KalVista Pharmaceuticals Provides Operational Update and Fiscal Year Financial Results

July 7, 2023

– Sebetralstat Phase 3 KONFIDENT Clinical Trial Achieves Target Enrollment; Data Readout Expected in Q4 –

– Company Funded Into 2025 With NDA Planned for H1 2024 –

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Jul. 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 fiscal year ended April 30, 2023.

"We have made a great deal of progress over the last fiscal year in the development of sebetralstat," said Andrew Crockett, Chief Executive Officer of KalVista. "Consistent with prior guidance, we have achieved the target enrollment for the sebetralstat phase 3 KONFIDENT trial. We expect to have data readout in the fourth quarter of this year and submit an NDA in the first half of 2024. In addition, we continue to expand the potential of our oral Factor XIIa inhibitor program beyond HAE by presenting positive preclinical data in several other therapeutic areas, including thrombosis. We remain well-capitalized, with funding into 2025."

Fiscal 2023 and Recent Business Highlights:

Sebetralstat

- In June 2023, the Company achieved its enrollment target of 114 patients in the phase 3 KONFIDENT trial. KalVista expects data from the event-driven trial in the fourth quarter of 2023 and, if successful, anticipates submitting an NDA to the FDA in the first half of 2024.
- Presented real-world patient data at the 13th C1-inhibitor Deficiency & Angioedema Workshop and the 2023 Meeting of the European Academy of Allergy and Clinical Immunology (EAACI) showing the persistent burden in patients receiving modern long-term prophylaxis, and the challenges associated with on-demand treatment decision-making during HAE attacks.
- Received guidance from the Japanese regulatory authority (PMDA) on the clinical development pathway to a regulatory submission in that country. KONFIDENT is the first pivotal phase 3 global trial in HAE to include Japanese sites and patients.
- Published sebetralstat phase 2 data evaluating the efficacy and safety of oral sebetralstat for the on-demand treatment of hereditary angioedema (HAE) attacks in *The Lancet*.
- Reported positive phase 1 data for an oral disintegrating tablet (ODT) formulation of sebetralstat. KalVista also received FDA feedback on its proposed ODT development program to support a supplemental NDA, which did not include a requirement to conduct efficacy trials.
- Initiated KONFIDENT-S, a two-year open-label extension trial assessing the long-term safety and tolerability profile of sebetralstat. The study will also examine the potential use of sebetralstat as a treatment for short-term prophylaxis in medical and dental procedures.

Oral Factor XIIa Inhibitor Program

- Reported promising preclinical data for the Company's oral factor XIIa inhibitor program at the 2023 Congress of The International Society on Thrombosis and Haemostasis (ISTH). Data showed that KalVista's potent and selective FXIIa inhibitor with high oral availability inhibited thrombosis in mice, the first oral FXIIa inhibitor shown to protect against thrombosis.

Organizational

- Promoted Benjamin L. Palleiko to the role of President of KalVista. In addition to his other duties, Mr. Palleiko will now be responsible for leading broadly the Company's future business growth, including development of the commercial organization for the intended worldwide launch of sebetralstat.
- Raised $58 million in a registered direct offering, with the intent to use those proceeds to fund clinical trials, commercial sales development, research, working capital, capital expenditures and other general corporate purposes. With the financing, KalVista now expects to be able to fund operations into 2025.
- Appointed Brian J.G. Pereira, M.D. as Chairman of the KalVista Board of Directors.

Fourth Quarter and Full Year Financial Results:

- Revenue: No revenue was recognized for the three months and fiscal years ended April 30, 2023, or April 30, 2022, respectively.
- R&D Expenses: Research and development expenses were $24.0 million for the three months ended April 30, 2023, compared to $19.2 million for the same period in the prior fiscal year. Research and development expenses were $80.3 million for the fiscal year ended April 30, 2023, compared to $70.2 million for the prior fiscal year. The increase in spending in the fiscal year ended April 30, 2023 primarily reflects increased costs related to the ongoing clinical trial for sebetralstat, increased preclinical spending, and a headcount driven increase in personnel costs.
- G&A Expenses: General and administrative expenses were $7.8 million for the three months ended April 30, 2023, compared to $7.6 million for the same period in the prior fiscal year. General and administrative expenses were $30.6 million for the fiscal year ended April 30, 2023, compared to $26.4 million for the prior fiscal year. The increase in G&A expenses was primarily due to an increase in commercial strategy expenses and to a lesser extent, increases in public relations costs and other administrative costs.
- Net Loss: Net loss was $26.3 million, or $(0.77) per weighted average basic and diluted share, for the three months ended April 30, 2023, compared to net loss of $24.1 million, or $(0.98) per weighted average basic and diluted share for the same period in the prior fiscal year. Net loss was $92.9 million, or $(3.33) per weighted average basic and diluted share for the fiscal year ended April 30, 2023, compared to net loss of $82.3 million, or $(3.36) per weighted average basic and diluted share 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 $149.4 million on April 30, 2023, compared to $166.2 million on April 30, 2022. The decrease in the net cash position over the fiscal year is primarily 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 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, 2022, 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)

