

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 11, 2021

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 02142
(Address of Principal Executive Offices) (Zip Code)

(857) 999-0075
(Registrant's telephone number, including area code)

(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 11, 2021, KalVista Pharmaceuticals, Inc. (the “Company”) reported its financial results for the fiscal quarter ended January 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

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press release dated March 11, 2021

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

KALVISTA PHARMACEUTICALS, INC.

Date: March 11, 2021

By: /s/ Benjamin L. Palleiko

Benjamin L. Palleiko
Chief Business Officer and Chief Financial Officer

KalVista Pharmaceuticals Reports Third Fiscal Quarter Results

– Recent KVD900 Phase 2 Clinical Trial Results Statistically and Clinically Significant –

*– IND Submitted for Oral Prophylactic HAE Treatment Candidate KVD824; Phase 2 Expected to Initiate in Q2 2021 –
– Following Upsized Public Offering, Funded to KVD900 NDA Filing –*

Cambridge, MA and Salisbury, England, March 11, 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 third fiscal quarter ended January 31, 2021.

“We are making excellent progress in our commitment to providing those with hereditary angioedema a complete set of oral options to manage their disease. The data announced last month for KVD900 as an oral on-demand therapy were overwhelmingly positive and show that patients don’t have to compromise on efficacy or rely on injectables. We view this data as validation of our work in oral plasma kallikrein inhibition, which also includes KVD824 as a development candidate for an oral prophylactic treatment for HAE,” said Andrew Crockett, Chief Executive Officer of KalVista. “Our next step is to meet with regulatory agencies to finalize the Phase 3 program for KVD900 while we push ahead with preparations to be ready to begin that trial as quickly as possible. We have also filed the IND for a Phase 2 clinical trial of KVD824 and expect to initiate that trial in the second quarter of 2021. The closing of our recent upsized financing puts us in a position to execute on plans across our oral HAE franchise, thanks to a cash balance sufficient to get us to the KVD900 NDA filing.”

Third Fiscal Quarter and Recent Business Highlights:

- Reported positive results for KVD900 in a Phase 2 clinical trial demonstrating statistically and clinically significant responses across primary and secondary endpoints as an oral on-demand treatment for HAE attacks. The trial met its primary endpoint comparing the time to use of conventional attack treatment within 12 hours on KVD900 versus placebo ($p=0.0010$) with rates of use at 12 hours of 15.1% following treatment with KVD900 versus 30.2% after placebo. The trial also met all secondary endpoints: reduced worsening of attacks ($p<0.0001$; PGI-S or use of rescue) and reduced time to onset of symptom relief measured using both patient’s global impression of change (PGI-C) ($p<0.0001$) and visual analogue scale (VAS) ($p<0.0001$). The trial included 126 administrations of KVD900 and 55 of placebo. During the uncontrolled, open label phase, 5 of 68 patients dosed reported 8 adverse events suspected to be related to treatment. During the randomized, placebo-controlled phase, 5 patients reported adverse events suspected to be treatment-related (3 of 58 dosed with KVD900 and 2 of 55 dosed with placebo).
 - Closed an upsized public offering of common stock and full exercise of the underwriters’ options to purchase additional shares. The gross proceeds, before deducting the underwriting discounts and commissions and other offering expenses were
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approximately \$222.5 million based on 6,181,250 shares at a price to the public of \$36.00 per share.

Third Fiscal Quarter Financial Results:

- **Revenue:** No revenue was recognized for the three months ended January 31, 2021, compared to \$1.6 million for the same period in the prior fiscal year. The decrease of \$1.6 million was due to the expiration of the Merck Option Agreement in February 2020. No future revenue remains to be recognized under this agreement.
- **R&D Expenses:** Research and development expenses were \$9.1 million for the three months ended January 31, 2021, compared to \$11.2 million for the same period in the prior fiscal year. The decrease in expenses during the quarter primarily reflect a decrease in spending on KVD001, which concluded a Phase 2 clinical trial in December 2019, a decrease in spending on KVD900, and a decrease in spending on preclinical activities. These decreases were somewhat offset by increased spending related to the development of KVD824.
- **G&A Expenses:** General and administrative expenses were \$3.6 million for the three months ended January 31, 2021, compared to \$3.1 million for the same period in the prior fiscal year. The \$0.5 million increase in expenses primarily reflects an increase in employee related and commercial development expenses.
- **Net Loss:** Net loss was \$10.1 million, or \$(0.56) per weighted average basic and diluted share, for the three months ended January 31, 2021, compared to net loss of \$9.3 million, or \$(0.52) 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 in the three months ended January 31, 2021 compared to the same period in the prior fiscal year was primarily due to decreases in revenue and other income in the three months ended January 31, 2021, somewhat offset by the decrease in research and development expenses.
- **Cash:** Cash, cash equivalents and marketable securities were \$50.3 million as of January 31, 2021, compared to \$67.7 million as of April 30, 2020. The decrease in net cash position was due to increased spending, primarily on research and development activities.

