
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

**CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934
Date of Report (Date of earliest event reported): July 27, 2018**

KALVISTA PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36830
(Commission
File Number)

20-0915291
(IRS Employer
Identification No.)

55 Cambridge Parkway
Suite 901E
Cambridge, Massachusetts
(Address of Principal Executive Offices) (Zip Code)

(857) 999-0075
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 1.02 Termination of a Material Definitive Agreement.

On July 13, 2017, KalVista Pharmaceuticals, Inc. (the “Company”) entered into an At-the-Market Sales Agreement (the “Sales Agreement”) with BTIG, LLC (“BTIG”).

On July 27, 2018, the Company sent a notice to BTIG terminating the Sales Agreement (the “Notice”) in connection with its sale of 1,778,320 shares of common stock priced at \$8.21 per share, representing the five-day volume-weighted average price, in a registered direct transaction executed under the Company’s existing shelf registration statement on Form S-3 (Reg. No. 333-217009). Pursuant to the terms of the Sales Agreement, and upon waiver of the notice period by BTIG, such termination was effective July 27, 2018, and neither the Company nor BTIG have any continuing obligations under the Sales Agreement.

Item 2.02. Results of Operations and Financial Condition.

On July 31, 2018, the Company reported its financial results for the three months ended April 30, 2018. A copy of the press release issued by the Company is furnished as Exhibit 99.1 to this report.

Item 7.01. Regulation FD.

On July 31, 2018, the Company updated its corporate presentation slide deck. A copy of the corporate presentation slide deck of the Company is furnished as Exhibit 99.2 to this report.

The information furnished with Items 2.02 and 7.01 of this report, including Exhibit 99.1 and Exhibit 99.2, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any other filing under the Exchange Act or under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press release dated July 31, 2018.
99.2	Corporate presentation slide deck dated July 31, 2018.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

KALVISTA PHARMACEUTICALS, INC.

By: /s/ Benjamin L. Palleiko

Name: Benjamin L. Palleiko

Title: Chief Financial Officer

Date: July 31, 2018

KalVista Pharmaceuticals Provides Operational Update and Fiscal Year Financial Results

– *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, MA and Salisbury, England, July 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.
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- 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.

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.

Contact:

KalVista Pharmaceuticals, Inc.

Leah Monteiro

Director, Corporate Communications & Investor Relations

857-999-0808

leah.monteiro@kalvista.com

KalVista Pharmaceuticals Inc.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share amounts)
(Unaudited)

	<u>April 30,</u> <u>2018</u>	<u>April 30,</u> <u>2017</u>
Assets		
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
Total current assets	<u>59,380</u>	<u>34,198</u>
Other assets	173	50
Property and equipment, net	1,836	97
Total assets	<u>\$61,389</u>	<u>\$34,345</u>
Liabilities and Stockholders' Equity		
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	-
Total current liabilities	<u>23,216</u>	<u>3,018</u>
Long-term liabilities:		
Deferred revenue - net of current portion	10,862	-
Capital lease liability - net of current portion	58	-
Total long-term liabilities	<u>10,920</u>	<u>-</u>
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)
Total stockholders' equity	<u>27,253</u>	<u>31,327</u>
Total liabilities and stockholders' equity	<u>\$61,389</u>	<u>\$34,345</u>

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
Revenue	\$4,840	\$114	\$8,394	\$1,504
Operating expenses:				
Research and development	5,852	2,996	18,237	12,666
General and administrative	1,957	2,204	8,862	11,177
Total operating expenses	7,809	5,200	27,099	23,843
Operating loss	(2,969)	(5,086)	(18,705)	(22,339)
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
Total other income	2,312	884	2,900	3,736
Net loss	\$(657)	\$(4,202)	\$(15,805)	\$(18,603)
Net loss per share to common stockholders, basic and diluted	\$(0.06)	\$(0.43)	\$(1.53)	\$(4.47)
Weighted average common shares outstanding, basic and diluted	10,797,055	9,713,042	10,321,780	4,646,764

3KalVista Pharmaceuticals Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands, unaudited)

	Years Ended	
	April 30	
	2018	2017
Cash Flows from Operating Activities		
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)
Cash Flows from Investing Activities		
Cash acquired in transaction	-	34,139
Acquisition of property and equipment	(1,427)	(74)

Net cash provided by (used in) investing activities	<u>(1,427)</u>	<u>34,065</u>
Cash Flows from Financing Activities		
Capital lease principal payments	(151)	-
Proceeds from issuance of common stock	9,137	2
Net cash provided by financing activities	<u>8,986</u>	<u>2</u>
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	<u>\$51,055</u>	<u>\$30,950</u>



Corporate Presentation

July 2018

Forward-Looking Statements

This presentation and the accompanying oral presentation contain "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. Examples of forward-looking statements include, among others, statements we make regarding our future financial performance, business plans and objectives, timing and success of our clinical trials, our ability to obtain regulatory approval or the timing of regulatory filings, the potential therapeutic benefits and economic value of our lead product candidates, financing plans, competitive position, industry environment and potential market opportunities.

Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, the following: those related to our future financial performance, our ability to raise additional funding when needed, our ability to develop and maintain partnerships, our ability to identify and develop new products in a timely manner, the outcome, cost and timing of our product development activities and clinical trials, market size and acceptance of our products, our ability to maintain, protect and enhance our brand and intellectual property, our ability to continue to stay in compliance with applicable laws and regulations, our ability to scale our business and make key hires and such other factors as discussed under the section titled "Risk Factors" and elsewhere in our definitive proxy statement and quarterly reports on Form 10-Q that we file with the Securities and Exchange Commission ("SEC") as well as our other filings and the documents incorporated by reference therein, with the SEC.

Any forward-looking statement made by us in this presentation and the accompanying oral presentation is based only on information currently available to us and speaks only as of the date on which it is made. 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.



Company Highlights

- Discovery and development of small molecule protease inhibitors, with leading expertise on plasma kallikrein role in disease mechanisms
- Creating a portfolio of oral plasma kallikrein inhibitors to treat orphan disease hereditary angioedema (HAE) and diabetic macular edema (DME)
- HAE program KVD900 advancing to Phase 2 as acute therapy, with data mid-2019
- Collaboration with Merck in DME; lead program KVD001 Phase 2 data H2 2019
- Internal discovery and development capabilities enable high productivity and strong IP positions, supporting best-in-class programs
- \$51.1 million at April 30, 2018 funds beyond key data points in both DME and HAE
 - Additional \$14.6 million financing in July 2018



Product Portfolio

	Route	Preclinical	Phase 1	Phase 2	Phase 3	Status
HAE Franchise						
KVD900 Target: Plasma Kallikrein	Oral					• Phase 2 initiating in 2018
KVD818 Target: Plasma Kallikrein	Oral					• Phase 1 complete
KVDXXX Target: Plasma Kallikrein	Oral					• Expected to enter clinic in 2018
DME Franchise						
KVD001* Target: Plasma Kallikrein	Intravitreal					• Phase 2 ongoing
Oral Program* Target: Plasma Kallikrein	Oral					
Other Targets						
Additional Proteases Target: <i>Undisclosed</i>	Various					• Discovery profiling phase

4 *Under Option Agreement with Merck



A decorative graphic consisting of a network of white and light blue nodes connected by thin white lines, resembling a molecular or biological structure. The nodes vary in size, and the network is more dense in some areas than others, particularly in the top-left and bottom-right corners of the dark blue header.

Hereditary Angioedema (HAE)

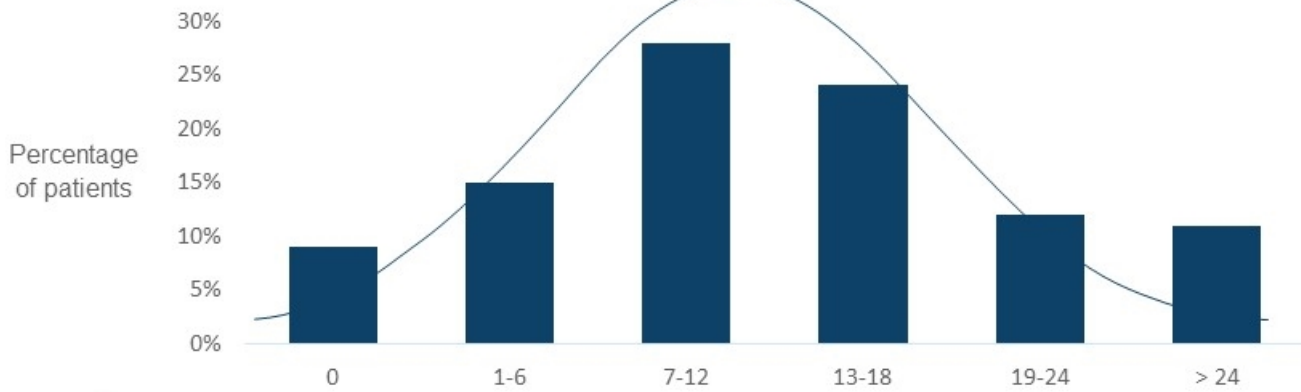
Hereditary Angioedema (HAE)

