



KalVista Pharmaceuticals Provides Operational Update and Fiscal Year Financial Results

Jul 01, 2020

– KVD900 Phase 2 Clinical Trial for Oral Treatment of Hereditary Angioedema (HAE) Data Expected in 2H 2020 –

– Oral HAE Prophylactic Candidate KVD824 Phase 2 Clinical Trial Planned to Commence in 2H 2020 –

– Operations Funded into 2022 –

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Jul. 1, 2020-- KalVista Pharmaceuticals, Inc. (NASDAQ: KALV), a clinical stage pharmaceutical company focused on the discovery, development, and commercialization of small molecule protease inhibitors today provided an operational update and released financial results for the fiscal year ended April 30, 2020.

“We have two oral candidates in clinical trials that have the potential to provide HAE patients with a complete set of options to treat their disease,” said Andrew Crockett, Chief Executive Officer of KalVista. “We are pleased with our progress with the formulation work for KVD824 to deliver a twice-daily treatment for prevention of HAE attacks. Subjects have begun dosing with these new formulations to obtain additional pharmacokinetic and pharmacodynamic data, and we look forward to providing these data later this year in advance of starting a Phase 2 clinical trial. Patients also continue to be treated in our Phase 2 clinical trial for KVD900 as an on-demand therapy, and we expect data from that trial in the second half of this year.”

Fiscal 2020 and Recent Business Highlights:

- Opened an Investigational New Drug (IND) Application for KVD900 with the U.S. Food and Drug Administration (FDA) to enable clinical development in the United States.
- Presented at The International Symposium on Ocular Pharmacology and Therapeutics (ISOPT). KalVista’s Chief Scientific Officer, Edward P. Feener, PhD, spoke on “Kallikrein-Kinin System in Diabetic Retinopathy – Novel Target.”
- Received Fast Track designation for KVD900 from the FDA, supporting KalVista’s belief in the high level of unmet need in HAE for oral therapy and providing a potentially expedited path to drug approval.
- Announced results of the Phase 2 trial of KVD001, an intravitreal candidate for treatment of diabetic macular edema (DME). KVD001 did not meet its primary endpoint in the overall study population, but it did demonstrate a protection against vision loss and a pre-specified subgroup analysis showed a clinical benefit on vision. The trial was designed to evaluate patients who were poor responders to previous treatment with anti-VEGF therapy. KVD001 was generally safe and well tolerated with no drug-related serious adverse events. Both KVD001 and future oral DME molecules were subject to an option agreement with Merck, which subsequently expired in February.
- Selected KVD824 for development as a twice-daily oral prophylactic treatment for HAE. KVD824 is a highly potent and selective plasma kallikrein inhibitor which achieved high exposures and a favorable safety and tolerability profile in a first-in-human study. Additional formulation work on KVD824 is ongoing, and the Company expects to provide this and other data before initiating a Phase 2 clinical trial, which is anticipated to be in the second half of 2020.
- Adjusted expectations for KVD900 data to the second half of 2020 due to the impact of COVID-19, and revised financial guidance that activities are funded into at least early 2022.

Fourth Quarter and Full Year Financial Results:

