KalVista Pharmaceuticals Reports Second Fiscal Quarter Results and Provides Operational Update

Dec 05, 2024

–Continuing to build commercial infrastructure; on track for potential sebetralstat launch in Q2 2025–

–Multinational regulatory submissions for sebetralstat position Company to transform hereditary angioedema (HAE) treatment worldwide–

–Pro forma cash and cash equivalents of $292.2 million provide runway into second half 2027–

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Dec. 5, 2024-- KalVista Pharmaceuticals, Inc. (NASDAQ: KALV), today released financial results for the second fiscal quarter ended October 31, 2024. The Company also provided an operational update, highlighted by the U.S. Food and Drug Administration (FDA) acceptance of a New Drug Application (NDA) for sebetralstat, a novel, investigational treatment for hereditary angioedema (HAE).

“KalVista is successfully executing on the key milestones we announced at the beginning of our fiscal year as we move towards multiple potential commercial launches of sebetralstat in 2025,” said Ben Palleiko, Chief Executive Officer of KalVista. “With six marketing authorization applications filed to date and the first potential approval expected next June, we remain focused on achieving our goal of making sebetralstat available to people living with HAE globally. In support of that goal, during the quarter, we presented additional data from our clinical program at multiple conferences, demonstrating that patients used sebetralstat to treat attacks early and that early treatment with on-demand therapy resulted in meaningful clinical benefit. Finally, the additional capital we recently raised, including the non-dilutive synthetic royalty financing, will support our continued planning for the potential launch of sebetralstat in multiple markets.”

Second Fiscal Quarter and Recent Business Highlights:

Sebetralstat

- In September 2024, KalVista announced that the FDA accepted its NDA for sebetralstat, a novel, investigational oral plasma kallikrein inhibitor that has the potential to be the first and only oral on-demand treatment for HAE attacks in people aged 12 years and older. The FDA has set a Prescription Drug User Fee Act (PDUFA) goal date of June 17, 2025.
- Also in September, KalVista announced Marketing Authorization Application (MAA) submissions to regulatory authorities in the United Kingdom, Switzerland, Australia and Singapore via the Access Consortium framework, designed to maximize regulatory collaboration across countries and support a timely review process. This follows the August European Medicines Agency (EMA) validation of the MAA for sebetralstat.
- KalVista presented new sebetralstat data at the 2024 American College of Allergy Asthma and Immunology. Presentations included Phase 3 trial data that showed early treatment is correlated with shorter attack duration, as well as a rigorous comparison of Phase 3 results for oral sebetralstat and pivotal trial results of IV recombinant C1-inhibitor for on-demand treatment of HAE attacks that showed no differences in time to the beginning of symptom relief.
- In addition, KalVista presented new data at the 2024 HAEi Global Angioedema Forum that highlighted the effectiveness of sebetralstat in reducing anxiety during HAE attacks and underscored the importance of having an oral, on-demand treatment option that could help people manage attacks earlier and more frequently. Patient perspectives shared at the forum also reinforced the high prevalence of anxiety associated with the use of injectable therapies, further supporting the call for more accessible oral alternatives.

Organizational

- In November, KalVista raised a total of $160 million in aggregate gross proceeds through concurrent synthetic royalty financing and equity offerings. The synthetic royalty financing agreement with DRI Healthcare provides up to $179 million in non-dilutive funding, including $100 million upfront. In addition, the Company closed a public offering raising $55 million as well as $5 million in a private placement to DRI Healthcare.
- The Company appointed Brian Piekos as Chief Financial Officer.

Second Fiscal Quarter Financial Results

- The Company did not record any revenue for the three months ended October 31, 2024 or three months ended October 31, 2023.
- Research and development expenses were $16.6 million for the three months ended October 31, 2024, compared to $19.1 million for the same period in the prior fiscal year. The decrease was primarily attributable to reduced preclinical activities and recognizing expense associated with sebetralstat pre-commercial awareness within *General & Administrative*.
- General and administrative expenses were $29.2 million for the three months ended October 31, 2024, compared to $10.7 million for the same period in the prior fiscal year. The increase was primarily due to pre-commercial planning activities related to sebetralstat.

- As of October 31, 2024, the Company had cash, cash equivalents and marketable securities of approximately $135.8 million ($292.2 million, on a pro forma basis, including the approximately $156.4 million net proceeds raised in November 2024 through the synthetic royalty financing and equity offerings). The Company anticipates that this pro forma balance provides sufficient runway into the second half of 2027.

About KalVista Pharmaceuticals, Inc.

KalVista Pharmaceuticals, Inc. is a global pharmaceutical company whose mission is to develop and deliver life-changing oral medicines for people affected by rare diseases with significant unmet needs. Sebetralstat, our novel, investigational candidate for the oral, on-demand treatment of hereditary angioedema, is under regulatory review by the FDA with a PDUFA goal date of June 17, 2025. We have also completed Marketing Authorization Applications for sebetralstat to the European Medicines Agency and multiple other countries. For more information, please visit www.kalvista.com or follow us on social media at @KalVista and LinkedIn.

About Sebetralstat

Discovered and developed entirely by KalVista, sebetralstat is a novel, investigational oral plasma kallikrein inhibitor for the treatment of hereditary angioedema (HAE). Our initial goal is to deliver sebetralstat as the first oral, on-demand treatment for HAE in people aged 12 years and older. In addition, we are studying the potential of sebetralstat for the on-demand treatment of HAE in children aged 2 to 11 years. We believe that, if approved, sebetralstat has the potential to become the foundational therapy for HAE disease management globally.

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, 2024, 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)

	October 31, 2024	April 30, 2024
Cash, Cash Equivalents & Marketable Securities	$ 135,776	$ 210,401
Other Current Assets	16,491	15,289
Total Current Assets	152,267	225,690
Other Assets	8,564	9,714
Total Assets	**$ 160,831**	**$ 235,404**
Current Liabilities	22,164	22,807
Long-term Liabilities	4,675	6,015
Total Liabilities	26,839	28,822
Total Stockholders' Equity	133,992	206,582
Total Liabilities and Stockholders' Equity	**$ 160,831**	**$ 235,404**

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

	Three Months Ended October 31,		Six Months Ended October 31,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	16,610	19,089	43,225	38,396
General and administrative	29,201	10,657	46,801	20,443
Total operating expenses	45,811	29,746	90,026	58,839
Operating loss	**(45,811)**	**(29,746)**	**(90,026)**	**(58,839)**

Other income:				
Interest income	1,357	776	3,050	1,699
Foreign currency exchange rate (loss) gain	67	(1,299)	581	(843)
Other income	2,119	2,619	3,685	5,016
Total other income	**3,543**	**2,096**	**7,316**	**5,872**
Net loss	**$ (42,268)**	**$ (27,650)**	**$ (82,710)**	**$ (52,967)**
Net loss per share, basic and diluted	**$ (0.91)**	**$ (0.80)**	**$ (1.78)**	**$ (1.54)**
Weighted average common shares outstanding, basic and diluted	46,695,220	34,565,955	46,464,099	34,490,090

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