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 05, 2024

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 September 5, 2024, KalVista Pharmaceuticals, Inc. (the "Company") reported its financial results for the fiscal quarter ended July 31, 2024. 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 5, 2024
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: September 5, 2024

By: /s/ Benjamin L. Palleiko

Benjamin L. Palleiko
Chief Executive Officer
(Principal Executive, Financial and Accounting Officer)

Exhibit 99.1

KalVista Pharmaceuticals Reports First Fiscal Quarter Results and Provides Operational Update

–U.S. FDA accepts NDA for sebetralstat for oral on-demand treatment of HAE; Sets PDUFA goal date of June 17, 2025–

–European Medicines Agency (EMA) validated the submission of Marketing Authorization Application (MAA) for sebetralstat–

Cambridge, MA and Salisbury, England, September 5, 2024 – KalVista Pharmaceuticals, Inc. (NASDAQ: KALV), today provided an operational update and released financial results for the first fiscal quarter ended July 31, 2024.

"We are excited about the steady progress we've made over the last few months including the most recent acceptance of our NDA by FDA and the EMA's validation of our MAA," said Ben Palleiko, CEO of KalVista. "We look forward to building on these recent milestones as we move toward filing for approval in the UK, Japan, and other countries later in 2024 and aim for our first commercial launch of sebetralstat in June 2025. I am grateful for the hard work of the entire KalVista team as we remain dedicated to getting this important treatment to people living with HAE."

First Fiscal Quarter and Recent Business Highlights:

Sebetralstat

- In September, KalVista announced the U.S. Food and Drug Administration (FDA) accepted its New Drug Application (NDA) for sebetralstat, a novel, investigational oral plasma kallikrein inhibitor for the on-demand treatment of hereditary angioedema (HAE) attacks in adult and pediatric patients aged 12 years and older. The FDA has set a Prescription Drug User Fee Act (PDUFA) goal date of June 17, 2025.
- Last month, the Company announced that the European Medicines Agency (EMA) validated the submission of the Marketing Authorization Application (MAA) for sebetralstat.
- KalVista expects to file for approval in the UK, Japan, and other countries later in 2024. The Company has also engaged with the Access Consortium to maximize regulatory collaboration across countries and support a timely review process.
- In June, ahead of schedule, KalVista initiated a pediatric clinical trial (KONFIDENT-KID) using an orally disintegrating tablet (ODT) formulation of sebetralstat designed for this population. KONFIDENT-KID will enroll approximately 24 children, with an age range of 2 to 11 years, across seven countries in North America, Europe and Asia. The trial has since started dosing patients and if approved, sebetralstat would be the first oral, on demand treatment for this population and only the second approved on-demand therapy of any type.
- Data from the phase 3 KONFIDENT trial of sebetralstat was published in the *New England Journal of Medicine* (NEJM) and presented at the European Academy of Allergy and Clinical Immunology Congress 2024 (EAACI).

First Fiscal Quarter Financial Results

- Revenue: No revenue was recognized for the three months ended July 31, 2024, or July 31, 2023, respectively.
- R&D Expenses: Research and development expenses were $26.6 million for the three months ended July 31, 2024, compared to $19.3 million for the same period in the prior fiscal year. The increase in R&D expenses during the quarter primarily reflects the phase 3 KONFIDENT trial which concluded in February 2024, the ongoing KONFIDENT-S trial, and a headcount driven increase in personnel costs.
- G&A Expenses: General and administrative expenses were $17.6 million for the three months ended July 31, 2024, compared to $9.8 million for the same period in the prior fiscal year. The increase in G&A expenses was primarily due to increases in commercial planning expenses and employee-related expenses.
- Net Loss: Net loss was $40.4 million, or $(0.87) per weighted average basic and diluted share, for the three months ended July 31, 2024, compared to net loss of $25.3 million, or $(0.74) 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, both research and development and general and administrative.
- Cash position: Cash, cash equivalents and marketable securities were $174.3 million on July 31, 2024, compared to $210.4 million on April 30, 2024. The decrease in the net cash and marketable securities position was due to cash consumption from operating expenses.

About KalVista Pharmaceuticals, Inc.

