

**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 08, 2022

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**
(Address of Principal Executive Offices)

02142
(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 8, 2022, KalVista Pharmaceuticals, Inc. (the “Company”) reported its financial results for the fiscal quarter ended July 31, 2022. 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

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press release dated September 8, 2022
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 8, 2022

By: /s/ Benjamin L. Palleiko

Benjamin L. Palleiko

Chief Business Officer and Chief Financial Officer

KalVista Pharmaceuticals Reports First Fiscal Quarter Results

- *KVD824 Phase 2 Clinical Trial Reaches 50% Enrollment Milestone* -
 - *Open Label Extension Study Initiated for Sebetrastat* -

Cambridge, MA and Salisbury, England, September 8, 2022 – KalVista Pharmaceuticals, Inc. (NASDAQ: KALV), a clinical stage pharmaceutical company focused on the discovery, development, and commercialization of oral, small molecule protease inhibitors, today provided an operational update and released financial results for the first fiscal quarter ended July 31, 2022.

“We are pleased to announce we have surpassed the 50% enrollment mark for our KVD824 KOMPLETE Phase 2 clinical trial, a major milestone in its development as a potential oral prophylactic treatment for hereditary angioedema (HAE),” said Andrew Crockett, Chief Executive Officer of KalVista. “Enrollment for our Phase 3 KONFIDENT trial for the first potential oral on-demand HAE treatment is also progressing as anticipated. We look forward to continuing to advance both programs 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:

- Announced the initiation of the KONFIDENT-S open label extension study for sebetrastat in the on-demand treatment of HAE. The study will provide up to two years of additional safety and tolerability data, assess sebetrastat’s pharmacokinetic (PK) profile in adolescents aged 12-17, and evaluate the compound for use as a short-term prophylactic treatment prior to medical procedures.
- Reported new data from the Phase 2 clinical trial of sebetrastat at the Australasian Society of Clinical Immunology and Allergy (ASCIA) 2022 conference. The data showed that sebetrastat treatment provided relief of mild and moderate HAE attacks, showing meaningful treatment effect regardless of baseline attack severity, as shown by measurements of Patient Global Impression of Change (PGI-C), Patient Global Impression of Severity (PGI-S), and Visual Analog Scale (VAS).
- Enrollment is proceeding as expected for the Phase 3 KONFIDENT trial for sebetrastat, with data expected in the second half of 2023. The Phase 2 KOMPLETE clinical trial for KVD824 also remains on track with its enrollment targets. Data from the KOMPLETE trial is expected in mid-2023.
- Presented at the 1st Annual H.C. Wainwright Hereditary Angioedema Conference. KalVista CEO Andrew Crockett also participated on an expert panel discussing oral treatments in HAE.

First Fiscal Quarter Financial Results:

- Revenue: No revenue was recognized for the three months ended July 31, 2022 or July 31, 2021.
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- **R&D Expenses:** Research and development expenses were \$18.2 million for the three months ended July 31, 2022, compared to \$13.7 million for the same period in the prior fiscal year. The increase in R&D expenses during the quarter primarily reflects the ongoing Phase 3 KONFIDENT trial for sebetralstat, increased preclinical spending, and increased personnel costs.
- **G&A Expenses:** General and administrative expenses were \$8.1 million for the three months ended July 31, 2022, compared to \$5.9 million for the same period in the prior fiscal year. The increase in G&A expenses was primarily due to an increase in commercial planning expenses, investor and public relations expenses, and to a lesser extent, increases in compensation expenses and other administrative costs.
- **Net Loss:** Net loss was \$23.0 million, or \$(0.94) per weighted average basic and diluted share, for the three months ended July 31, 2022, compared to net loss of \$16.1 million, or \$(0.66) 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 \$142.1 million as of July 31, 2022, compared to \$166.2 million as of April 30, 2022. 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 pharmaceutical company focused on the discovery, development, and commercialization of oral, 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 sebetralstat as an oral on-demand therapy for acute HAE attacks and is enrolling the Phase 3 KONFIDENT clinical trial. KVD824 is in development for prophylactic treatment of HAE, with the Phase 2 KOMLETE 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 about KalVista, please visit www.kalvista.com.