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, demonstrating statistical and clinical significance across all endpoints. KVD824 is in development for prophylactic treatment of HAE with a Phase 2 clinical trial expected to initiate in the second quarter of 2021. 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 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, 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 annual report on Form 10-K filed on July 1, 2020, our quarterly reports on Form 10-Q, and other filings 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.

Leah Monteiro
Senior Director, Corporate Communications & Investor Relations
857-999-0808

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

	<u>January 31,</u> <u>2021</u>	<u>April 30,</u> <u>2020</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 17,727	\$ 15,789
Marketable securities	32,584	51,925
Research and development tax credit receivable	7,589	16,527
Prepaid expenses and other current assets	4,604	4,455
Total current assets	<u>62,504</u>	<u>88,696</u>
Property and equipment, net	1,868	2,043
Right of use assets	1,653	1,612
Other assets	181	178
Total assets	<u><u>\$ 66,206</u></u>	<u><u>\$ 92,529</u></u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 641	\$ 1,677
Accrued expenses	5,285	5,455
Lease liability - current portion	592	588
Total current liabilities	<u>6,518</u>	<u>7,720</u>
Long-term liabilities:		
Lease liability - net of current portion	1,123	1,057
Total long-term liabilities	<u>1,123</u>	<u>1,057</u>
Stockholders' equity:		
Common stock, \$0.001 par value	18	18
Additional paid-in capital	212,694	207,208
Accumulated deficit	(152,880)	(121,592)
Accumulated other comprehensive loss	(1,267)	(1,882)
Total stockholders' equity	<u>58,565</u>	<u>83,752</u>
Total liabilities and stockholders' equity	<u><u>\$ 66,206</u></u>	<u><u>\$ 92,529</u></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,	
	2021	2020	2021	2020
Revenue	\$ —	\$ 1,577	\$ —	\$ 8,866
Operating expenses:				
Research and development	9,097	11,233	29,409	30,709
General and administrative	3,560	3,068	10,472	9,733
Total operating expenses	12,657	14,301	39,881	40,442
Operating loss	(12,657)	(12,724)	(39,881)	(31,576)
Other income:				
Interest income	137	372	589	1,467
Foreign currency exchange rate gain (loss)	301	138	715	245
Other income	2,171	2,923	7,289	7,332
Total other income	2,609	3,433	8,593	9,044
Net loss	\$ (10,048)	\$ (9,291)	\$ (31,288)	\$ (22,532)
Net loss per share, basic and diluted	\$ (0.56)	\$ (0.52)	\$ (1.75)	\$ (1.27)
Weighted average common shares outstanding, basic and diluted	17,961,802	17,838,872	17,905,926	17,717,057

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

	Nine Months Ended January 31,	
	2021	2020
Cash flows from operating activities		
Net loss	\$ (31,288)	\$ (22,532)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	397	382
Stock-based compensation expense	3,677	3,358
Realized gain from sale of marketable securities	(192)	(229)
Non-cash operating lease expense	25	2
Amortization of premium on marketable securities	247	136
Foreign currency exchange (gain) loss	(441)	(224)
Changes in operating assets and liabilities:		
Research and development tax credit receivable	10,135	(3,405)
Prepaid expenses and other current assets	35	(187)
Accounts payable	(1,182)	133
Accrued expenses	(539)	(766)
Deferred revenue	—	(8,866)
Net cash used in operating activities	<u>(19,126)</u>	<u>(32,198)</u>
Cash flows from investing activities		
Purchases of marketable securities	(26,814)	(45,114)
Sales and maturities of marketable securities	45,692	52,052
Acquisition of property and equipment	(49)	(212)
Net cash provided by (used in) investing activities	<u>18,829</u>	<u>6,726</u>
Cash flows from financing activities		
Issuance of common stock, net of offering expenses	1,648	11,422
Issuance of common stock from equity incentive plans	161	214
Finance lease principal payments	—	(53)
Net cash provided by financing activities	<u>1,809</u>	<u>11,583</u>
Effect of exchange rate changes on cash and cash equivalents	426	498
Net increase (decrease) in cash and cash equivalents	1,938	(13,391)
Cash and cash equivalents at beginning of period	15,789	32,006
Cash and cash equivalents at end of period	<u>\$ 17,727</u>	<u>\$ 18,615</u>