



## KalVista Pharmaceuticals Provides Operational Update and Fiscal Year Financial Results

July 31, 2018

- KVD900 Selected to Advance to Phase 2 as Potential On-Demand Treatment of Acute Attacks in Patients with Hereditary Angioedema (HAE) –
- KVD001 Phase 2 Clinical Trial for Patients with Diabetic Macular Edema (DME) Enrollment Remains on Track with Data Expected in H2 2019 –
- \$14.6 Million Financing Funds into H1 2020, Past Anticipated Key Milestones for Both Programs –

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Jul. 31, 2018-- 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 fourth quarter and full year ended April 30, 2018. KalVista also announced the sale of approximately \$14.6 million in common stock to Venrock Healthcare Capital Partners (Venrock) and BVF Partners L.P. (BVF) in a registered direct transaction.

"We are pleased to announce that based upon results observed in our Phase 1 trial of KVD900, we will be moving the compound forward as a potential on-demand therapy for acute HAE attacks, and anticipate beginning a Phase 2 clinical trial before the end of 2018," said Andrew Crockett, Chief Executive Officer of KalVista. "We believe that a conveniently administered oral, on-demand product for acute HAE attacks could capture a significant portion of a currently all injectable acute market, as well as offer a better option for many patients who may currently use prophylactic therapies because of the lack of suitable options. In DME, our Phase 2 clinical trial of KVD001 continues to enroll patients and, based on recruitment rates seen to date, we remain on track to have data from this trial available in the second half of 2019. Finally, the sale of common stock to Venrock and BVF provides us with sufficient capital to advance our programs beyond the anticipated dates of key data points, funding the Company into the first half of 2020."

### Fiscal 2018 Business Highlights:

- Announced collaboration with Merck for investigational plasma kallikrein inhibitors for treatment of diabetic macular edema (DME). Under the terms of the agreement, KalVista granted to Merck certain rights including an option to acquire KVD001 through a period following completion of the Phase 2 proof-of-concept trial that KalVista commenced in December 2017. KalVista also granted to Merck a similar option to acquire investigational orally delivered molecules for DME that KalVista continues to develop as part of its ongoing research and development activities. Merck paid KalVista a \$37 million upfront fee and KalVista is further eligible to receive payments associated with the exercise of the options by Merck and the achievement of milestones for each program that potentially total up to \$715 million. KalVista also will receive tiered royalties on net sales for therapeutic candidates commercialized under this agreement. In addition to the collaboration, KalVista entered into a separate \$9.1 million private placement transaction with Merck under which Merck acquired a 9.9% ownership stake in KalVista concurrent with the execution of the Option Agreement.
- Initiated two clinical trials: A Phase 2 proof-of-concept clinical trial evaluating the safety, tolerability, and efficacy of KVD001 as a potential treatment for DME, as well as a Phase 1 trial for KVD900, a clinical candidate in the HAE portfolio.
- Presented data at The Association for Research in Vision and Ophthalmology (ARVO) 2018 Annual Meeting, showing that oral plasma kallikrein inhibitor KV123833 blocks VEGF-induced retinal vascular hyperpermeability in mice.
- Presented data at the European Academy of Allergy and Clinical Immunology (EAACI) Congress 2018, from an immunoassay KalVista developed that demonstrates that KVD900 protects high molecular weight kininogen from plasma kallikrein mediated cleavage in HAE and control plasma.
- On July 30, KalVista sold 1,778,320 shares of common stock priced at \$8.21 per share, representing the five-day volume-weighted average price, to Venrock and BVF in a registered direct transaction executed under the Company's existing shelf registration. In conjunction with this sale, the Company terminated its At-the-Market (ATM) share sale agreement. This financing is expected to provide KalVista with sufficient capital beyond the anticipated dates of key data points for both KVD001 and KVD900, and into the first half of 2020.

### HAE Portfolio Update:

- KalVista has created a structurally diverse portfolio of oral plasma kallikrein inhibitors and advanced chosen candidates into Phase 1 clinical trials for HAE in order to create what we believe will be one or more best-in-class oral therapies. We also evaluate these molecules for different market segments, such as acute or prophylactic therapy. Molecules are only selected for preclinical or clinical advancement if they meet a stringent set of criteria, and we routinely terminate programs that do not meet our requirements.
- KVD900 data supports development as an oral, on-demand therapy for acute HAE attacks. Our Phase 1 study for KVD900

