21,241)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	259	261
Stock-based compensation expense	5,655	2,436
Realized loss (gain) from sale of marketable securities	120	(116)
Non-cash operating lease expense	46	17
Amortization of premium on marketable securities	1,424	137
Foreign currency exchange loss (gain)	266	(168)
Changes in operating assets and liabilities:		
Research and development tax credit receivable	(7,252)	2,322
Prepaid expenses and other current assets	(2,419)	3,031
Accounts payable	1,163	446
Accrued expenses	(784)	1,335
Net cash used in operating activities	(37,280)	(11,540)
Cash flows from investing activities		
Purchases of marketable securities	(51,695)	(19,342)
Sales and maturities of marketable securities	84,862	31,261
Acquisition of property and equipment	(643)	(35)
Net cash provided by investing activities	32,524	11,884
Cash flows from financing activities		
Issuance of common stock from equity incentive plans	671	106
Net cash provided by financing activities	671	106
Effect of exchange rate changes on cash and cash equivalents	(16)	(65)
Net (decrease) increase in cash and cash equivalents	(4,101)	385
Cash and cash equivalents at beginning of period	50,592	15,789
Cash and cash equivalents at end of period	$ 46,491	$ 16,174