



KalVista Pharmaceuticals Reports Second Fiscal Quarter Results and Provides Operational Update

Dec 07, 2023

- Sebetralstat Phase 3 KONFIDENT Clinical Trial Achieves Targeted Number of Attacks to Complete Trial -

- Data Readout on Track for Early 2024; NDA Filing Expected H1 2024 -

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Dec. 7, 2023-- [KalVista Pharmaceuticals, Inc.](https://www.kalvista.com) (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 second fiscal quarter ended October 31, 2023.

"We are in the process of completing the KONFIDENT trial and we look forward to advancing sebetralstat for a NDA submission in the first half of 2024," said Andrew Crockett, Chief Executive Officer of KalVista. "As we plan on several regulatory filings in the coming year, we are also continuing to build out our commercial organization in order to support a rapid launch upon FDA approval."

Second Fiscal Quarter and Recent Business Highlights:

- Achieved the targeted number of on-treatment attacks required to complete the phase 3 KONFIDENT trial. Topline data readout is expected in early 2024, remaining on track for a New Drug Application (NDA) submission to the U.S. Food and Drug Administration (FDA) in the first half of 2024. The Company also expects to file for approval in the European Union and Japan later in 2024
- Received Orphan Drug Status (ODS) approval from Switzerland for sebetralstat, allowing for shorter review time, priority authorization, and 15 years market protection and exclusivity
- Presented real-world patient data at the 2023 Annual Scientific Meeting of the American College of Allergy, Asthma & Immunology discussing compliance challenges of currently available parenteral on-demand HAE treatments and evidence of the global prevalence of normal C1-inhibitor HAE (HAE-nC1-INH)
- Conducted fireside chats at the Cantor Global Healthcare Conference, Stifel 2023 Healthcare Conference, and Jefferies London Healthcare Conference
- Reported data at the Asia Pacific Association of Allergy, Asthma and Clinical Immunology 2023 International Conference characterizing HAE attacks in patients receiving long-term prophylaxis (LTP)

Second Fiscal Quarter Financial Results:

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

R&D Expenses: Research and development expenses were \$19.1 million for the three months ended October 31, 2023, compared to \$18.1 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 and KONFIDENT-S trials.

G&A Expenses: General and administrative expenses were \$10.7 million for the three months ended October 31, 2023, compared to \$7.8 million for the same period in the prior fiscal year. The increase in G&A expenses was primarily due to increases in employee-related expenses, commercial strategy and supply chain expenses.

Net Loss: Net loss was \$27.7 million, or \$(0.80) per weighted average basic and diluted share, for the three months ended October 31, 2023, compared to net loss of \$22.3 million, or \$(0.90) per weighted average basic and diluted share for the same period in the prior fiscal year. The increase in net loss primarily resulted from the increase in operating expenses, primarily research and development.

Cash Position: Cash, cash equivalents and marketable securities were \$103.2 million as of October 31, 2023, compared to \$149.4 million as of April 30, 2023. 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 is developing sebetralstat as an oral on-demand therapy for HAE and anticipates providing data from the phase 3 KONFIDENT clinical trial in early 2024. 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, 2023, 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.

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

	<u>October 31,</u> <u>2023</u>	<u>April 30,</u> <u>2023</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 57,666	\$ 56,238
Marketable securities	45,506	93,137
Research and development tax credit receivable	19,976	16,568
Prepaid expenses and other current assets	5,458	6,383
Total current assets	<u>128,606</u>	<u>172,326</u>
Property and equipment, net	2,502	2,948
Right of use assets	7,298	7,822
Other assets	337	106
Total assets	<u>\$ 138,743</u>	<u>\$ 183,202</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 4,896	\$ 4,817
Accrued expenses	11,707	9,128
Lease liability - current portion	1,148	1,087
Total current liabilities	<u>17,751</u>	<u>15,032</u>
Long-term liabilities:		
Lease liability - net of current portion	6,546	7,145
Total long-term liabilities	<u>6,546</u>	<u>7,145</u>
Stockholders' equity:		
Common stock, \$0.001 par value	34	34
Additional paid-in capital	513,926	507,133
Accumulated deficit	(396,049)	(343,082)
Accumulated other comprehensive loss	(3,465)	(3,060)
Total stockholders' equity	<u>114,446</u>	<u>161,025</u>
Total liabilities and stockholders' equity	<u>\$ 138,743</u>	<u>\$ 183,202</u>

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

	Three Months Ended		Six Months Ended	
	October 31,		October 31,	
	2023	2022	2023	2022
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	19,089	18,077	38,396	36,262
General and administrative	10,657	7,806	20,443	15,936
Total operating expenses	<u>29,746</u>	<u>25,883</u>	<u>58,839</u>	<u>52,198</u>
Operating loss	<u>(29,746)</u>	<u>(25,883)</u>	<u>(58,839)</u>	<u>(52,198)</u>
Other income:				
Interest income	776	449	1,699	691
Foreign currency exchange rate (loss) gain	(1,299)	(317)	(843)	(834)
Other income	2,619	3,494	5,016	7,042
Total other income	<u>2,096</u>	<u>3,626</u>	<u>5,872</u>	<u>6,899</u>

Net loss	\$ (27,650)	\$ (22,257)	\$ (52,967)	\$ (45,299)
Net loss per share, basic and diluted	\$ (0.80)	\$ (0.90)	\$ (1.54)	\$ (1.84)
Weighted average common shares outstanding, basic and diluted	34,565,955	24,595,039	34,490,090	24,576,327

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

	Six Months Ended	
	October 31,	
	2023	2022
Cash flows from operating activities		
Net loss	\$ (52,967)	\$ (45,299)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	390	331
Stock-based compensation expense	6,461	5,148
Realized loss (gain) from sale of marketable securities	(909)	85
Non-cash operating lease expense	(13)	42
Amortization of premium on marketable securities	83	678
Foreign currency exchange loss (gain)	811	(739)
Changes in operating assets and liabilities:		
Research and development tax credit receivable	(4,109)	(7,137)
Prepaid expenses and other current assets	761	3,650
Accounts payable	163	(81)
Accrued expenses	2,774	(14)
Net cash used in operating activities	<u>(46,555)</u>	<u>(43,336)</u>
Cash flows from investing activities		
Purchases of marketable securities	(29,537)	(10,102)
Sales and maturities of marketable securities	77,917	61,356
Acquisition of property and equipment	(8)	(1,112)
Website development costs	(203)	—
Net cash provided by investing activities	<u>48,169</u>	<u>50,142</u>
Cash flows from financing activities		
Issuance of common stock from equity incentive plans	332	336
Net cash provided by financing activities	<u>332</u>	<u>336</u>
Effect of exchange rate changes on cash and cash equivalents	(518)	711
Net (decrease) increase in cash and cash equivalents	1,428	7,853
Cash and cash equivalents at beginning of period	56,238	30,732
Cash and cash equivalents at end of period	<u>\$ 57,666</u>	<u>\$ 38,585</u>

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