suggests that the compound displays a profile well-suited for use as an on-demand therapy for acute attacks, with a combination of rapid uptake into the plasma and high plasma concentrations. The compound was tested in healthy volunteers at single ascending doses up to 600 mg, showing exposures that increased in a dose proportional manner, to concentrations well above 100 times those we believe are required to demonstrate efficacy. Importantly for acute treatment, concentrations increased rapidly following dosing with effective concentrations typically reached within 30 minutes or less. This combination of rapid uptake to very high drug levels compares favorably to the existing injected therapies. Our pharmacodynamic analysis of plasma samples collected following dosing of KVD900 revealed a strong PK/PD correlation with inhibition of plasma kallikrein for up to 10 hours following a single dose, which we believe to be sufficient to effectively treat HAE attacks. The plasma concentrations reached in the healthy volunteers are also well above those needed to protect kininogen from cleavage in activated HAE patient plasma. To date, KVD900 has been generally well tolerated. The safety data remains blinded but there was a total of twelve adverse events reported across the eight dosing cohorts. All but one, lightheadedness seen in the first cohort, were judged unrelated or unlikely related to KVD900 and no adverse events were reported at the two highest dose levels. The most commonly seen adverse events were back pain, common cold/flu symptoms, and pyrexia. There were no gastrointestinal adverse events reported at any dose.

- KVD900 development will accelerate as we plan to initiate a Phase 2 clinical trial in late 2018 that is anticipated to be completed in mid-2019. This trial will be designed as a proof-of-concept study in HAE patients, intended to determine the safety and efficacy of KVD900 as an on-demand treatment for acute HAE attacks. Following this trial, we intend to interact with regulators to determine the requirements for future clinical trials to support filing of a New Drug Approval (NDA) and also discuss Fast Track and Orphan Designation. We believe there is a well-defined regulatory pathway for potential treatments of acute HAE attacks.
- We will continue to both discover and develop additional oral candidates, as well as explore different formulations of KVD900, to potentially address the prophylactic segment of the HAE market. A structurally diverse portfolio containing multiple additional oral candidates is under development and will continue to be advanced as progression criteria are met. We anticipate that one additional candidate will enter the clinic this year and potentially more molecules in 2019.

#### **DME Programs:**

- KVD001 Phase 2 clinical trial enrollment remains on track. In December 2017, we commenced a Phase 2 clinical trial of KVD001 that we expect will complete in mid-2019, with data in the second half of 2019. This study is anticipated to enroll 123 patients to evaluate the safety and efficacy of KVD001 in patients with DME who have received previous anti-VEGF therapy but continue to experience reduced visual acuity and significant edema. The double-masked study consists of two active arms receiving low or high dose injections, and a sham control arm. Patients will receive a total of four injections over a three-month period, with evaluation at the end of the dosing period and for three months following. The endpoints include safety and tolerability, best corrected visual acuity, central subfield thickness, and the diabetic retinopathy severity scale.
- In parallel with the clinical development of intravitreal product candidate KVD001, we continue our activities on discovery and development of plasma kallikrein inhibitors as oral therapies for DME. We believe that a safe and orally delivered therapeutic could provide a major advance in treatment for DME patients compared to the current approved DME drugs, which are all delivered via injection.

#### **Fourth Quarter and Full Year Financial Results:**

- Revenue: Revenue was \$4.8 million for the three months ended April 30, 2018, compared to \$0.1 million for the same period in the prior year. Revenue was \$8.4 million for the fiscal year ended April 30, 2018, compared to \$1.5 million in the prior year. Revenue in 2018 primarily reflected recognition of the upfront payment from Merck related to the agreement signed in October 2017.
- R&D Expenses: Research and development expenses were \$5.9 million for the three months ended April 30, 2018, compared to \$3.0 million for the same period in the prior year. Research and development expenses were \$18.2 million for the fiscal year ended April 30, 2018, compared to \$12.7 million in the prior year. The increase in spending primarily reflects increased costs related to the commencement of clinical trials for both KVD001 and KVD900, as well as increased expenses on earlier stage programs.
- G&A Expenses: General and administrative expenses were \$2.0 million for the three months ended April 30, 2018, compared to \$2.2 million for the same period in the prior year. General and administrative expenses were \$8.9 million for the fiscal year ended April 30, 2018, compared to \$11.2 million in the prior year. The decline in G&A expenses was primarily due to costs incurred in fiscal 2017 associated with the share purchase transaction completed in November 2016, partially offset by increased expenses related to our expansion of the company and costs related to operating as a public company.
- Net Loss: Net loss was \$0.7 million, or \$(0.06) per weighted average basic and diluted share, for the three months ended April 30, 2018, compared to net loss of \$4.2 million, or \$(0.43) per share for the same period in the prior year. Net loss was \$15.8 million, or \$1.53 per basic and diluted share for the fiscal year ended April 30, 2018, compared to a net loss of \$18.6 million, or \$4.47 per weighted average basic and diluted share in the prior year. This decrease in the net loss and

net loss per share was primarily related to revenue recognized from the Merck agreement.

- **Cash Position:** Cash and cash equivalents were \$51.1 million as of April 30, 2018, compared to \$31.0 million as of April 30, 2017. The increase in the net cash position is primarily the result of the \$37 million upfront payment made by Merck in October 2017, along with \$9.1 million paid by Merck for shares acquired in a private placement that closed concurrently.

