KalVista Pharmaceuticals Provides Operational Update and Reports Fiscal Quarter Financial Results

Sep 11, 2025

-EKTERLY® now approved in the US and UK; first and only oral on-demand therapy for acute attacks of hereditary angioedema-

-Initiated US EKTERLY launch in July; received 460 patient start forms through August-

-European Medicines Agency adopted a positive opinion recommending approval of sebetralstat and confirmed maintenance of orphan designation in EU; decision expected early October-

-$191M in cash, providing runway into 2027-

-Management to host conference call today at 8:30 a.m. ET-

FRAMINGHAM, Mass. & SALISBURY, England--(BUSINESS WIRE)--Sep. 11, 2025-- KalVista Pharmaceuticals, Inc. (Nasdaq: KALV), today provided an operational update and released financial results for the fiscal quarter ended July 31, 2025.

"This quarter marked a defining moment in the history of KalVista with the FDA approval of EKTERLY—the first and only oral on-demand treatment for HAE," stated Ben Palleiko, CEO of KalVista. "Approval and launch on the same day propelled us immediately into our next chapter of growth as a commercial company, and the response has been extraordinary. In just eight weeks following approval, we have received 460 patient start forms, representing almost five percent of the reported HAE patient population in the US. This early demand has exceeded our expectations, validating both the urgent unmet need that EKTERLY addresses and its potential to redefine management of HAE. Backed by a strong balance sheet and a world-class team, we are well positioned to maximize the global opportunity for EKTERLY to become the foundational therapy for people living with HAE."

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.
- Initiated US commercial launch on July 7, 2025 and received 460 patient start forms for the period ended August 29, 2025.
- In July 2025, the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom (UK) granted marketing authorization for EKTERLY (sebetralstat). EKTERLY also met the requirements of the MHRA Orphan Designation criteria and will be added to the Orphan Register held by the MHRA, allowing it to benefit from up to 10 years of market exclusivity.
- Also in July, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending marketing authorization for sebetralstat. The European Commission (EC) final decision is expected in October 2025.
- Additionally, the Committee for Orphan Medicinal Products (COMP) of the EMA confirmed maintenance of orphan designation for sebetralstat. The decision was based on a finding of comparable efficacy to injectable on-demand treatments with a major contribution to patient care by reducing the HAE attack morbidity. This designation secures important regulatory and financial benefits, including 10 years of EU market exclusivity, making sebetralstat one of only two HAE medicines to retain orphan status and underscoring its unique position within the HAE treatment landscape.

First Fiscal Quarter Financial Results

- Recognized $1.4 million in net product revenue for the three months ended July 31, 2025. Net product revenue consists of US sales of EKTERLY, which was commercially available in the middle of July following FDA approval.
- Cost of revenue was $0.6 million for the three months ended July 31, 2025 which included EKTERLY manufacturing and inventory overhead costs incurred after US approval. Cost of revenue was not recognized during the three months ended July 31, 2024, given that no product sales were recorded.
- Research and development expenses were $15.2 million and $26.6 million in the three months ended July 31, 2025, and 2024, respectively. The decrease in R&D was primarily attributable to reduced clinical trial expenses and recognizing expenses associated with EKTERLY pre-commercial awareness within selling, general and administrative expenses.
- Selling, general and administrative expenses were $44.7 million and $17.6 million in the three months ended July 31, 2025, and 2024, respectively. The increase in SG&A was primarily attributable to commercialization expenses related to EKTERLY.
- As of July 31, 2025, the Company had cash, cash equivalents and marketable securities of approximately $191.5 million.

Earnings Conference Call and Webcast

KalVista management will host a webcast today, September 11, 2025, at 8:30 a.m. ET. The webcast will be available on the Investors and News section of KalVista's website at https://ir.kalvista.com. A replay of the webcast will be archived and available for at least 30 days following the event.

About EKTERLY® (sebetralstat)

EKTERLY (sebetralstat) is a novel plasma kallikrein inhibitor approved in the United States and United Kingdom for the treatment of acute attacks of hereditary angioedema (HAE) in people 12 years of age and older. EKTERLY is the first and only oral on-demand treatment for HAE, offering efficacious and safe treatment of attacks without the burden of injections. With ongoing studies exploring its use in children aged two to 11 and multiple regulatory applications under review in key global markets, EKTERLY has the potential to become the foundational therapy for HAE management worldwide. For more information, including the full U.S. Prescribing Information, visit EKTERLY.com.

About KalVista Pharmaceuticals, Inc.

KalVista is a global pharmaceutical company dedicated to delivering life-changing oral therapies for individuals affected by rare diseases with significant unmet needs. The KalVista team discovered and developed EKTERLY®—the first and only oral on-demand treatment for hereditary angioedema (HAE)—and continues to work closely with the global HAE community to improve treatment and care for this disease around the world. 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," "position," "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, including revenues from sales of EKTERLY, 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
(in thousands except share and per share amounts)
(Unaudited)

	July 31, 2025	April 30, 2025
Cash, cash equivalents & Marketable securities	$ 191,465	$ 220,617
Other current assets	14,431	21,073
Total current assets	205,896	241,690
Other assets	9,609	9,080
Total assets	**$ 215,505**	**$ 250,770**
Current liabilities	$ 38,375	$ 45,167
Long-term liabilities	136,340	110,212
Total Liabilities	174,715	155,379
Stockholders' equity	40,790	95,391
Total liabilities and stockholders' equity	$ **215,505**	**$ 250,770**

KALVISTA PHARMACEUTICALS, INC.
Consolidated Statements of Operations
(in thousands, except share and per share amounts)
(Unaudited)

	For the Three Months Ended July 31,	
	2025	2024
Product revenue, net	$ 1,426	$ —
Cost of revenue	590	—
Research and development	15,162	26,614
Selling, general and administrative	44,683	17,601
Total operating expenses	60,435	44,215
Operating loss	(59,009)	(44,215)
Other income:		
Interest income	1,849	1,692

Interest expense	(3,522)	—
Foreign currency exchange gain	1,925	514
Other income, net	818	1,566
Total other income	1,070	3,772
Loss before income taxes	(57,939)	(40,443)
Income tax expense	2,157	—
Net loss	$ (60,096)	$ (40,443)
Net loss per share, basic and diluted	$ (1.12)	$ (0.87)
Weighted average common shares outstanding, basic and diluted	53,497,128	46,232,977

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