

**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 10, 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 March 10, 2022, KalVista Pharmaceuticals, Inc. (the “Company”) reported its financial results for the fiscal quarter ended January 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 March 10, 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: March 10, 2022

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

KalVista Pharmaceuticals Reports Third Fiscal Quarter Results

– KVD900 Phase 3 KONFIDENT Trial Initiated–

– KVD824 Phase 2 KOMLETE Clinical Trial Enrollment on Track –

Cambridge, MA and Salisbury, England, March 10, 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 third fiscal quarter ended January 31, 2022.

“We made many significant clinical advances this quarter,” said Andrew Crockett, Chief Executive Officer of KalVista. “We are excited that the KVD900 Phase 3 KONFIDENT trial for on-demand treatment of HAE attacks is now underway, and we are encouraged by the progress of our KVD824 Phase 2 KOMLETE trial for HAE prophylaxis. Based on initial enrollment trends, we expect we will be able to provide data for both studies in 2023.”

Third Fiscal Quarter and Recent Business Highlights:

- Initiated KONFIDENT, the Phase 3 clinical trial of KVD900, that is expected to be sufficient to support an NDA filing. Data from this trial is currently anticipated in the second half of 2023.
- Continued to enroll KOMLETE, the Phase 2 clinical trial of KVD824. As of early March, the trial is enrolling on track with the Company’s targets and it is currently anticipated that data from this trial will be available in mid-2023.
- Presented data for KVD900 at American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Scientific Meeting. Data presentations included two poster presentations with additional data from the Phase 2 clinical trial. The first poster showed that KVD900 was rapidly absorbed, leading to near-complete suppression of plasma kallikrein and significantly shorter time to symptom relief. The second poster provided data demonstrating that the Patient Global Impression of Change (PGI-C) scale was an effective tool to monitor attack symptoms and predict attack resolution for patients experiencing HAE attacks. PGI-C is the primary outcome measure in the KONFIDENT clinical trial.
- Continued progress in the Factor XIIa inhibitor program, with multiple compounds advancing in the preclinical stage and an expected first IND for an oral Factor XIIa inhibitor candidate in 2023.

Third Fiscal Quarter Financial Results:

- Revenue: No revenue was recognized for the three months ended January 31, 2022 or January 31, 2021.
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- **R&D Expenses:** Research and development expenses were \$19.7 million for the three months ended January 31, 2022, 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 the initiation of the Phase 3 KONFIDENT clinical trial for KVD900, the ongoing Phase 2 KOMLETE clinical trial for KVD824, and increased preclinical spending.
- **G&A Expenses:** General and administrative expenses were \$6.9 million for the three months ended January 31, 2022, 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 professional fees, commercial planning expenses, and other administrative costs.
- **Net Loss:** Net loss was \$22.5 million, or \$(0.92) per weighted average basic and diluted share, for the three months ended January 31, 2022, compared to net loss of \$10.0 million, or \$(0.56) 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 \$194.8 million as of January 31, 2022, 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 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 KVD900 as an oral on-demand therapy for acute HAE attacks and has initiated 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 KVD900 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 KVD900, KVD824 and other candidates in development, the ability of KVD900, KVD824 and other candidates in development to treat HAE or DME, 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, 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.

Ben Palleiko

CBO & CFO

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

	<u>January 31,</u> <u>2022</u>	<u>April 30,</u> <u>2021</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 45,577	\$ 50,592
Marketable securities	149,212	198,337
Research and development tax credit receivable	11,287	10,418
Prepaid expenses and other current assets	8,388	4,917
Total current assets	214,464	264,264
Property and equipment, net	2,215	1,791
Right of use assets	8,180	5,758
Other assets	193	200
Total assets	\$ 225,052	\$ 272,013
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,185	\$ 1,981
Accrued expenses	6,450	6,930
Lease liability - current portion	1,014	863
Total current liabilities	9,649	9,774
Long-term liabilities:		
Lease liability - net of current portion	7,467	5,046
Total long-term liabilities	7,467	5,046
Stockholders' equity:		
Common stock, \$0.001 par value	24	24
Additional paid-in capital	436,313	426,437
Accumulated deficit	(226,062)	(167,836)
Accumulated other comprehensive loss	(2,339)	(1,432)
Total stockholders' equity	207,936	257,193
Total liabilities and stockholders' equity	\$ 225,052	\$ 272,013

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,	
	2022	2021	2022	2021
Revenue	\$—	\$—	\$—	\$—
Operating expenses:				
Research and development	19,738	9,097	50,954	29,409
General and administrative	6,945	3,560	18,848	10,472
Total operating expenses	<u>26,683</u>	<u>12,657</u>	<u>69,802</u>	<u>39,881</u>
Operating loss	<u>(26,683)</u>	<u>(12,657)</u>	<u>(69,802)</u>	<u>(39,881)</u>
Other income:				
Interest income	258	137	822	589
Foreign currency exchange (loss) gain	(198)	301	(529)	715
Other income	4,156	2,171	11,283	7,289
Total other income	<u>4,216</u>	<u>2,609</u>	<u>11,576</u>	<u>8,593</u>
Net loss	<u>\$(22,467)</u>	<u>\$(10,048)</u>	<u>\$(58,226)</u>	<u>\$(31,288)</u>
Net loss per share, basic and diluted	\$(0.92)	\$(0.56)	\$(2.38)	\$(1.75)
Weighted average common shares outstanding, basic and diluted	24,479,660	17,961,802	24,449,788	17,905,926

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

	Nine Months Ended January 31,	
	2022	2021
Cash flows from operating activities		
Net loss	\$ (58,226)	\$ (31,288)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	408	397
Stock-based compensation expense	8,432	3,677
Realized loss (gain) from sale of marketable securities	296	(192)
Non-cash operating lease expense	153	25
Amortization of premium on marketable securities	2,081	247
Foreign currency exchange loss (gain)	698	(441)
Changes in operating assets and liabilities:		
Research and development tax credit receivable	(1,477)	10,135
Prepaid expenses and other current assets	(3,659)	35
Accounts payable	228	(1,182)
Accrued expenses	(279)	(539)
Net cash used in operating activities	(51,345)	(19,126)
Cash flows from investing activities		
Purchases of marketable securities	(84,415)	(26,814)
Sales and maturities of marketable securities	130,686	45,692
Acquisition of property and equipment	(845)	(49)
Net cash provided by investing activities	45,426	18,829
Cash flows from financing activities		
Issuance of common stock , net of offering expenses	-	1,648
Issuance of common stock from equity incentive plans	1,443	161
Net cash provided by financing activities	1,443	1,809
Effect of exchange rate changes on cash and cash equivalents	(539)	426
Net (decrease) increase in cash and cash equivalents	(5,015)	1,938
Cash and cash equivalents at beginning of period	50,592	15,789
Cash and cash equivalents at end of period	\$ 45,577	\$ 17,727