- Rare, genetic condition causing painful and dramatic swelling in various parts of the body
- Orphan disease: incidence 1 in 10,000 to 1 in 50,000¹
- Driven by uncontrolled plasma kallikrein activity leading to excessive bradykinin release; primarily caused by defect in C1 inhibitor activity
- Plasma kallikrein inhibition is a validated method for the treatment of HAE – product approved targeting this enzyme
- All current approved therapies injected/infused - high unmet need for oral
- HAE market is estimated to be over \$2 billion market by 2020
- We intend to bring at least three molecules through Phase 1 and target both acute and prophylactic segments



Diverse HAE Market – Opportunities in Prophylaxis and Acute

Patient Attacks per Year ¹



Patient treatment preference is influenced by attack frequency

7 ¹Nordenfelt P et al. *Acta Derm Venereol* 2016; 96: 540–545 [PMID: 26540175](https://pubmed.ncbi.nlm.nih.gov/26540175/)



Oral Acute Therapy Meets Unmet Patient Needs

1. A safe, oral therapy for acute attacks could help patients with less frequent attacks effectively manage their disease on-demand
2. All patients would have the option of a convenient, effective oral treatment in lieu of an injectable if desired
3. Patients on prophylaxis still require therapy for breakthrough attacks
 - WAO/EAACI 2017 revision and update for management of HAE recommends all patients carry medication for on- demand treatment of two attacks, at all times

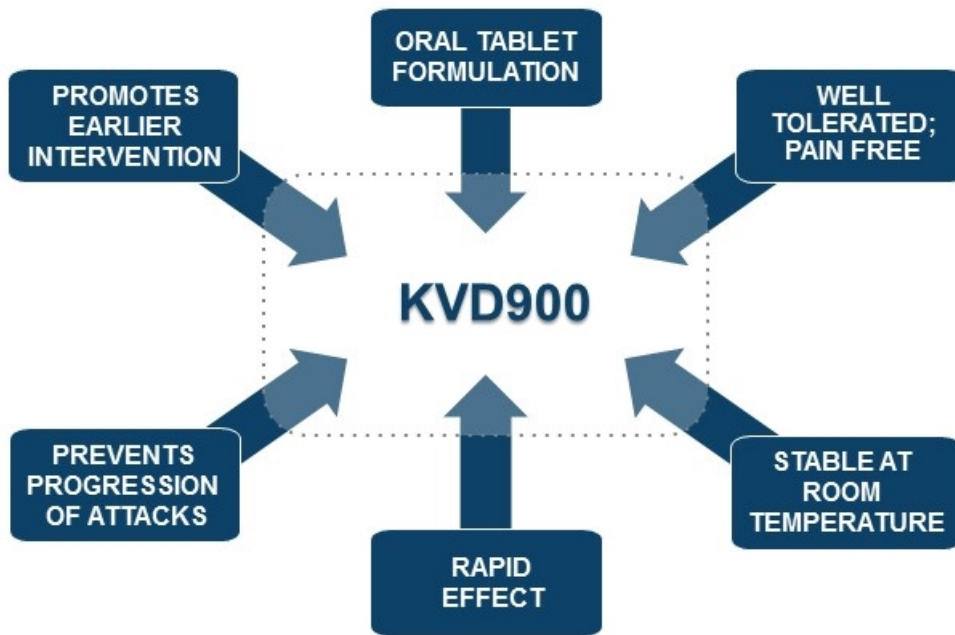


The majority of patients already manage their disease with acute therapies

8 ¹2017 Revenues from Shire full-year results, February 14, 2018 ²2017 Revenue from Pharming Financial Results, March 7, 2018



Requirements for Best-In-Class Treatment of Acute Attacks



KVD900 Phase 1 Overview

- Double-blind, randomized investigation of oral KVD900 in healthy, male volunteers
 - Single ascending dose with cross-over to tablet formulation
 - 8 cohorts assessed up to 600 mg
- Safety and tolerability
 - AEs, laboratory measurements and clinical outcomes
- Pharmacokinetics
 - PK profile and PK parameters
- Pharmacodynamics
 - Ex vivo assays assessing enzyme activity and plasma kininogen substrate cleavage



