KalVista Pharmaceuticals Reports Second Fiscal Quarter Results

Dec 08, 2022

- Phase 1 Clinical Trial for Orally Disintegrating Tablet Formulation of Sebetralstat Completed –

- Sebetralstat Data Published in the Journal of Medicinal Chemistry and Xenobiotica –

- Sebetralstat Phase 3 Data Remain on Track for H2 2023 –

CAMBRIDGE, Mass. & SALISBURY, United Kingdom--(BUSINESS WIRE)--Dec. 8, 2022-- KalVista Pharmaceuticals, Inc. (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 second fiscal quarter ended October 31, 2022.

"We made a very difficult decision this quarter in terminating our phase 2 KOMPLETE trial for KVD824, but the safety of patients is of utmost importance to our Company," said Andrew Crockett, Chief Executive Officer of KalVista. "We remain committed to providing best-in-class oral treatments for the hereditary angioedema (HAE) community. We are particularly excited about our recent data for the orally disintegrating tablet (ODT) formulation of sebetralstat, which will enable people to take a dose without requiring chewing or swallowing. We are also pleased with the progress of our Phase 3 KONFIDENT clinical trial for sebetralstat, which remains on our enrollment target for data in the second half of 2023."

Second Fiscal Quarter and Recent Business Highlights:

- Presented at both the Stifel 2022 Healthcare Conference and the Jefferies London Healthcare Conference.
- Reported new patient-focused data at the American College of Allergy Asthma & Immunology (ACAAI) 2022 meeting. The data showed the impact of attacks on mental health, daily activities, and quality of life in people living with HAE and demonstrated the treatment burden associated with on-demand parenteral HAE therapies.
- Announced data from a Phase 1 study of an ODT formulation of sebetralstat. KalVista believes this data supports further development of the formulation, which may have significant benefit for pediatric patients and those who experience difficulty swallowing.
- Published new sebetralstat data in both the *Journal of Medicinal Chemistry* and *Xenobiotica*, focusing on the medicinal chemistry KalVista conducted that led to the discovery of sebetralstat, and how sebetralstat's absorption, metabolism, and excretion properties are beneficial for on-demand treatment of HAE attacks.
- Appointed Brian J. G. Pereira, M.D., as Chairman of the Board of Directors.
- Presented data at the 2022 HAEi Global Leadership Workshop with patient perspectives that support the use of the Patient Global Impression of Change (PGI-C) scale as a clinical endpoint to assess the efficacy of on-demand treatments for HAE attacks in the phase 3 KONFIDENT trial of sebetralstat.
- Announced the termination of the Phase 2 KOMPLETE study for KVD824, due to elevations in liver enzymes observed in patients during the trial. The Company intends to evaluate the unblinded data prior to making any final decisions as to the potential future development of KVD824.
- Enrollment is proceeding as expected for the Phase 3 KONFIDENT trial for sebetralstat, with data expected in the second half of 2023 and an NDA filing planned for the first half of 2024.

Second Fiscal Quarter Financial Results:

Revenue: No revenue was recognized for the three months ended October 31, 2022 or October 31, 2021.

R&D Expenses: Research and development expenses were $18.1 million for the three months ended October 31, 2022, compared to $17.5 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.

G&A Expenses: General and administrative expenses were $7.8 million for the three months ended October 31, 2022, compared to $6.1 million for the same period in the prior fiscal year. The increase in G&A expenses was primarily due to an increase in commercial planning expenses, professional fees, and to a lesser extent, increases in investor and public relations expenses.

Net Loss: Net loss was $22.3 million, or $(0.90) per weighted average basic and diluted share, for the three months ended October 31, 2022, compared to net loss of $19.7 million, or $(0.80) per weighted average basic and diluted share for the same period in the prior fiscal year. The increase in net loss and net loss per share primarily resulted from the increase in operating expenses, primarily research and development.

Cash Position: Cash, cash equivalents and marketable securities were $122.3 million as of October 31, 2022, compared to $166.2 million as of April 30, 2022. The decrease in the net cash and marketable securities position was due to cash consumption from operating expenses.

