



KalVista Pharmaceuticals Reports Third Fiscal Quarter Results

March 9, 2023

- Enrollment in sebetralstat KONFIDENT phase 3 trial passes 50% milestone; data remains H2 2023-

- Sebetralstat phase 2 data published in *The Lancet* -

- Company funded into 2025 -

CAMBRIDGE, Mass. & SALISBURY, United Kingdom--(BUSINESS WIRE)--Mar. 9, 2023-- [KalVista Pharmaceuticals, Inc.](https://www.kalvista.com) (NASDAQ: KALV), a clinical stage pharmaceutical company focused on the discovery, development, and commercialization of oral, small molecule protease inhibitors, today provided an operational update and released financial results for the third fiscal quarter ended January 31, 2023.

"We have made significant advances at KalVista over this quarter, including completing a financing that funds us into 2025, well beyond our phase 3 data results, which remain on track for the second half of this year," said Andrew Crockett, Chief Executive Officer of KalVista. "We continue to publish sebetralstat data across a wide variety of outlets, including influential medical journals such as *The Lancet*, and make presentations at prestigious medical and patient meetings. We remain committed to addressing the unmet needs of the hereditary angioedema (HAE) community by providing sebetralstat as a significant advancement in treatment for this disease."

Third Fiscal Quarter and Recent Business Highlights:

- Reported new data in five posters at the 2023 American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting. The data showed the impact of HAE attacks on anxiety and quality of life in people living with HAE, that sebetralstat significantly decreased cumulative attack and symptom severity while increasing cumulative symptom relief of HAE attacks relative to placebo over a 24-hour period following administration, and that phase 1 data for an orally disintegrating tablet formulation supported further clinical development of that formulation.
- Provided multiple progress updates on sebetralstat development, including the announcement that KalVista has enrolled more than 50% of the targeted number of patients in the pivotal phase 3 KONFIDENT clinical trial. In addition, the Company received FDA regulatory guidance that efficacy trials are not required to support a supplemental NDA (sNDA) filing for the orally disintegrating tablet (ODT) formulation of sebetralstat. KalVista also received guidance from the Japanese regulatory authority (PMDA) on the clinical development pathway to a regulatory submission in that country.
- Published a manuscript in *The Lancet* focused on the phase 2 clinical trial results for sebetralstat.
- Presented data at Western Society of Allergy, Asthma & Immunology (WSAAI) 60th Annual Scientific Session examining the use of sebetralstat as a possible treatment for short-term prophylaxis (STP) as part of the KONFIDENT-S open-label extension clinical trial. Other data assessed the pharmacokinetic and pharmacodynamic parameters of sebetralstat in Japanese adults supporting the expansion of the KONFIDENT phase 3 trial to Japan and delineated a post hoc analysis of phase 2 trial data demonstrating that sebetralstat provided similar symptom relief, reduction in attack severity, and use of rescue regardless of abdominal or peripheral attack location.
- Promoted Chief Financial/Business Officer Benjamin L. Palleiko to President of KalVista and tasked him with the development of the Company's commercial and business organization.
- Announced \$58 million of new funding via a registered direct offering. KalVista intends to use the proceeds of this \$58 million offering to fund clinical trials, commercial sales development, research, working capital, capital expenditures and other general corporate purposes. With the financing, the Company now expects to be able to fund operations into 2025.

Third Fiscal Quarter Financial Results:

Revenue: No revenue was recognized for the three months ended January 31, 2023 or January 31, 2022.

R&D Expenses: Research and development expenses were \$20.1 million for the three months ended January 31, 2023, compared to \$19.7 million for the same period in the prior fiscal year. The increase in R&D expenses during the quarter primarily reflects the ongoing Phase 3 KONFIDENT trial for sebetralstat, increased preclinical spending, and increased personnel costs, offset by a decrease in expense from KVD824.

G&A Expenses: General and administrative expenses were \$6.9 million for the three months ended January 31, 2023, compared to \$6.9 million for the same period in the prior fiscal year. G&A expenses remained consistent primarily due to increases in commercial planning and other administrative expenses offset by decreases in employee related expenses and professional fees.

Net Loss: Net loss was \$21.3 million, or \$(0.75) per weighted average basic and diluted share, for the three months ended January 31, 2023, compared to net loss of \$22.5 million, or \$(0.92) per weighted average basic and diluted share for the same period in the prior fiscal year. The decrease in net loss and net loss per share primarily resulted from increases in interest income and currency exchange rate gains from transactions

denominated in foreign currencies in our U.K. subsidiary.

Cash Position: Cash, cash equivalents and marketable securities were \$171.7 million as of January 31, 2023, compared to \$166.2 million as of April 30, 2022. The increase in the net cash and marketable securities position was primarily due to the net proceeds received from the December 2022 registered direct offering of common stock and pre-funded warrants.

