KalVista Pharmaceuticals Reports First Fiscal Quarter Results and Provides Operational Update

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- Sebetralstat Phase 3 KONFIDENT Clinical Trial Achieves Target Enrollment; Data Readout on Track for Q4 -

- Preparations Continue for NDA filing H1 2024 and Rapid Commercialization Upon Approval -

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Sep. 7, 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 first fiscal quarter ended July 31, 2023.

"We know from our extensive interactions with people living with hereditary angioedema (HAE) at the recent conferences how much they are anticipating having sebetralstat available to them, and the data from the KONFIDENT trial in Q4 is the next step," said Andrew Crockett, Chief Executive Officer of KalVista. "We continue to build our Commercial operation with the addition of Nicole Sweeny as Chief Commercial Officer and other key members of the team to support an NDA submission in the first half of 2024 and a rapid launch upon FDA approval."

First Fiscal Quarter and Recent Business Highlights:

- Published "Evaluation of patient-reported outcome measures for on-demand treatment of hereditary angioedema attacks and design of KONFIDENT, a phase 3 trial of sebetralstat" in *Clinical and Translational Allergy*. This publication outlines the rigorous, multi-factorial approach used to design a phase 3 trial with an optimized, patient- and physician-preferred measure to assess measure efficacy, and discusses reasons for the superiority of the selected primary endpoint over other potential measures
- Presented real-world patient data on the HAE Attack Journey at the HAEi Regional Conference EMEA meeting showing there remain important unmet needs for both people using only on-demand therapies as well as those on long-term prophylaxis
- Achieved enrollment target of 114 patients in the phase 3 KONFIDENT trial. Data readout remains on track for the fourth quarter of 2023 and, if the trial is successful, KalVista anticipates submitting an NDA to the FDA in the first half of 2024
- Presented real-world patient data at the 2023 US HAEA National Summit showing people living with HAE continue to delay treatment for attacks due to challenges from injections or infusions, even though they know early treatment means an earlier return to normal activities
- Announced that Nicole Sweeny joined the Senior Leadership Team at KalVista as Chief Commercial Officer
- Reported new data in five posters at the 2023 Meeting of the European Academy of Allergy and Clinical Immunology. The presentations showed that sebetralstat pharmacokinetic and pharmacodynamic data support globalization of the KONFIDENT phase 3 clinical trial and use in short-term prophylaxis and that patients receiving modern long-term prophylaxis continued to have challenges associated with treatment decisions
- Presented at the 2023 Jefferies Global Healthcare Conference, Stifel Tailoring Genes: Genetic Medicines Day and Stifel Biotech Summer Summit
- Revealed patient survey data at the 13th C1-inhibitor Deficiency & Angioedema Workshop demonstrating the burden associated with injectable on-demand treatments for HAE and that those living with HAE had a strong preference for oral medication for on-demand treatment of attacks over self-administered injectable treatments when efficacy and safety profiles were similar
- Continued to advance plans for the eventual worldwide launch of sebetralstat by hiring a General Manager, Japan. Based on interactions to date with Japanese physicians and regulatory authorities, KalVista believes sebetralstat has the potential to significantly improve HAE therapeutic options in Japan.

First Fiscal Quarter Financial Results:

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

R&D Expenses: Research and development expenses were $19.3 million for the three months ended July 31, 2023, compared to $18.2 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 and increased personnel costs.

G&A Expenses: General and administrative expenses were $9.8 million for the three months ended July 31, 2023, compared to $8.1 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 professional fees.

Net Loss: Net loss was $25.3 million, or $(0.74) per weighted average basic and diluted share, for the three months ended July 31, 2023, compared to net loss of $23.0 million, or $(0.94) 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 $123.3 million as of July 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 attacks and has achieved target enrollment for 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, 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)

	July 31, 2023	**April 30, 2023**
Assets		
Current assets:		
Cash and cash equivalents	$ 49,409	$ 56,238
Marketable securities	73,848	93,137
Research and development tax credit receivable	19,057	16,568
Prepaid expenses and other current assets	7,528	6,383
Total current assets	149,842	172,326
Property and equipment, net	2,813	2,948
Right of use assets	7,571	7,822
Other assets	106	106
Total assets	**$ 160,332**	**$ 183,202**
Liabilities and stockholders' equity		
Current liabilities:		

Accounts payable	$ 5,060	$ 4,817
Accrued expenses	7,950	9,128
Lease liability - current portion	1,122	1,087
Total current liabilities	14,132	15,032
Long-term liabilities:		
Lease liability - net of current portion	6,865	7,145
Total long-term liabilities	6,865	7,145
Stockholders' equity:		
Common stock, $0.001 par value	34	34
Additional paid-in capital	510,591	507,133
Accumulated deficit	(368,399)	(343,082)
Accumulated other comprehensive loss	(2,891)	(3,060)
Total stockholders' equity	139,335	161,025
Total liabilities and stockholders' equity	**$ 160,332**	**$ 183,202**

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

	Three Months Ended July 31,	
	2023	**2022**
Revenue	**$ —**	**$ —**
Operating expenses:		
Research and development	19,307	18,186
General and administrative	9,786	8,130
Total operating expenses	29,093	26,316
Operating loss	**(29,093)**	**(26,316)**
Other income:		
Interest income	923	242
Foreign currency exchange gain (loss)	456	(517)

Other income	2,397	3,549
Total other income	**3,776**	**3,274**
Net loss	**$ (25,317)**	**$ (23,042)**
Net loss per share, basic and diluted	**$ (0.74)**	**$ (0.94)**
Weighted average common shares outstanding, basic and diluted	34,414,226	24,557,615

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

	Three Months Ended July 31,	
	2023	**2022**
Cash flows from operating activities		
Net loss	$ (25,317)	$ (23,042)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	193	158
Stock-based compensation expense	3,254	2,642
Realized (gain) loss from sale of marketable securities	(314)	16
Non-cash operating lease expense	6	23
Amortization of premium on marketable securities	62	391
Foreign currency exchange (gain) loss	(395)	426
Changes in operating assets and liabilities:		
Research and development tax credit receivable	(2,084)	(3,570)
Prepaid expenses and other current assets	(1,003)	1,935
Accounts payable	108	(678)
Accrued expenses	(1,240)	(1,043)
Net cash used in operating activities	(26,730)	(22,742)
Cash flows from investing activities		
Purchases of marketable securities	(25,767)	(10,102)
Sales and maturities of marketable securities	45,386	41,066

Acquisition of property and equipment	(6)	(920)
Net cash provided by investing activities	19,613	30,044
Cash flows from financing activities		
Issuance of common stock from equity incentive plans	204	168
Net cash provided by financing activities	204	168
Effect of exchange rate changes on cash and cash equivalents	84	(339)
Net increase (decrease) in cash and cash equivalents	(6,829)	7,131
Cash and cash equivalents at beginning of period	56,238	30,732
Cash and cash equivalents at end of period	$ 49,409	$ 37,863

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