

**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): March 09, 2023

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 March 9, 2023, KalVista Pharmaceuticals, Inc. (the “Company”) reported its financial results for the fiscal quarter ended January 31, 2023. 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 March 9, 2023
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: March 9, 2023

By: /s/ Benjamin L. Palleiko
Benjamin L. Palleiko
President, Chief Business Officer and Chief Financial Officer
(Principal Financial and Accounting Officer)

KalVista Pharmaceuticals Reports Third Fiscal Quarter Results

- Enrollment in sebetralstat KONFIDENT phase 3 trial passes 50% milestone; data remains H2 2023 -

- Sebetralstat phase 2 data published in *The Lancet* -

- Company funded into 2025 -

Cambridge, MA and Salisbury, England, March 9, 2023 –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 third fiscal quarter ended January 31, 2023.

“We have made significant advances at KalVista over this quarter, including completing a financing that funds us into 2025, well beyond our phase 3 data results, which remain on track for the second half of this year,” said Andrew Crockett, Chief Executive Officer of KalVista. “We continue to publish sebetralstat data across a wide variety of outlets, including influential medical journals such as *The Lancet*, and make presentations at prestigious medical and patient meetings. We remain committed to addressing the unmet needs of the hereditary angioedema (HAE) community by providing sebetralstat as a significant advancement in treatment for this disease.”

Third Fiscal Quarter and Recent Business Highlights:

- Reported new data in five posters at the 2023 American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting. The data showed the impact of HAE attacks on anxiety and quality of life in people living with HAE, that sebetralstat significantly decreased cumulative attack and symptom severity while increasing cumulative symptom relief of HAE attacks relative to placebo over a 24-hour period following administration, and that phase 1 data for an orally disintegrating tablet formulation supported further clinical development of that formulation.
 - Provided multiple progress updates on sebetralstat development, including the announcement that KalVista has enrolled more than 50% of the targeted number of patients in the pivotal phase 3 KONFIDENT clinical trial. In addition, the Company received FDA regulatory guidance that efficacy trials are not required to support a supplemental NDA (sNDA) filing for the orally disintegrating tablet (ODT) formulation of sebetralstat. KalVista also received guidance from the Japanese regulatory authority (PMDA) on the clinical development pathway to a regulatory submission in that country.
 - Published a manuscript in *The Lancet* focused on the phase 2 clinical trial results for sebetralstat.
 - Presented data at Western Society of Allergy, Asthma & Immunology (WSAAI) 60th Annual Scientific Session examining the use of sebetralstat as a possible treatment for short-term prophylaxis (STP) as part of the KONFIDENT-S open-label extension clinical trial. Other data assessed the pharmacokinetic and pharmacodynamic parameters of sebetralstat in Japanese adults supporting the expansion of the KONFIDENT phase 3 trial to Japan and delineated a post hoc analysis of phase 2 trial data demonstrating that sebetralstat provided similar symptom relief, reduction in attack severity, and use of rescue regardless of abdominal or peripheral attack location.
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- Promoted Chief Financial/Business Officer Benjamin L. Palleiko to President of KalVista and tasked him with the development of the Company's commercial and business organization.
- Announced \$58 million of new funding via a registered direct offering. KalVista intends to use the proceeds of this \$58 million offering to fund clinical trials, commercial sales development, research, working capital, capital expenditures and other general corporate purposes. With the financing, the Company now expects to be able to fund operations into 2025.

Third Fiscal Quarter Financial Results:

Revenue: No revenue was recognized for the three months ended January 31, 2023 or January 31, 2022.

R&D Expenses: Research and development expenses were \$20.1 million for the three months ended January 31, 2023, compared to \$19.7 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, offset by a decrease in expense from KVD824.

G&A Expenses: General and administrative expenses were \$6.9 million for the three months ended January 31, 2023, compared to \$6.9 million for the same period in the prior fiscal year. G&A expenses remained consistent primarily due to increases in commercial planning and other administrative expenses offset by decreases in employee related expenses and professional fees.

Net Loss: Net loss was \$21.3 million, or \$(0.75) per weighted average basic and diluted share, for the three months ended January 31, 2023, compared to net loss of \$22.5 million, or \$(0.92) per weighted average basic and diluted share for the same period in the prior fiscal year. The decrease in net loss and net loss per share primarily resulted from increases in interest income and currency exchange rate gains from transactions denominated in foreign currencies in our U.K. subsidiary.

