



KalVista Pharmaceuticals Reports Third Fiscal Quarter Results and Provides Operational Update

Mar 11, 2024

- *Sebetralstat Phase 3 KONFIDENT clinical trial met all endpoints and demonstrated a favorable safety profile as first oral on-demand therapy for hereditary angioedema -*

- *CEO transition supports ongoing evolution into commercial company -*

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Mar. 11, 2024-- [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, 2024.

"This has been an exciting and busy period for KalVista, as we achieved key milestones with the release of our phase 3 KONFIDENT data and the completion of a substantial financing," said Ben Palleiko, Chief Executive Officer of KalVista. "We remain on track to file the NDA with the U.S. Food and Drug Administration in the first half of this year, and we look forward to presenting further phase 3 data for sebetralstat at upcoming patient and medical meetings. We also continue to grow the commercial organization to enable us to deliver on the promise of providing the first oral, on-demand treatment option to the HAE community."

Third Fiscal Quarter and Recent Business Highlights:

- In February, the Company announced positive topline data from the Phase 3 KONFIDENT clinical trial evaluating the safety and efficacy of sebetralstat as the potential first oral, on-demand therapy for hereditary angioedema (HAE). KONFIDENT was the largest and most representative trial ever conducted in HAE, enrolling a total of 136 patients from 66 clinical sites across 20 countries. Eligible participants included adolescents, patients using long-term prophylaxis, and the trial evaluated all attack severities and locations. The clinical trial met all primary and key secondary endpoints across both the 300 and 600 mg doses and demonstrated a safety profile similar to placebo.
- Also in February, KalVista closed an underwritten offering to sell an aggregate of 7,016,312 shares of common stock at price of \$15.25 per share and pre-funded warrants to purchase up to 3,483,688 shares of common stock at a price of \$15.249 per pre-funded warrant. The net proceeds from the offering were approximately \$150.1 million and are expected to provide funding into 2026.
- The Company announced that Benjamin L. Palleiko, the Company's prior President, CBO and CFO, was appointed as Chief Executive Officer and a director of the Company. This appointment is the result of a planned transition as KalVista prepares to become a commercial entity following the success of the KONFIDENT Phase 3 trial for its program sebetralstat.
- The UK Medicines and Healthcare products Regulatory Agency (MHRA) awarded the Innovation Passport for sebetralstat, providing entry to the UK Innovative Licensing and Access Pathway (ILAP), which aims to accelerate time to market and facilitate patient access to innovative medicines.
- Presented additional Phase 3 KONFIDENT data as well as data on unmet need in HAE from a patient perspective at the 2024 American Academy of Allergy Asthma & Immunology Annual Meeting (AAAAI) in Washington, D.C.
- Announced publication of the first report of a potent and specific Factor XIIa inhibitor with high oral availability in a peer-reviewed journal. The *Frontiers in Pharmacology* article describes the pharmacology of a representative compound from KalVista's portfolio of structurally diverse, oral Factor XII inhibitors.

Third Fiscal Quarter Financial Results:

Revenue: No revenue was recognized for the three months ended January 31, 2024, or January 31, 2023.

R&D Expenses: Research and development expenses were \$22.5 million for the three months ended January 31, 2024, compared to \$20.1 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 \$10.6 million for the three months ended January 31, 2024, compared to \$6.9 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 and commercial planning expenses.

Net Loss: Net loss was \$29.0 million, or \$(0.84) per weighted average basic and diluted share, for the three months ended January 31, 2024, compared to net loss of \$21.3 million, or \$(0.75) 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 \$75.6 million as of January 31, 2024, 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 disclosed positive phase 3 data for the KONFIDENT trial for its oral, on-demand therapy sebetralstat in February 2024. The Company anticipates submitting a new drug application to the U.S. Food and Drug Administration (FDA) for sebetralstat in the first half of 2024 and expects to file for approval in Europe and Japan later in 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.

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, our ability 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)

	January 31, 2024	April 30, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 23,056	\$ 56,238
Marketable securities	52,530	93,137
Research and development tax credit receivable	23,011	16,568
Prepaid expenses and other current assets	5,506	6,383
Total current assets	104,103	172,326
Property and equipment, net	2,423	2,948
Right of use assets	7,045	7,822
Other assets	397	106
Total assets	\$ 113,968	\$ 183,202
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 3,101	\$ 4,817
Accrued expenses	14,840	9,128
Lease liability - current portion	1,187	1,087
Total current liabilities	19,128	15,032
Long-term liabilities:		
Lease liability - net of current portion	6,257	7,145
Total long-term liabilities	6,257	7,145
Stockholders' equity:		
Common stock, \$0.001 par value	34	34
Additional paid-in capital	516,920	507,133
Accumulated deficit	(425,077)	(343,082)
Accumulated other comprehensive loss	(3,294)	(3,060)
Total stockholders' equity	88,583	161,025
Total liabilities and stockholders' equity	\$ 113,968	\$ 183,202

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

	Three Months Ended		Nine Months Ended	
	January 31, 2024	2023	2024	2023
Revenue	\$ —	\$ —	\$ —	\$ —

Operating expenses:				
Research and development	22,523	20,063	60,919	56,325
General and administrative	10,628	6,882	31,071	22,818
Total operating expenses	33,151	26,945	91,990	79,143
Operating loss	(33,151)	(26,945)	(91,990)	(79,143)
Other income:				
Interest income	684	732	2,383	1,424
Foreign currency exchange rate gain (loss)	1,120	597	277	(237)
Other income	2,319	4,313	7,335	11,354
Total other income	4,123	5,642	9,995	12,541
Net loss	\$ (29,028)	\$ (21,303)	\$ (81,995)	\$ (66,602)
Net loss per share, basic and diluted	\$ (0.84)	\$ (0.75)	\$ (2.37)	\$ (2.58)
Weighted average common shares outstanding, basic and diluted	34,723,379	28,278,453	34,567,853	25,810,369

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

	Nine Months Ended	
	January 31,	
	2024	2023
Cash flows from operating activities		
Net loss	\$ (81,995)	\$ (66,602)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	597	530
Stock-based compensation expense	9,172	7,481
Realized (gain) loss from sale of marketable securities	(1,130)	84
Non-cash operating lease expense	(11)	52
Amortization of premium on marketable securities	88	890
Foreign currency exchange loss (gain)	596	(1,339)
Changes in operating assets and liabilities:		
Research and development tax credit receivable	(6,215)	2,049
Prepaid expenses and other current assets	906	4,440
Accounts payable	(1,778)	(1,911)
Accrued expenses	5,644	1,701
Net cash used in operating activities	<u>(74,126)</u>	<u>(52,625)</u>
Cash flows from investing activities		
Purchases of marketable securities	(47,687)	(63,757)
Sales and maturities of marketable securities	89,475	112,509
Acquisition of property and equipment	(27)	(1,127)
Website development costs	(294)	—
Net cash provided by investing activities	<u>41,467</u>	<u>47,625</u>
Cash flows from financing activities		
Issuance of common stock from equity incentive plans	616	482
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	<u>616</u>	<u>58,149</u>
Effect of exchange rate changes on cash and cash equivalents	<u>(1,139)</u>	<u>1,168</u>
Net (decrease) increase in cash and cash equivalents	<u>(33,182)</u>	<u>54,317</u>
Cash and cash equivalents at beginning of period	<u>56,238</u>	<u>30,732</u>
Cash and cash equivalents at end of period	<u>\$ 23,056</u>	<u>\$ 85,049</u>

KalVista Pharmaceuticals, Inc.

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