



KalVista Pharmaceuticals Provides Operational Update and Fiscal Year Financial Results

July 13, 2021

– FDA End-of-Phase 2 Meeting on KVD900 Oral HAE Phase 3 Program Scheduled for Late Q3 2021 –

– FDA Response Submission for KVD824 Phase 2 Clinical Hold Expected Q3 2021 –

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Jul. 13, 2021-- 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, 2021.

“This past fiscal year we made great strides in providing data to support the development of the candidates in our oral hereditary angioedema franchise,” said Andrew Crockett, Chief Executive Officer of KalVista. “Now we are at an important inflection point as we work with regulatory agencies to both finalize the Phase 3 program for KVD900 and begin the Phase 2 clinical trial of KVD824. With our financing earlier this year we are well-capitalized to focus on execution of these activities, and we look forward to providing additional details on the trials later this year as they begin.”

Fiscal 2021 and Recent Business Highlights:

- Reported positive results for KVD900 in a Phase 2 clinical trial demonstrating statistically and clinically significant responses across primary and secondary endpoints as an oral on-demand treatment for hereditary angioedema (HAE) attacks. An end-of-Phase 2 meeting has been scheduled late in the third quarter of calendar year 2021 with the Food and Drug Administration (FDA) to review the planned KVD900 Phase 3 program.
- Provided data on KVD824 as a twice-daily oral candidate for prophylactic treatment of HAE. Work to optimize the exposure profile of KVD824 yielded a formulation that maintained the plasma concentrations that KalVista believes are required to compete with approved injectable therapies, while showing an encouraging safety and tolerability profile in up to 14 days of dosing.
- Announced a novel oral Factor XIIa inhibitor program as the next area of focus. KalVista’s internal research team has discovered multiple series of oral Factor XIIa inhibitors, initially being advanced with the potential to provide the next generation of HAE therapeutics. Investigational New Drug (IND)-enabling studies for oral Factor XIIa inhibitor candidates are expected to commence in calendar year 2021.
- Closed an upsized public offering of common stock and full exercise of the underwriters’ options to purchase additional shares. The gross proceeds, before deducting the underwriting discounts and commissions and other offering expenses were approximately \$222.5 million.
- Appointed Nancy Stuart to the Board of Directors of the Company.
- Submitted an IND for a Phase 2 clinical trial to evaluate KVD824 as a potential prophylactic treatment for the prevention of HAE attacks. The U.S. FDA notified the Company in a letter that it has placed a clinical hold on the proposed Phase 2 clinical trial of KVD824. The FDA letter requested further information and analysis related to certain preclinical studies of KVD824 submitted to support the planned Phase 2 trial, as well as refinements to the intended KVD824 Phase 2 study protocol. The Company intends to submit its response to the FDA during the third quarter of calendar year 2021. KalVista also continues to progress regulatory filings for other countries where it plans to initiate sites for the KVD824 Phase 2.
- Expanded senior leadership team with appointment of Paul K. Audhya, MD, MBA as Chief Medical Officer.
- Presented data from oral HAE franchise at the C1-Inhibitor Deficiency & Angioedema Workshop.

Fourth Quarter and Full Year Financial Results:

- Revenue: No revenue was recognized for the three months ended April 30, 2021, compared to \$3.8 million for the same period in the prior fiscal year. No revenue was recognized for the fiscal year ended April 30, 2021, compared to \$12.7 million for the prior fiscal year. All of the revenue recognized in the prior fiscal year was attributable to the revenue recognized from the Merck Option Agreement and the absence of revenue in the current year was due to the expiration of that agreement in February 2020.
- R&D Expenses: Research and development expenses were \$11.9 million for the three months ended April 30, 2021, compared to \$9.5 million for the same period in the prior fiscal year. Research and development expenses were \$41.3 million for the fiscal year ended April 30, 2021, compared to \$40.2 million for the prior fiscal year. The increase in spending in the fiscal year ended April 30, 2021 primarily reflects increased costs related to the ongoing clinical trials for KVD900 and KVD824, offset by a decrease in spending on KVD001 due to the conclusion of the Phase 2 clinical trial in December 2019 and a decrease in preclinical spending.

- **G&A Expenses:** General and administrative expenses were \$6.2 million for the three months ended April 30, 2021, compared to \$3.3 million for the same period in the prior fiscal year. General and administrative expenses were \$16.6 million for the fiscal year ended April 30, 2021, compared to \$13.0 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 professional fees, insurance costs, facility costs and other administrative costs.
- **Net Loss:** Net loss was \$15.0 million, or \$(0.65) per weighted average basic and diluted share, for the three months ended April 30, 2021, compared to net loss of \$6.6 million, or \$(0.37) per weighted average basic and diluted share for the same period in the prior fiscal year. Net loss was \$46.2 million, or \$(2.42) per weighted average basic and diluted share for the fiscal year ended April 30, 2021, compared to net loss of \$29.1 million, or \$(1.64) per weighted average basic and diluted share in the prior fiscal year. The increase in net loss and net loss per share primarily resulted from the absence of revenue in the current fiscal year due to the expiration of the Merck Option Agreement in February 2020, as well as increased spending on research and development activities in the current fiscal year.
- **Cash Position:** Cash, cash equivalents and marketable securities were \$248.9 million as of April 30, 2021, compared to \$67.7 million as of April 30, 2020. The increase in the net cash position in the current fiscal year is primarily due to the proceeds received in the February 2021 public offering of common stock.