KalVista Pharmaceuticals, Inc. is a global pharmaceutical company focused on the development and delivery of oral medicines for diseases with significant unmet need. KalVista announced positive phase 3 data from the KONFIDENT trial for its oral, on-demand therapy, sebetralstat for HAE in February 2024. The Company’s NDA for sebetralstat has been accepted by the FDA with a PDUFA goal date of June 17, 2025. KalVista received validation of its MAA from the EMA in August 2024. KalVista expects to file for approval in the UK, Japan, and other countries later in 2024.

For more information about KalVista, please visit **www.kalvista.com** or follow on social media at **@KalVista** and **LinkedIn**.

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, timing or outcomes of communications with the FDA, our expectations about safety and efficacy of our product candidates and timing of clinical trials and its results, our ability to commence clinical studies or complete ongoing clinical studies, including our KONFIDENT-S and KONFIDENT-KID trials, and to obtain regulatory approvals for sebetralstat and other candidates in development, the success of any efforts to commercialize sebetralstat, the ability of sebetralstat and other candidates in

development to treat HAE or other diseases, and the future progress and potential success of our oral Factor XIIa program. 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, 2024, 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.

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Exhibit 99.1

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

	July 31, 2024	April 30, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 31,848	$ 31,789
Marketable securities	142,424	178,612
Research and development tax credit receivable	9,908	8,439
Prepaid expenses and other current assets	7,454	6,850
Total current assets	191,634	225,690
Property and equipment, net	2,100	2,227
Right of use assets	5,859	6,920
Other assets	605	567
Total assets	**$ 200,198**	**$ 235,404**
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 10,792	$ 9,107
Accrued expenses	10,355	12,398
Lease liability - current portion	1,264	1,302
Total current liabilities	22,411	22,807
Long-term liabilities:		
Lease liability - net of current portion	4,988	6,015
Total long-term liabilities	4,988	6,015
Stockholders’ equity:		
Common stock, $0.001 par value	43	42
Additional paid-in capital	685,794	679,754
Accumulated deficit	(510,169)	(469,726)
Accumulated other comprehensive loss	(2,869)	(3,488)
Total stockholders’ equity	172,799	206,582
Total liabilities and stockholders' equity	**$ 200,198**	**$ 235,404**

Exhibit 99.1

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

	Three Months Ended July 31,	
	2024	**2023**
Revenue	**$ —**	**$ —**
Operating expenses:		
Research and development	26,614	19,307
General and administrative	17,601	9,786
Total operating expenses	44,215	29,093
Operating loss	**(44,215)**	**(29,093)**
Other income:		
Interest income	1,692	923
Foreign currency exchange gain	514	456
Other income	1,566	2,397
Total other income	**3,772**	**3,776**
Net loss	**$ (40,443)**	**$ (25,317)**
Net loss per share, basic and diluted	**$ (0.87)**	**$ (0.74)**
Weighted average common shares outstanding, basic and diluted	46,232,977	34,414,226

Exhibit 99.1

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

	Three Months Ended July 31,	
	2024	**2023**
Cash flows from operating activities		
Net loss	$ (40,443)	$ (25,317)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	224	193
Stock-based compensation expense	3,040	3,254
Realized gain from sale of marketable securities	(317)	(314)
Non-cash operating lease (benefit) expense	(5)	6
Amortization of premium on marketable securities	5	62
Foreign currency exchange gain	(414)	(395)
Changes in operating assets and liabilities:		
Research and development tax credit receivable	(1,253)	(2,084)
Prepaid expenses and other current assets	(783)	(1,003)
Accounts payable	1,502	108
Accrued expenses	(1,776)	(1,240)
Net cash used in operating activities	(40,220)	(26,730)
Cash flows from investing activities		
Purchases of marketable securities	(983)	(25,767)
Sales and maturities of marketable securities	38,230	45,386
Acquisition of property and equipment	(21)	(6)
Capitalized website development costs	(64)	-
Net cash provided by investing activities	37,162	19,613
Cash flows from financing activities		
Issuance of common stock from equity incentive plans	3,000	204
Net cash provided by financing activities	3,000	204
Effect of exchange rate changes on cash and cash equivalents	117	84
Net increase (decrease) in cash and cash equivalents	59	(6,829)
Cash and cash equivalents at beginning of period	31,789	56,238
Cash and cash equivalents at end of period	$ 31,848	$ 49,409