About KalVista Pharmaceuticals, Inc.

KalVista Pharmaceuticals, Inc. is a pharmaceutical company focused on the discovery, development, and commercialization of oral, small molecule protease inhibitors for diseases with significant unmet need. KalVista is developing sebetrastat as an oral on-demand therapy for HAE attacks and is enrolling the Phase 3 KONFIDENT clinical trial. In addition, KalVista's oral Factor XIIa inhibitor program represents a new generation of therapies that may further improve the treatment for people living with HAE and other diseases.

For more information about KalVista, please visit www.kalvista.com.

For more information on the sebetrastat HAE on-demand Phase 3 KONFIDENT study, please visit www.konfidentstudy.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 Phase 3 KONFIDENT trial, and to obtain regulatory approvals for sebetrastat and other candidates in development, the success of any efforts to commercialize sebetrastat, the ability of sebetrastat 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, 2022, 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)

	January 31, April 30,	
	2023	2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 85,049	\$ 30,732
Marketable securities	86,636	135,470
Research and development tax credit receivable	11,892	14,098
Prepaid expenses and other current assets	8,556	13,347
Total current assets	192,133	193,647
Property and equipment, net	3,037	2,178
Right of use assets	8,101	7,862
Other assets	197	193
Total assets	\$ 203,468	\$ 203,880

Liabilities and stockholders' equity

Current liabilities:

Accounts payable	\$ 1,698	\$ 3,638
Accrued expenses	8,851	6,961
Lease liability - current portion	1,057	977
Total current liabilities	11,606	11,576
Long-term liabilities:		
Lease liability - net of current portion	7,421	7,211
Total long-term liabilities	7,421	7,211
Stockholders' equity:		
Common stock, \$0.001 par value	34	25
Additional paid-in capital	504,725	439,104
Accumulated deficit	(316,777)	(250,175)
Accumulated other comprehensive loss	(3,541)	(3,861)
Total stockholders' equity	184,441	185,093
Total liabilities and stockholders' equity	\$ 203,468	\$ 203,880

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

	Three Months Ended		Nine Months Ended	
	January 31,		January 31,	
	2023	2022	2023	2022
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	20,063	19,738	56,325	50,954
General and administrative	6,882	6,945	22,818	18,848
Total operating expenses	26,945	26,683	79,143	69,802
Operating loss	(26,945)	(26,683)	(79,143)	(69,802)
Other income:				
Interest income	732	258	1,424	822

Foreign currency exchange rate (loss) gain	597	(198)	(237)	(529)
Other income	4,313	4,156	11,354	11,283
Total other income	5,642	4,216	12,541	11,576
Net loss	\$ (21,303)	\$ (22,467)	\$ (66,602)	\$ (58,226)
Net loss per share, basic and diluted	\$ (0.75)	\$ (0.92)	\$ (2.58)	\$ (2.38)
Weighted average common shares outstanding, basic and diluted	28,278,453	24,479,660	25,810,369	24,449,788

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

Nine Months Ended

January 31,

2023 2022

Cash flows from operating activities

Net loss	\$ (66,602)	\$ (58,226)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	530	408
Stock-based compensation expense	7,481	8,432
Realized loss (gain) from sale of marketable securities	84	296
Non-cash operating lease expense	52	153
Amortization of premium on marketable securities	890	2,081
Foreign currency exchange loss (gain)	(1,339)	698
Changes in operating assets and liabilities:		
Research and development tax credit receivable	2,049	(1,477)
Prepaid expenses and other current assets	4,440	(3,659)
Accounts payable	(1,911)	228
Accrued expenses	1,701	(279)
Net cash used in operating activities	(52,625)	(51,345)

Cash flows from investing activities

Purchases of marketable securities	(63,757)	(84,415)
Sales and maturities of marketable securities	112,509	130,686
Acquisition of property and equipment	(1,127)	(845)
Net cash provided by investing activities	47,625	45,426
Cash flows from financing activities		
Issuance of common stock from equity incentive plans	482	1,443
Issuance of common stock, net of offering expenses of \$0.3 million	56,582	-
Issuance of pre-funded warrants, net of offering expenses	1,085	-
Net cash provided by financing activities	58,149	1,443
Effect of exchange rate changes on cash and cash equivalents	1,168	(539)
Net (decrease) increase in cash and cash equivalents	54,317	(5,015)
Cash and cash equivalents at beginning of period	30,732	50,592
Cash and cash equivalents at end of period	\$ 85,049	\$ 45,577

View source version on [businesswire.com](https://www.businesswire.com/news/home/20230309005246/en/): <https://www.businesswire.com/news/home/20230309005246/en/>

KalVista Pharmaceuticals, Inc.

Jarrold Aldom

Vice President, Corporate Communications

(201) 705-0254

jarrod.aldom@kalvista.com

Source: KalVista Pharmaceuticals, Inc.