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 has developed a proprietary portfolio of novel, small molecule plasma kallikrein inhibitors initially targeting hereditary angioedema (HAE) and diabetic macular edema (DME). KalVista is developing sebetralstat 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. In DME, an intravitreally administered plasma kallikrein inhibitor, called KVD001, has completed a Phase 2 clinical trial.

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

For more information on the sebetralstat 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, including the potential impact of COVID-19, 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 sebetralstat and other candidates in development, the ability of sebetralstat and other candidates in development to treat HAE or DME, 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)

	October 31, 2022	April 30, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 38,585	$ 30,732
Marketable securities	83,688	135,470
Research and development tax credit receivable	20,029	14,098
Prepaid expenses and other current assets	8,914	13,347
Total current assets	151,216	193,647
Property and equipment, net	3,060	2,178
Right of use assets	8,365	7,862
Other assets	197	193
Total assets	**$ 162,838**	**$ 203,880**
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,384	$ 3,638
Accrued expenses	6,910	6,961
Lease liability - current portion	1,026	977
Total current liabilities	11,320	11,576
Long-term liabilities:		
Lease liability - net of current portion	7,705	7,211
Total long-term liabilities	7,705	7,211
Stockholders' equity:		
Common stock, $0.001 par value	25	25
Additional paid-in capital	444,588	439,104
Accumulated deficit	(295,474)	(250,175)
Accumulated other comprehensive loss	(5,326)	(3,861)
Total stockholders' equity	143,813	185,093
Total liabilities and stockholders' equity	**$ 162,838**	**$ 203,880**

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,	
	2022	2021	2022	2021
Revenue	**$ —**	**$ —**	**$ —**	**$ —**

Operating expenses:				
Research and development	18,077	17,546	36,262	31,215
General and administrative	7,806	6,057	15,936	11,903
Total operating expenses	25,883	23,603	52,198	43,118
Operating loss	**(25,883)**	**(23,603)**	**(52,198)**	**(43,118)**
Other income:				
Interest income	449	290	691	564
Foreign currency exchange rate (loss) gain	(317)	(280)	(834)	(331)
Other income	3,494	3,943	7,042	7,127
Total other income	**3,626**	**3,953**	**6,899**	**7,360**
Net loss	**$ (22,257)**	**$ (19,650)**	**$ (45,299)**	**$ (35,758)**
Net loss per share, basic and diluted	**$ (0.90)**	**$ (0.80)**	**$ (1.84)**	**$ (1.46)**
Weighted average common shares outstanding, basic and diluted	24,595,039	24,439,623	24,576,327	24,434,852

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

	Six Months Ended October 31,	
	2022	**2021**
Cash flows from operating activities		
Net loss	$ (45,299)	$ (35,758)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	331	259
Stock-based compensation expense	5,148	5,655
Realized loss (gain) from sale of marketable securities	85	120
Non-cash operating lease expense	42	46
Amortization of premium on marketable securities	678	1,424
Foreign currency exchange loss (gain)	(739)	266
Changes in operating assets and liabilities:		
Research and development tax credit receivable	(7,137)	(7,252)
Prepaid expenses and other current assets	3,650	(2,419)
Accounts payable	(81)	1,163
Accrued expenses	(14)	(784)
Net cash used in operating activities	(43,336)	(37,280)
Cash flows from investing activities		
Purchases of marketable securities	(10,102)	(51,695)
Sales and maturities of marketable securities	61,356	84,862
Acquisition of property and equipment	(1,112)	(643)
Net cash provided by investing activities	50,142	32,524
Cash flows from financing activities		
Issuance of common stock from equity incentive plans	336	671
Net cash provided by financing activities	336	671
Effect of exchange rate changes on cash and cash equivalents	711	(16)
Net (decrease) increase in cash and cash equivalents	7,853	(4,101)
Cash and cash equivalents at beginning of period	30,732	50,592
Cash and cash equivalents at end of period	$ 38,585	$ 46,491

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Source: KalVista Pharmaceuticals, Inc.