For more information on the sebetralstat HAE on-demand Phase 3 KONFIDENT study, please visit www.konfidentstudy.com.

For more information on the KVD824 HAE prophylaxis Phase 2 KOMLETE study, please visit www.kompletestudy.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, 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 Phase 3 KONFIDENT and Phase 2 KOMplete clinical trials, and to obtain regulatory approvals for sebetralstat, KVD824 and other candidates in development, the ability of sebetralstat, KVD824 and other candidates in development to treat HAE or DME, and the future progress and potential success of our oral Factor XIIIa 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, 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.

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

	<u>July 31, 2022</u>	<u>April 30, 2022</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 37,863	\$ 30,732
Marketable securities	104,212	135,470
Research and development tax credit receivable	17,248	14,098
Prepaid expenses and other current assets	11,084	13,347
Total current assets	<u>170,407</u>	<u>193,647</u>
Property and equipment, net	3,030	2,178
Right of use assets	8,664	7,862
Other assets	218	193
Total assets	<u>\$ 182,319</u>	<u>\$ 203,880</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,908	\$ 3,638
Accrued expenses	5,828	6,961
Lease liability - current portion	997	977
Total current liabilities	<u>9,733</u>	<u>11,576</u>
Long-term liabilities:		
Lease liability - net of current portion	8,014	7,211
Total long-term liabilities	<u>8,014</u>	<u>7,211</u>
Stockholders' equity:		
Common stock, \$0.001 par value	25	25
Additional paid-in capital	441,914	439,104
Accumulated deficit	(273,217)	(250,175)
Accumulated other comprehensive loss	(4,150)	(3,861)
Total stockholders' equity	<u>164,572</u>	<u>185,093</u>
Total liabilities and stockholders' equity	<u>\$ 182,319</u>	<u>\$ 203,880</u>

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

	Three Months Ended July 31,	
	2022	2021
Revenue	\$ —	\$ —
Operating expenses:		
Research and development	18,186	13,669
General and administrative	8,130	5,847
Total operating expenses	26,316	19,516
Operating loss	(26,316)	(19,516)
Other income:		
Interest income	242	274
Foreign currency exchange (loss) gain	(517)	(51)
Other income	3,549	3,184
Total other income	3,274	3,407
Net loss	\$ (23,042)	\$ (16,109)
Net loss per share, basic and diluted	\$ (0.94)	\$ (0.66)
Weighted average common shares outstanding, basic and diluted	24,557,615	24,429,919

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

	Three Months Ended	
	July 31,	
	2022	2021
Cash flows from operating activities		
Net loss	\$ (23,042)	\$ (16,109)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	158	132
Stock-based compensation expense	2,642	2,795
Realized loss (gain) from sale of marketable securities	16	23
Non-cash operating lease expense	23	22
Amortization of premium on marketable securities	391	753
Foreign currency exchange loss (gain)	426	14
Changes in operating assets and liabilities:		
Research and development tax credit receivable	(3,570)	(3,211)
Prepaid expenses and other current assets	1,935	(625)
Accounts payable	(678)	(528)
Accrued expenses	(1,043)	(1,001)
Net cash used in operating activities	(22,742)	(17,735)
Cash flows from investing activities		
Purchases of marketable securities	(10,102)	(19,036)
Sales and maturities of marketable securities	41,066	34,204
Acquisition of property and equipment	(920)	(287)
Net cash provided by investing activities	30,044	14,881
Cash flows from financing activities		
Issuance of common stock from equity incentive plans	168	608
Net cash provided by financing activities	168	608
Effect of exchange rate changes on cash and cash equivalents	(339)	(3)
Net increase (decrease) in cash and cash equivalents	7,131	(2,249)
Cash and cash equivalents at beginning of period	30,732	50,592
Cash and cash equivalents at end of period	\$ 37,863	\$ 48,343

