KalVista Pharmaceuticals Provides Operational Update and Fiscal Year Financial Results

Jul 11, 2024

– Submitted NDA for sebetralstat as first-ever, oral on-demand treatment for HAE attacks, a pivotal moment for the HAE community –

– Potential FDA approval and launch of sebetralstat in first half 2025 -

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Jul. 11, 2024-- KalVista Pharmaceuticals, Inc. (NASDAQ: KALV), today provided an operational update and released financial results for the fiscal year ended April 30, 2024.

"This last fiscal quarter was the most important in the history of KalVista," said Ben Palleiko, CEO of KalVista. "Not only did we submit the NDA for sebetralstat to the FDA, but the KONFIDENT phase 3 trial results were published in *The New England Journal of Medicine*, supporting our view on the importance of this potential therapy. We look forward to building on these milestones as we submit additional marketing authorization applications to other national health authorities throughout 2024 and anticipate approval and launch in the US in the first half of 2025."

Fiscal 2024 and Recent Business Highlights:

Sebetralstat

- In June 2024, KalVista submitted a New Drug Application (NDA) for U.S. Food and Drug Administration (FDA) review of sebetralstat, a novel investigational oral plasma kallikrein inhibitor for the treatment of hereditary angioedema (HAE) attacks in adults and pediatric patients aged 12 years and older.
- Also in June, the Company initiated ahead of schedule a pediatric clinical trial (KONFIDENT-KID) using an orally disintegrating tablet (ODT) formulation of sebetralstat designed for this population. KONFIDENT-KID will enroll approximately 24 children, with an age range of 2 to 11 years, across seven countries in North America, Europe and Asia. If approved, sebetralstat would be the first oral, on demand treatment for this population and only the second approved on-demand therapy of any type.
- Data from phase 3 KONFIDENT trial of sebetralstat was published in the *New England Journal of Medicine* (NEJM) and presented concurrently at the European Academy of Allergy and Clinical Immunology Congress 2024 (EAACI).
- Presented the U.S. subgroup analysis from the phase 3 KONFIDENT trial at the Eastern Allergy Conference (EAC) 2024, as well as the Japanese subgroup from KONFIDENT at the 123rd Annual Meeting of the Japanese Dermatological Association (JDA) 2024.
- KalVista is on track for Market Authorization Application submissions to both European Medicines Agency and UK Medicines and Healthcare Products Regulatory Agency in Q3 2024 as well as a JNDA submission to the Japanese Pharmaceuticals and Medical Devices Agency in Q4 2024.

Oral Factor XIIa Inhibitor Program

- The Company believes its preclinical Factor XIIa inhibitor program may have the potential to yield the first orally delivered Factor XIIa inhibitor for a variety of therapeutic indications. KalVista is undergoing a strategic review of this program to evaluate the potential for further development.

Organizational

- In March 2024, KalVista announced the promotion of Benjamin L. Palleiko to Chief Executive Officer and his appointment as a member of the Board.
- In February, KalVista entered into an underwriting agreement with Jefferies LLC, Leerink Partners LLC, Stifel, Nicolaus & Company, Incorporated, and Cantor Fitzgerald & Co., as the representatives of several underwriters to sell an aggregate of 7,016,312 shares of the Company's 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, after deducting estimated expenses, were approximately $150.1 million.
- In April, William C. Fairey was appointed to 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, 2024, or April 30, 2023, respectively.
- R&D Expenses: Research and development expenses were $25.3 million for the three months ended April 30, 2024, compared to $24.0 million for the same period in the prior fiscal year. Research and development expenses were $86.2 million for the fiscal year ended April 30, 2024, compared to $80.3 million for the prior fiscal year. The increase in spending in the fiscal year ended April 30, 2024 primarily reflects the phase 3 KONFIDENT trial which concluded in February 2024, the ongoing KONFIDENT-S trial, and a headcount driven increase in personnel costs.

- G&A Expenses: General and administrative expenses were $23.2 million for the three months ended April 30, 2024, compared to $7.8 million for the same period in the prior fiscal year. General and administrative expenses were $54.3 million for the fiscal year ended April 30, 2024, compared to $30.6 million for 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 $44.7 million, or $(1.02) per weighted average basic and diluted share, for the three months ended April 30, 2024, compared to net loss of $26.3 million, or $(0.77) per weighted average basic and diluted share for the same period in the prior fiscal year. Net loss was $126.6 million, or $(3.44) per weighted average basic and diluted share for the fiscal year ended April 30, 2024, compared to net loss of $92.9 million, or $(3.33) 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, both research and development and general and administrative.
- Cash position: Cash, cash equivalents and marketable securities were $210.4 million on April 30, 2024, compared to $149.4 million on April 30, 2023. The increase in the net cash and marketable securities position was primarily due to the net proceeds received from the February 2024 underwritten offering of common stock and pre-funded warrants.