	April 30, 2023	April 30, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 56,238	$ 30,732

Marketable securities	93,137	135,470
Research and development tax credit receivable	16,568	14,098
Prepaid expenses and other current assets	6,383	13,347
Total current assets	172,326	193,647
Property and equipment, net	2,948	2,178
Right of use assets	7,822	7,862
Other assets	106	193
Total assets	**$ 183,202**	**$ 203,880**
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,817	$ 3,638
Accrued expenses	9,128	6,961
Lease liability - current portion	1,087	977
Total current liabilities	15,032	11,576
Long-term liabilities:		
Lease liability - net of current portion	7,145	7,211
Total long-term liabilities	7,145	7,211
Stockholders’ equity:		
Common stock, $0.001 par value	34	25
Additional paid-in capital	507,133	439,104
Accumulated deficit	(343,082)	(250,175)
Accumulated other comprehensive loss	(3,060)	(3,861)
Total stockholders’ equity	161,025	185,093
Total liabilities and stockholders' equity	**$ 183,202**	**$ 203,880**

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

	Three Months Ended	**Years Ended**
	April 30,	**April 30,**

	2023	2022	2023	2022
Revenue	**$ —**	**$ —**	**$ —**	**$ —**
Operating expenses:				
Research and development	23,951	19,213	80,276	70,167
General and administrative	7,777	7,598	30,595	26,446
Total operating expenses	31,728	26,811	110,871	96,613
Operating loss	**(31,728)**	**(26,811)**	**(110,871)**	**(96,613)**
Other income:				
Interest income	808	268	2,232	1,090
Foreign currency exchange rate (loss) gain	327	(1,008)	90	(1,537)
Other income	4,288	3,438	15,642	14,721
Total other income	**5,423**	**2,698**	**17,964**	**14,274**
Net loss	**$ (26,305)**	**$ (24,113)**	**$ (92,907)**	**$ (82,339)**
Net loss per share, basic and diluted	**$ (0.77)**	**$ (0.98)**	**$ (3.33)**	**$ (3.36)**
Weighted average common shares outstanding, basic and diluted	34,342,664	24,545,360	27,890,846	24,473,092

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

	Years Ended April 30,	
	2023	**2022**
Cash flows from operating activities		
Net loss	$ (92,907)	$ (82,339)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	718	564
Stock-based compensation expense	9,922	11,086
Realized loss (gain) from sale of marketable securities	139	581
Non-cash operating lease expense	84	179

Amortization of premium on marketable securities	988	2,565
Foreign currency exchange loss (gain)	(1,618)	1,552
Changes in operating assets and liabilities:		
Research and development tax credit receivable	(2,316)	(5,201)
Prepaid expenses and other current assets	6,690	(9,280)
Accounts payable	1,107	1,687
Accrued expenses	1,932	472
Net cash used in operating activities	(75,261)	(78,134)
Cash flows from investing activities		
Purchases of marketable securities	(98,246)	(136,920)
Sales and maturities of marketable securities	140,857	195,711
Acquisition of property and equipment	(1,196)	(931)
Net cash provided by investing activities	41,415	57,860
Cash flows from financing activities		
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	-
Issuance of common stock from equity incentive plans	449	1,581
Net cash provided by financing activities	58,116	1,581
Effect of exchange rate changes on cash and cash equivalents	1,236	(1,167)
Net (decrease) increase in cash and cash equivalents	25,506	(19,860)
Cash and cash equivalents at beginning of period	30,732	50,592
Cash and cash equivalents at end of period	$ 56,238	$ 30,732

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