KalVista Pharmaceuticals Provides Operational Update and Reports Third Quarter Financial Results

Nov 10, 2025

US launch of EKTERLY® gaining strong momentum with $13.7 million in net product revenue for the third quarter

937 patient start forms received through October, reflecting rapid adoption as first and only oral on-demand treatment for hereditary angioedema (HAE)

Launched EKTERLY in Germany with initial orders signaling encouraging demand

$309M in cash expected to fund the Company through profitability

Management to host conference call Tuesday, November 11th at 8:30 a.m. ET

FRAMINGHAM, Mass. & SALISBURY, England--(BUSINESS WIRE)--Nov. 10, 2025-- KalVista Pharmaceuticals, Inc. (Nasdaq: KALV), today provided an operational update and reported financial results for the third quarter ended September 30, 2025.

"The US launch of EKTERLY is progressing with significant momentum, driven by strong early demand and rapid adoption among physicians and people living with HAE. We continue to see encouraging trends, with both new patient starts and repeat prescriptions increasing consistently, reflecting sustained uptake and confidence in the clinical value of EKTERLY as the first and only oral on-demand treatment for hereditary angioedema," said Ben Palleiko, CEO of KalVista. "We also recently launched EKTERLY in Germany, with very positive initial demand. And with our most recent approval in Australia, we now hold five regulatory approvals and are on our way to making EKTERLY a truly global product. With the successful closing of our recent $144 million convertible note offering, we have the financial resources to continue advancing our global launch strategy and building long-term growth."

Recent Business Highlights

EKTERLY® (sebetralstat) Commercial Progress and Clinical Highlights

- **United States Launch:** Initiated US commercial launch of EKTERLY on July 7, 2025, with 937 patient start forms received and 423 unique prescribers activated through the period ended October 31, 2025.
- **European Union (EU) and Switzerland Approvals**: In September, the European Commission (EC) and Swiss Agency for Therapeutic Products, Swissmedic, approved EKTERLY for the treatment of acute attacks of HAE in adults and adolescents aged 12 and older. The EC approval is applicable to all 27 EU member states as well as Iceland, Liechtenstein and Norway. EKTERLY is the first and only oral on-demand treatment for HAE in the EU and Switzerland.
- **Germany Launch:** In October, KalVista initiated its first European launch in Germany with patients receiving initial shipments of EKTERLY.
- **Australia Approval**: Also in October, the Therapeutic Goods Administration (TGA) of Australia approved EKTERLY for the treatment of HAE attacks caused by C1 inhibitor deficiency or dysfunction in patients aged 12 years and older.
- **Medical Congress Update:** Presented new EKTERLY (sebetralstat) data on pediatrics and patient satisfaction at the American College of Allergy, Asthma & Immunology (ACAAI) 2025 Annual Scientific Meeting:
    - Interim results from KONFIDENT-KID, an open-label clinical trial of sebetralstat for on-demand treatment of HAE attacks in pediatric patients aged 2-11, enabled early and safe treatment with a median time to dosing of 30-minutes and a median time to symptom relief of 1.5-hours.
    - For 1,089 attacks treated with sebetralstat by patients in KONFIDENT-S who had switched from injectable on-demand treatments (icatibant, pdC1INH, rhC1INH), 84% of attacks were rated as satisfied, with a median treatment satisfaction score of 2 (very satisfied).

Organizational Updates

- Bilal Arif and Linea Aspesi joined KalVista as Chief Operating Officer and Chief People Officer, respectively.
- Bethany L. Sensenig joined KalVista's Board of Directors and the Audit Committee of the Board.

Third Quarter Financial Results

- Recognized $13.7 million in net product revenue for the three months ended September 30, 2025.
- Cost of revenue was $1.2 million for the three months ended September 30, 2025 which included EKTERLY manufacturing and inventory overhead costs incurred after US approval.
- Research and development expenses were $12.0 million and $18.7 million in the three months ended September 30, 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 $46.5 million and $24.8 million in the three months ended September 30, 2025, and 2024, respectively. The increase in SG&A was primarily attributable to commercialization expenses related to EKTERLY.
- As of September 30, 2025, the Company had cash, cash equivalents and marketable securities of approximately $309.2 million. We anticipate that cash, cash equivalents and marketable securities as of September 30, 2025, along with projected revenues associated with the sale of EKTERLY will fund the Company through profitability.

Earnings Conference Call and Webcast
KalVista management will host a conference call and webcast to discuss the results at 8:30 a.m. ET on Tuesday, November 11, 2025. The live audio webcast will be accessible on the Investors section of the Company's website at www.ir.kalvista.com/event-calendar. An archived replay will be available on the site approximately two hours after completion of the event.

About EKTERLY® (sebetralstat)
EKTERLY (sebetralstat) is a novel plasma kallikrein inhibitor approved in the United States, European Union, United Kingdom, Switzerland and Australia 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 additional 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, 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)

	September 30, 2025	December 31, 2024
Cash, cash equivalents & marketable securities	$ 309,158	$ 268,345
Other current assets	16,068	17,634
Total current assets	325,226	285,979
Other assets	14,705	8,837
Total assets	**$ 339,931**	**$ 294,816**
Current liabilities	$ 45,069	$ 26,114
Long-term liabilities	277,863	104,343
Total Liabilities	322,932	130,457
Stockholders' equity	16,999	164,359
Total liabilities and stockholders' equity	$ 339,931	**$ 294,816**

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

	For the Three Months Ended September 30,	
	2025	2024
Product revenue, net	$ 13,692	$ —
Cost of revenue	1,232	—
Research and development	11,993	18,680
Selling, general and administrative	46,517	24,800

Total operating expenses	59,742	43,480
Operating loss	(46,050)	(43,480)
Other (expense) income:		
Interest income	1,875	1,580
Interest expense	(4,757)	—
Foreign currency exchange (loss) gain	(884)	1,072
Other income, net	2,491	1,744
Total other (expense) income	(1,275)	4,396
Loss before income taxes	(47,325)	(39,084)
Income tax expense	2,157	—
Net loss	$ (49,482)	$ (39,084)
Net loss per share, basic and diluted	$ (0.92)	$ (0.84)
Weighted average common shares outstanding, basic and diluted	53,883,681	46,590,514

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