About KalVista Pharmaceuticals, Inc.

KalVista Pharmaceuticals, Inc. is a global pharmaceutical company focused on the development and delivery of oral medicines for diseases with significant unmet need. KalVista announced positive phase 3 data for the KONFIDENT trial for its oral, on-demand therapy sebetralstat in February 2024 and submitted an NDA with the FDA in June 2024. KalVista expects to file for approval in the UK, the European Union, and Japan later in 2024.

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 and timing of clinical trials and its results, our ability to commence clinical studies or complete ongoing clinical studies, including our KONFIDENT-S and KONFIDENT-KID trials, 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)

	April 30, 2024	April 30, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 31,789	$ 56,238
Marketable securities	178,612	93,137
Research and development tax credit receivable	8,439	16,568
Prepaid expenses and other current assets	6,850	6,383
Total current assets	225,690	172,326
Property and equipment, net	2,227	2,948
Right of use assets	6,920	7,822
Other assets	567	106
Total assets	**$ 235,404**	**$ 183,202**
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 9,107	$ 4,817
Accrued expenses	12,398	9,128
Lease liability - current portion	1,302	1,087
Total current liabilities	22,807	15,032
Long-term liabilities:		
Lease liability - net of current portion	6,015	7,145
Total long-term liabilities	6,015	7,145
Stockholders' equity:		
Common stock, $0.001 par value	42	34
Additional paid-in capital	679,754	507,133
Accumulated deficit	(469,726)	(343,082)

Accumulated other comprehensive loss	(3,488)	(3,060)
Total stockholders' equity	206,582	161,025
Total liabilities and stockholders' equity	**$ 235,404**	**$ 183,202**

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

	Three Months Ended April 30,		Years Ended April 30,	
	2024	**2023**	**2024**	**2023**
Revenue	**$ —**	**$ —**	**$ —**	**$ —**
Operating expenses:				
Research and development	25,248	23,951	86,167	80,276
General and administrative	23,207	7,777	54,278	30,595
Total operating expenses	48,455	31,728	140,445	110,871
Operating loss	**(48,455)**	**(31,728)**	**(140,445)**	**(110,871)**
Other income:				
Interest income	1,513	808	3,896	2,232
Foreign currency exchange rate (loss) gain	(140)	327	138	90
Other income	2,432	4,288	9,767	15,642
Total other income	**3,805**	**5,423**	**13,801**	**17,964**
Net loss	**$ (44,650)**	**$ (26,305)**	**$ (126,644)**	**$ (92,907)**
Net loss per share, basic and diluted	**$ (1.02)**	**$ (0.77)**	**$ (3.44)**	**$ (3.33)**
Weighted average common shares outstanding, basic and diluted	43,590,657	34,342,664	36,786,575	27,890,846

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

	Years Ended April 30,	
	2024	**2023**
Cash flows from operating activities		
Net loss	$ (126,644)	$ (92,907)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	816	718
Stock-based compensation expense	21,915	9,922
Realized (gain) loss from sale of marketable securities	(1,325)	139
Non-cash operating lease expense	(12)	84
Amortization of premium on marketable securities	92	988
Foreign currency exchange loss (gain)	760	(1,618)
Changes in operating assets and liabilities:		
Research and development tax credit receivable	8,176	(2,316)
Prepaid expenses and other current assets	(538)	6,690
Accounts payable	4,320	1,107
Accrued expenses	3,209	1,932
Net cash used in operating activities	(89,231)	(75,261)
Cash flows from investing activities		
Purchases of marketable securities	(189,231)	(98,246)
Sales and maturities of marketable securities	104,955	140,857
Acquisition of property and equipment	(42)	(1,196)
Capitalized website development costs	(401)	-
Net cash provided by investing activities	(84,719)	41,415

Cash flows from financing activities		
Issuance of common stock, net of offering expenses	106,560	56,582
Issuance of pre-funded warrants, net of offering expenses	43,508	1,085
Issuance of common stock from equity incentive plans	646	449
Net cash provided by financing activities	150,714	58,116
Effect of exchange rate changes on cash and cash equivalents	(1,213)	1,236
Net (decrease) increase in cash and cash equivalents	(24,449)	25,506
Cash and cash equivalents at beginning of period	56,238	30,732
Cash and cash equivalents at end of period	$ 31,789	$ 56,238

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