Cash Position: Cash, cash equivalents and marketable securities were \$171.7 million as of January 31, 2023, compared to \$166.2 million as of April 30, 2022. The increase in the net cash and marketable securities position was primarily due to the net proceeds received from the December 2022 registered direct offering of common stock and pre-funded warrants.

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 is developing sebetralstat as an oral on-demand therapy for HAE attacks and is enrolling the Phase 3 KONFIDENT clinical trial. In addition, KalVista's oral Factor XIIa inhibitor program represents a new generation of therapies that may further improve the treatment for people living with HAE and other diseases.

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.

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 Phase 3 KONFIDENT trial, 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, 2022, 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.

Jarrod Aldom

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

	<u>January 31, 2023</u>	<u>April 30, 2022</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 85,049	\$ 30,732
Marketable securities	86,636	135,470
Research and development tax credit receivable	11,892	14,098
Prepaid expenses and other current assets	8,556	13,347
Total current assets	<u>192,133</u>	<u>193,647</u>
Property and equipment, net	3,037	2,178
Right of use assets	8,101	7,862
Other assets	197	193
Total assets	<u>\$ 203,468</u>	<u>\$ 203,880</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,698	\$ 3,638
Accrued expenses	8,851	6,961
Lease liability - current portion	1,057	977
Total current liabilities	<u>11,606</u>	<u>11,576</u>
Long-term liabilities:		
Lease liability - net of current portion	7,421	7,211
Total long-term liabilities	<u>7,421</u>	<u>7,211</u>
Stockholders' equity:		
Common stock, \$0.001 par value	34	25
Additional paid-in capital	504,725	439,104
Accumulated deficit	(316,777)	(250,175)
Accumulated other comprehensive loss	(3,541)	(3,861)
Total stockholders' equity	<u>184,441</u>	<u>185,093</u>
Total liabilities and stockholders' equity	<u>\$ 203,468</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 January 31,		Nine Months Ended January 31,	
	2023	2022	2023	2022
Revenue	\$—	\$—	\$—	\$—
Operating expenses:				
Research and development	20,063	19,738	56,325	50,954
General and administrative	6,882	6,945	22,818	18,848
Total operating expenses	<u>26,945</u>	<u>26,683</u>	<u>79,143</u>	<u>69,802</u>
Operating loss	<u>(26,945)</u>	<u>(26,683)</u>	<u>(79,143)</u>	<u>(69,802)</u>
Other income:				
Interest income	732	258	1,424	822
Foreign currency exchange rate (loss) gain	597	(198)	(237)	(529)
Other income	4,313	4,156	11,354	11,283
Total other income	<u>5,642</u>	<u>4,216</u>	<u>12,541</u>	<u>11,576</u>
Net loss	<u>\$(21,303)</u>	<u>\$(22,467)</u>	<u>\$(66,602)</u>	<u>\$(58,226)</u>
Net loss per share, basic and diluted	\$(0.75)	\$(0.92)	\$(2.58)	\$(2.38)
Weighted average common shares outstanding, basic and diluted	28,278,453	24,479,660	25,810,369	24,449,788

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

	Nine Months Ended January 31,	
	2023	2022
Cash flows from operating activities		
Net loss	\$ (66,602)	\$ (58,226)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	530	408
Stock-based compensation expense	7,481	8,432
Realized loss (gain) from sale of marketable securities	84	296
Non-cash operating lease expense	52	153
Amortization of premium on marketable securities	890	2,081
Foreign currency exchange loss (gain)	(1,339)	698
Changes in operating assets and liabilities:		
Research and development tax credit receivable	2,049	(1,477)
Prepaid expenses and other current assets	4,440	(3,659)
Accounts payable	(1,911)	228
Accrued expenses	1,701	(279)
Net cash used in operating activities	(52,625)	(51,345)
Cash flows from investing activities		
Purchases of marketable securities	(63,757)	(84,415)
Sales and maturities of marketable securities	112,509	130,686
Acquisition of property and equipment	(1,127)	(845)
Net cash provided by investing activities	47,625	45,426
Cash flows from financing activities		
Issuance of common stock from equity incentive plans	482	1,443
Issuance of common stock, net of offering expenses of \$0.3 million	56,582	-
Issuance of pre-funded warrants, net of offering expenses	1,085	-
Net cash provided by financing activities	58,149	1,443
Effect of exchange rate changes on cash and cash equivalents	1,168	(539)
Net (decrease) increase in cash and cash equivalents	54,317	(5,015)
Cash and cash equivalents at beginning of period	30,732	50,592
Cash and cash equivalents at end of period	\$ 85,049	\$ 45,577