On July 11, 2021, the Board of Directors adopted the KalVista Pharmaceuticals, Inc. 2021 Inducement Equity Incentive Plan (the "Plan"). The Plan reserves 350,000 shares of common stock to be used exclusively for grants of awards to individuals that were not previously employees or directors of KalVista, as an inducement material to the individual's entry into employment with KalVista within the meaning of Rule 5635(c)(4) of the Nasdaq Listing Rules. The Plan was approved by Board of Directors without stockholder approval pursuant to Rule 5635(c)(4), and the terms and conditions of the Plan are substantially similar to KalVista's stockholder-approved 2017 Equity Incentive Plan, as amended.

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. 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 KVD900 as an oral on-demand therapy for acute HAE attacks, which completed a Phase 2 efficacy trial in February 2021, demonstrating statistical and clinical significance across all endpoints. KVD824 is in development for prophylactic treatment of HAE. In addition, KalVista's oral Factor XIIa inhibitor program represents a new generation of therapies that may further improve the treatment of HAE for patients. In DME, an intravitreally administered plasma kallikrein inhibitor, called KVD001, has completed a Phase 2 clinical trial.

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, 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, our expectations about safety and efficacy of our product candidates and timing of clinical trials and its results, our ability to commence or complete clinical studies and to obtain regulatory approvals for KVD900, KVD824 and other candidates in development, our ability to resolve a clinical hold with regards to KVD824, the ability of KVD900, KVD824 and other candidates in development to treat HAE or DME, the future progress and potential success of our oral Factor XIIa program, and the sufficiency of our cash, cash equivalents and investments to fund our operations. 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, 2021 once filed, 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)

	April 30,	April 30,
	2021	2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 50,592	\$ 15,789
Marketable securities	198,337	51,925

Research and development tax credit receivable	10,418	16,527
Prepaid expenses and other current assets	4,917	4,455
Total current assets	264,264	88,696
Property and equipment, net	1,791	2,043
Right of use assets	5,758	1,612
Other assets	200	178
Total assets	\$ 272,013	\$ 92,529
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,981	\$ 1,677
Accrued expenses	6,930	5,455
Lease liability - current portion	863	588
Total current liabilities	9,774	7,720
Long-term liabilities:		
Lease liability - net of current portion	5,046	1,057
Total long-term liabilities	5,046	1,057
Stockholders' equity:		
Common stock, \$0.001 par value	24	18
Additional paid-in capital	426,437	207,208
Accumulated deficit	(167,836)	(121,592)
Accumulated other comprehensive loss	(1,432)	(1,882)
Total stockholders' equity	257,193	83,752
Total liabilities and stockholders' equity	\$ 272,013	\$ 92,529

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,	
2021	2020	2021	2020

Revenue	\$ -	\$ 3,824	\$ -	\$ 12,690
Operating expenses:				
Research and development	11,877	9,485	41,286	40,194
General and administrative	6,165	3,296	16,637	13,029
Total operating expenses	18,042	12,781	57,923	53,223
Operating loss	(18,042)	(8,957)	(57,923)	(40,533)
Other income:				
Interest income	314	363	903	1,830
Foreign currency exchange rate gain (loss)	132	(613)	847	(367)
Other income	2,639	2,498	9,929	9,830
Total other income	3,085	2,248	11,679	11,293
Loss before income taxes	(14,957)	(6,709)	(46,244)	(29,240)
Income tax (benefit) expense	-	(124)	-	(124)
Net loss	\$(14,957)	\$(6,585)	\$(46,244)	\$(29,116)
Net loss per share, basic and diluted	\$ (0.65)	\$ (0.37)	\$ (2.42)	\$ (1.64)
Weighted average common shares outstanding, basic and diluted	23,118,127	17,845,599	19,094,440	17,748,666

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

Years Ended

April 30,

2021 2020

Cash flows from operating activities

Net loss	\$ (46,244) \$ (29,116)	
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	537	512
Stock-based compensation expense	7,118	4,448
Realized (gain) from sale of marketable securities	(153)	(300)

Non-cash operating lease expense	114	13
Amortization of premium on available for sale securities	685	193
Foreign currency exchange (gain) loss	(574)	74
Changes in operating assets and liabilities:		
Research and development tax credit receivable	7,457	(5,781)
Prepaid expenses and other current assets	(222)	(1,112)
Other assets	(22)	(5)
Accounts payable	150	(1,004)
Accrued expenses	983	(48)
Deferred revenue	-	(12,690)
Net cash used in operating activities	(30,171)	(44,816)
Cash flows from investing activities		
Purchases of available for sale securities	(201,210)	(49,797)
Sales and maturities of available for sale securities	53,638	66,770
Acquisition of property and equipment	(82)	(220)
Net cash provided by (used in) investing activities	(147,654)	16,753
Cash flows from financing activities		
Issuance of common stock, net of offering expenses	210,582	11,422
Issuance of common stock from equity incentive plans	1,535	216
Finance lease principal payments	-	(54)
Net cash provided by financing activities	212,117	11,584
Effect of exchange rate changes on cash and cash equivalents	511	262
Net increase (decrease) in cash and cash equivalents	34,803	(16,217)
Cash and cash equivalents, beginning of year	15,789	32,006
Cash and cash equivalents, end of year	\$ 50,592	\$ 15,789

View source version on [businesswire.com](https://www.businesswire.com/news/home/20210713005347/en/): <https://www.businesswire.com/news/home/20210713005347/en/>

KalVista Pharmaceuticals, Inc.

Leah Monteiro
Senior Director, Corporate Communications & Investor Relations
857-999-0808
leah.monteiro@kalvista.com

Source: KalVista Pharmaceuticals, Inc.