#### 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 into Phase 1 clinical trials for HAE. The Company has selected KVD900 as its program to be advanced as an on-demand therapy for acute HAE attacks, and anticipates commencing a Phase 2 proof-of-concept study in HAE patients in late 2018. In DME, KalVista's most advanced program, an intravitreally administered plasma kallikrein inhibitor known as KVD001, began a Phase 2 clinical trial in 2017 that is anticipated to report data in the second half of 2019.

For more information, please visit [www.kalvista.com](http://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 and future clinical trial timing and results. Further information on potential risk factors that could affect our business and its financial results are detailed in the annual report on Form 10-K filed on July 30, 2018 and other reports as filed 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, 2018	April 30, 2017
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 51,055	\$ 30,950
Research and development tax credit receivable	6,834	2,250
Grants and other receivables	-	297
Prepaid expenses and other current assets	1,491	701
<b>Total current assets</b>	<b>59,380</b>	<b>34,198</b>
Other assets	173	50
Property and equipment, net	1,836	97
<b>Total assets</b>	<b>\$ 61,389</b>	<b>\$ 34,345</b>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 1,433	\$ 1,153
Accrued expenses	3,087	1,865
Deferred revenue - current portion	18,475	-
Capital lease liability - current portion	221	-
<b>Total current liabilities</b>	<b>23,216</b>	<b>3,018</b>
Long-term liabilities:		
Deferred revenue - net of current portion	10,862	-
Capital lease liability - net of current portion	58	-
<b>Total long-term liabilities</b>	<b>10,920</b>	<b>-</b>
Stockholders' equity:		
Common stock, \$0.001 par value	11	10
Additional paid-in capital	100,011	89,815
Accumulated deficit	(71,660 )	(55,855 )
Accumulated other comprehensive loss	(1,109 )	(2,643 )
<b>Total stockholders' equity</b>	<b>27,253</b>	<b>31,327</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 61,389</b>	<b>\$ 34,345</b>

KalVista Pharmaceuticals Inc.

**Condensed Consolidated Statement of Operations**  
(in thousands, except share and per share amounts)  
(Unaudited)

	Three Months Ended April 30,		Years Ended April 30,	
	2018	2017	2018	2017
<b>Revenue</b>	<b>\$ 4,840</b>	<b>\$ 114</b>	<b>\$ 8,394</b>	<b>\$ 1,504</b>
<b>Operating expenses:</b>				
Research and development	5,852	2,996	18,237	12,666
General and administrative	1,957	2,204	8,862	11,177
<b>Total operating expenses</b>	<b>7,809</b>	<b>5,200</b>	<b>27,099</b>	<b>23,843</b>
<b>Operating loss</b>	<b>(2,969 )</b>	<b>(5,086 )</b>	<b>(18,705 )</b>	<b>(22,339 )</b>
Other income:				
Interest income	65	5	82	36
Foreign currency exchange rate gain (loss)	262	(140 )	(1,574 )	1,371
Other income	1,985	1,019	4,392	2,329
<b>Total other income</b>	<b>2,312</b>	<b>884</b>	<b>2,900</b>	<b>3,736</b>
<b>Net loss</b>	<b>\$ (657 )</b>	<b>\$ (4,202 )</b>	<b>\$ (15,805 )</b>	<b>\$ (18,603 )</b>
Net loss per share to common stockholders, basic and diluted	<b>\$ (0.06 )</b>	<b>\$ (0.43 )</b>	<b>\$ (1.53 )</b>	<b>\$ (4.47 )</b>
Weighted average common shares outstanding, basic and diluted	10,797,055	9,713,042	10,321,780	4,646,764

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

	Years Ended April 30	
	2018	2017
<b>Cash Flows from Operating Activities</b>		
Net loss	\$ (15,805)	\$ (18,603)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities		
Depreciation and amortization	180	40
Stock-based compensation expense	1,060	394
Foreign currency remeasurement (gain) loss	(651 )	(1,371 )
Changes in operating assets and liabilities:		
Research and development tax credit receivable	(4,256 )	(600 )
Grants and other receivables	319	29
Prepaid expenses and other current assets	(746 )	(81 )
Other assets	(123 )	-
Accounts payable	217	(1,599 )
Accrued expenses	1,132	(1,931 )
Deferred revenue	29,231	-
Net cash provided by (used in) operating activities	10,558	(23,722)
<b>Cash Flows from Investing Activities</b>		
Cash acquired in transaction	-	34,139
Acquisition of property and equipment	(1,427 )	(74 )
Net cash provided by (used in) investing activities	(1,427 )	34,065
<b>Cash Flows from Financing Activities</b>		
Capital lease principal payments	(151 )	-
Proceeds from issuance of common stock	9,137	2
Net cash provided by financing activities	8,986	2
Effect of exchange rate changes on cash and cash equivalents	1,988	(1,159 )

Net increase in cash and cash equivalents	20,105	9,186
Cash and cash equivalents, beginning of year	30,950	21,764
Cash and cash equivalents, end of year	\$ 51,055	\$ 30,950

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**KalVista Pharmaceuticals, Inc.**

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