- Revenue: Revenue was \$3.8 million for the three months ended April 30, 2020, compared to \$2.9 million for the same period in the prior fiscal year. Revenue was \$12.7 million for the fiscal year ended April 30, 2020, compared to \$16.1 million for the prior fiscal year. All of the revenue recognized in the fiscal year ended April 30, 2020 was recognized from deferred revenue that existed at the beginning of the period. No future revenue exists under the Merck Option Agreement.
- R&D Expenses: Research and development expenses were \$9.5 million for the three months ended April 30, 2020, compared to \$11.1 million for the same period in the prior fiscal year. The decrease in spending during the quarter was primarily due to the conclusion of the Phase 2 clinical trial for KVD001 in the previous quarter. Research and development expenses were \$40.2 million for the fiscal year ended April 30, 2020, compared to \$35.0 million for the prior fiscal year. The increase in spending in the fiscal year ended April 30, 2020 primarily reflects increased costs related to the ongoing clinical trial for KVD900 as well as increased expenses on preclinical activities.
- G&A Expenses: General and administrative expenses were \$3.3 million for the three months ended April 30, 2020, compared to \$3.0 million for the same period in the prior fiscal year. General and administrative expenses were \$13.0 million for the fiscal year ended April 30, 2020, compared to \$10.9 million for the prior fiscal year. The increase in G&A expenses was primarily due to an increase in compensation related expenses and to a lesser extent, increases in commercial planning expenses, professional fees, and insurance costs.
- Net Loss: Net loss was \$6.6 million, or \$(0.37) per weighted average basic and diluted share, for the three months ended April 30, 2020, compared to net loss of \$8.5 million, or \$(0.49) per weighted average basic and diluted share for the same period in the prior fiscal year. Net loss was \$29.1 million, or \$(1.64) per weighted average basic and diluted share for the fiscal year ended April 30, 2020, compared to net loss of \$20.8 million, or \$(1.38) per weighted average basic and diluted

share in the prior fiscal year. The decrease in net loss and net loss per share in the three months ended April 30, 2020 as compared to the same period in the prior fiscal year primarily resulted from decreased research and development spending due to the completion of the Phase 2 clinical trial for KVD001 in the previous quarter. The increase in net loss and net loss per share in year ended April 30, 2020 was primarily related to the ramp up of research and development activities in the current year compared to the prior fiscal year.

- Cash Position: Cash, cash equivalents and marketable securities were \$67.7 million as of April 30, 2020, compared to \$100.8 million as of April 30, 2019. The decrease in the net cash position was due to increased spending, primarily on research and development activities during the year ended April 30, 2020 compared to the prior fiscal year.

About KalVista Pharmaceuticals, Inc.

KalVista Pharmaceuticals, Inc. is a pharmaceutical company focused on the discovery, development, and commercialization of small molecule protease inhibitors for diseases with significant unmet need. The initial focus is on inhibitors of plasma kallikrein, which is an important component of the body's inflammatory response and which, in excess, can lead to increased vascular permeability, edema and inflammation. KalVista has developed a proprietary portfolio of novel, small molecule plasma kallikrein inhibitors initially targeting hereditary angioedema (HAE) and diabetic macular edema (DME). The Company has created a structurally diverse portfolio of oral plasma kallikrein inhibitors and is advancing multiple drug candidates for HAE as well as DME. KalVista has selected KVD900 as its program to be advanced as an on-demand therapy for acute HAE attacks and is conducting a Phase 2 proof-of-concept study in HAE patients with data expected in the second half of 2020. KVD824 is in development for prophylactic treatment of HAE and is expected to enter a Phase 2 clinical trial in the second half of 2020. In DME, an intravitreally administered plasma kallikrein inhibitor known as KVD001, completed a Phase 2 clinical trial in 2019.

For more information, please visit www.kalvista.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, available funding, our cash runway, potential future clinical trial timing and results, potential benefits of our product candidates, and the impact of COVID-19. Further information on potential risk factors that could affect our business and its 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, 2020 once filed, and our other reports that we may file 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)

