KalVista Pharmaceuticals Provides Operational Update and Fiscal Year 2025 Financial Results

Jul 10, 2025

– Received FDA approval of EKTERLY® (sebetralstat)—the first and only oral on-demand treatment for hereditary angioedema; U.S. launch underway –

– Six additional global regulatory submissions under review –

– Entered licensing agreements for sebetralstat commercialization in Japan and Canada –

– $220.6M in cash, providing runway into 2027 –

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Jul. 10, 2025-- KalVista Pharmaceuticals, Inc. (Nasdaq: KALV), today provided an operational update and released financial results for the fiscal year ended April 30, 2025.

"The FDA approval of EKTERLY represents a major milestone—not only as the first commercial product for KalVista, but more importantly, as the first and only oral on-demand therapy for people living with HAE," said Ben Palleiko, CEO of KalVista Pharmaceuticals. "EKTERLY delivers a long-awaited treatment that is safe, effective, and easy to administer. Our commercial team is actively engaging in the field, leveraging their expertise to educate and activate patients and physicians to enable timely access, drive awareness, and support informed treatment decisions around this important new therapy. With commercial partners now in place in Canada and Japan, and six global regulatory submissions under review, we believe EKTERLY is poised to become the foundational therapy for HAE management worldwide."

Recent Business Highlights

EKTERLY® (sebetralstat)

- On July 7, 2025, KalVista announced FDA approval of EKTERLY (sebetralstat), a novel plasma kallikrein inhibitor, for the treatment of acute attacks of hereditary angioedema (HAE) in adult and pediatric patients aged 12 years and older.
- KalVista further strengthened the robust body of clinical evidence supporting the efficacy and safety of EKTERLY (sebetralstat) for the treatment of HAE. The Company presented new data at the European Academy of Allergy and Clinical Immunology Congress 2025 (EAACI), the 14th C1-inhibitor Deficiency & Angioedema (C1-INH) Workshop in Budapest, Hungary, and the Eastern Allergy Conference (EAC) in Palm Beach, Florida. Key highlights from these medical congresses are outlined below:
    - EAACI: Data showed the efficacy of EKTERLY (sebetralstat) for the on-demand treatment of HAE attacks among patients receiving long-term prophylaxis (LTP). Real world data highlighted significant challenges with LTP adherence, and ongoing reliance on on-demand medications. In KONFIDENT-S, EKTERLY (sebetralstat) delivered rapid, consistent relief for attacks, regardless of LTP mechanism of action with a median time to beginning of symptom relief of 1.3 hours.
    - C1-INH: Analysis from nearly 1,600 attacks in KONFIDENT-S showed a median time to end of attack progression of 19.8 minutes. These results aligned closely with KONFIDENT, reinforcing the rapid effect of EKTERLY (sebetralstat) after absorption. Interim data from KONFIDENT-S highlighted the role of EKTERLY (sebetralstat) in treating mucosal attacks with a median time to beginning of symptom relief of 1.3 hours for both abdominal and laryngeal attacks.
    - EAC: In KONFIDENT-S, EKTERLY (sebetralstat) was used to treat 76 attacks that had progressed to severe or very severe after a median of 2.16 hours from attack onset, demonstrating its utility in more advanced stages of HAE attacks. The median time to beginning of symptom relief for these attacks was 1.36 hours, with reduction in attack severity and substantial reduction of symptom burden in a median of 1.77 hours and 9.15 hours, respectively.

Organizational

- In April, KalVista entered into an exclusive agreement with Kaken Pharmaceutical, Co., Ltd. to commercialize sebetralstat in Japan. Under the terms of the deal, in June 2025 KalVista received an upfront payment of $11 million, and an additional $11 million will be paid upon achieving a regulatory milestone anticipated in early 2026. This agreement also includes potential commercial milestone payments of up to $2 million and royalties based on the Japan National Health Insurance (NHI) price, with royalties expected to be in the mid-twenties as a percentage of sales.
- In June, KalVista granted Pendopharm, a division of Pharmascience Inc., the exclusive rights to manage the regulatory approval process and commercialization of sebetralstat in Canada.

Financial Results for Fiscal Year Ended April 30, 2025:

- Research and development expenses were $71.7 million and $86.2 million for the fiscal years ended April 30, 2025, and 2024, respectively. The decrease in R&D was primarily attributable to reduced clinical trial expenses, preclinical activities and recognizing expense associated with EKTERLY (sebetralstat) pre-commercial awareness within General & Administrative.
- General and administrative expenses were $116.3 million and $54.3 million for the fiscal years ended April 30, 2025, and 2024, respectively. The increase in G&A expenses was primarily due to pre-commercial planning expenses related to EKTERLY (sebetralstat).
- Cash, cash equivalents and marketable securities were $220.6 million on April 30, 2025, compared to $210.4 million on April 30, 2024.

About KalVista Pharmaceuticals, Inc.

KalVista Pharmaceuticals, Inc., is a global biopharmaceutical company dedicated to developing and delivering life-changing oral therapies for individuals affected by rare diseases with significant unmet needs. In the U.S., KalVista markets EKTERLY®, the first and only oral on-demand treatment for hereditary angioedema (HAE). The Company has multiple regulatory applications under review in key global markets. For more information about KalVista, please visit www.kalvista.com and follow us on LinkedIn, X, Facebook and Instagram.

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, information relating to our business and business plans, the success of our efforts to commercialize EKTERLY® (sebetralstat), our ability to successfully obtain foreign regulatory approvals for sebetralstat, our expectations about the safety and efficacy of sebetralstat and our other product candidates, the timing of clinical trials and their results, our ability to commence clinical studies or complete ongoing clinical studies, including our KONFIDENT-S and KONFIDENT-KID trials, and the ability of EKTERLY to treat HAE , 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, 2025, 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.
Consolidated Balance Sheets
April 30, 2025 and 2024
(in thousands except share and per share amounts)
(Unaudited)

	2025	2024
Cash, cash equivalents & Marketable securities	$ 220,617	$ 210,401
Other current assets	21,073	15,289
Total current assets	241,690	225,690
Other assets	9,080	9,714
Total assets	**$ 250,770**	**$ 235,404**
Current liabilities	$ 45,167	$ 22,807
Long-term liabilities	110,212	6,015
Total Liabilities	155,379	28,822
Stockholders' equity	95,391	206,582
Total liabilities and stockholders' equity	**$ 250,770**	**$ 235,404**

KALVISTA PHARMACEUTICALS, INC.
Consolidated Statements of Operations and Comprehensive Loss
Years Ended April 30, 2025 and 2024
(in thousands, except share and per share amounts)
(Unaudited)

	2025	2024
Research and development	$ 71,709	$ 86,167
General and administrative	116,286	54,278
Total operating expenses	187,995	140,445
Operating loss	(187,995)	(140,445)
Other income:		
Interest income	6,435	3,896
Interest (expense)	(5,785)	—
Foreign currency exchange gain (loss)	2,481	138
Other income (expenses), net	4,812	9,767
Total other income	7,943	13,801

Loss before income taxes	(180,052)	(126,644)
Income tax (benefit) expense	3,392	—
Net loss	$ (183,444)	$ (126,644)
Net loss per share, basic and diluted	$ (3.69)	$ (3.44)
Weighted average common shares outstanding, basic and diluted	49,652,878	36,786,575

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