	<u>April 30,</u>	<u>April 30,</u>
	<u>2020</u>	<u>2019</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 15,789	\$ 32,006
Marketable securities	51,925	68,805
Research and development tax credit receivable	16,527	11,315
Prepaid expenses and other current assets	<u>4,455</u>	<u>3,420</u>
Total current assets	88,696	115,546
Property and equipment, net	2,043	2,413
Right of use assets	1,612	—
Other assets	<u>178</u>	<u>173</u>
Total assets	<u>\$ 92,529</u>	<u>\$ 118,132</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,677	\$ 2,860
Accrued expenses	5,455	5,647
Deferred revenue - current portion	—	9,545
Lease liability - current portion	<u>588</u>	<u>—</u>
Total current liabilities	<u>7,720</u>	<u>18,052</u>
Long-term liabilities:		
Deferred revenue - net of current portion	—	3,342
Lease liability - net of current portion	<u>1,057</u>	<u>—</u>
Total long-term liabilities	<u>1,057</u>	<u>3,342</u>
Stockholders' equity:		
Common stock, \$0.001 par value	18	17
Additional paid-in capital	207,208	191,123
Accumulated deficit	(121,592)	(92,476)
Accumulated other comprehensive loss	<u>(1,882)</u>	<u>(1,926)</u>
Total stockholders' equity	<u>83,752</u>	<u>96,738</u>

Total liabilities and stockholders' equity \$ 92,529 \$ 118,132

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

	Three Months Ended		Years Ended	
	April 30,		April 30,	
	2020	2019	2020	2019
Revenue	\$ 3,824	\$ 2,926	\$ 12,690	\$ 16,127
Operating expenses:				
Research and development	9,485	11,139	40,194	35,021
General and administrative	3,296	3,047	13,029	10,926
Total operating expenses	12,781	14,186	53,223	45,947
Operating loss	(8,957)	(11,260)	(40,533)	(29,820)
Other income:				
Interest income	363	381	1,830	1,397
Foreign currency exchange rate gain (loss)	(613)	(34)	(367)	49
Other income	2,498	2,511	9,830	7,682
Total other income	2,248	2,858	11,293	9,128
Loss before income taxes	(6,709)	(8,402)	(29,240)	(20,692)
Income tax (benefit) expense	(124)	124	(124)	124
Net loss	\$ (6,585)	\$ (8,526)	\$ (29,116)	\$ (20,816)
Net loss per share, basic and diluted	\$ (0.37)	\$ (0.49)	\$ (1.64)	\$ (1.38)

Weighted average common shares outstanding, basic and diluted 17,845,599 17,253,938 17,748,666 15,080,863

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

	Years Ended	
	April 30,	
	2020	2019
Cash flows from operating activities		
Net loss	\$ (29,116)	\$ (20,816)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	512	378
Stock-based compensation expense	4,448	2,966
Realized (gain) from marketable securities	(300)	(23)
Non-cash operating lease expense	13	—
Amortization of premium on available for sale securities	193	—
Foreign currency exchange (gain) loss	74	(80)
Changes in operating assets and liabilities:		
Research and development tax credit receivable	(5,781)	(4,883)
Prepaid expenses and other current assets	(1,112)	(1,979)
Other assets	(5)	—
Accounts payable	(1,004)	1,534
Accrued expenses	(48)	2,665
Deferred revenue	(12,690)	(16,127)
Net cash used in operating activities	<u>(44,816)</u>	<u>(36,365)</u>
Cash flows from investing activities		
Purchases of available for sale securities	(49,797)	(79,889)
Sales and maturities of available for sale securities	66,770	11,548
Acquisition of property and equipment	(220)	(1,081)
Net cash provided by (used in) investing activities	<u>16,753</u>	<u>(69,422)</u>
Cash flows from financing activities		
Issuance of common stock, net of offering expenses	11,422	87,910
Issuance of common stock from equity incentive plans	216	242

Finance lease principal payments	<u>(54)</u>	<u>(209)</u>
Net cash provided by financing activities	<u>11,584</u>	<u>87,943</u>
Effect of exchange rate changes on cash and cash equivalents	<u>262</u>	<u>(1,205)</u>
Net decrease in cash and cash equivalents	<u>(16,217)</u>	<u>(19,049)</u>
Cash and cash equivalents, beginning of year	<u>32,006</u>	<u>51,055</u>
Cash and cash equivalents, end of year	<u>\$ 15,789</u>	<u>\$ 32,006</u>

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