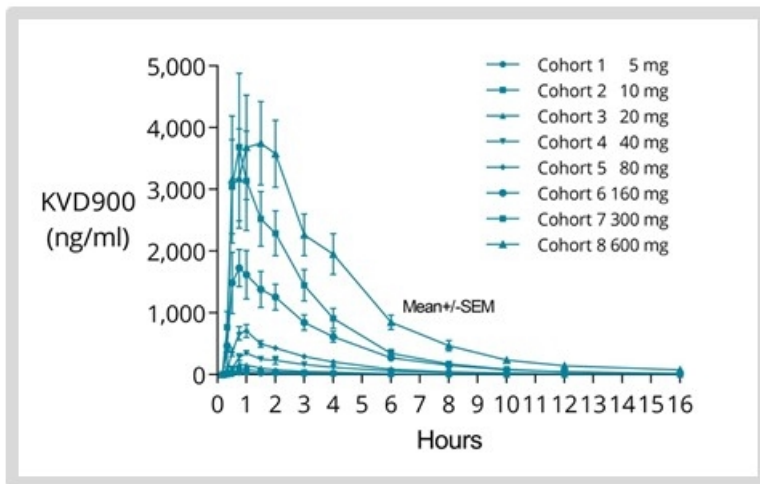
KVD900 Safety Profile to Date

- No SAEs reported
- Twelve AEs reported, 10 mild and 2 moderate
 - One mild AE (light headedness) considered possibly related (in the 5 mg/placebo cohort)
 - All other reported AEs unrelated/unlikely related
 - No AEs reported in 300 mg or 600 mg dose cohorts
- No subjects withdrew from the study
- No GI AEs reported at any dose level
- No clinically significant changes in vital signs, ECG, safety labs
- Study is still blinded
 - No assignment of AEs to active treatment or placebo
 - All results subject to final reporting

Cohort	AEs	Verbatim Reported Symptom
5mg / placebo	3	2 x Back pain Light headed
10mg / placebo	2	Cold sores Headache
20mg / placebo	1	Common cold symptoms
40mg / placebo	0	None reported
80mg / placebo	1	Cough
160mg / placebo	5	Wry neck Respiratory tract infection Sore throat Cold symptoms Muscular shoulder pain
300mg / placebo	0	None reported
600mg / placebo	0	None reported
100mg (bridge)	0	None reported



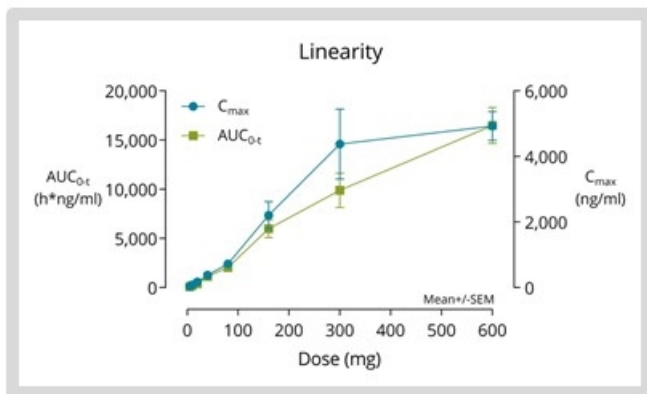
KVD900 Rapidly and Highly Absorbed at All Doses



- Mean T_{max} around 1 hour
- Mean C_{max} up to 3500 ng/ml

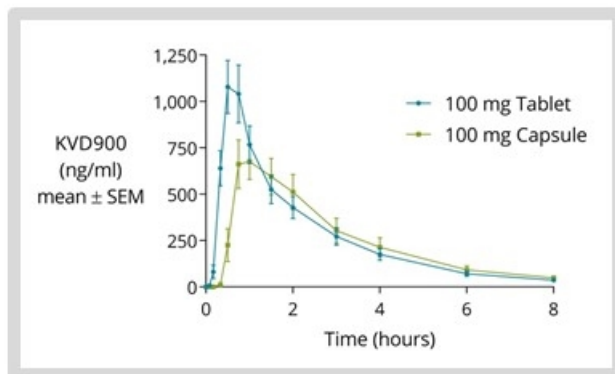


KVD900 Phase 1 Study – Single Dose PK



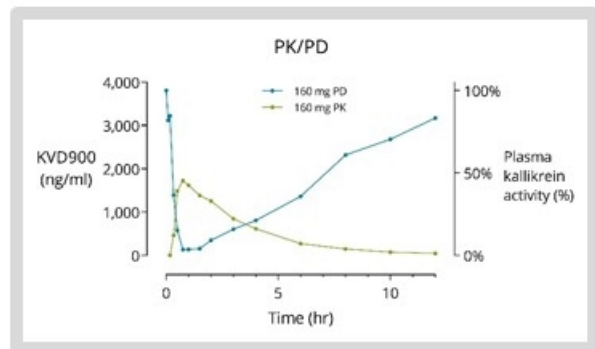
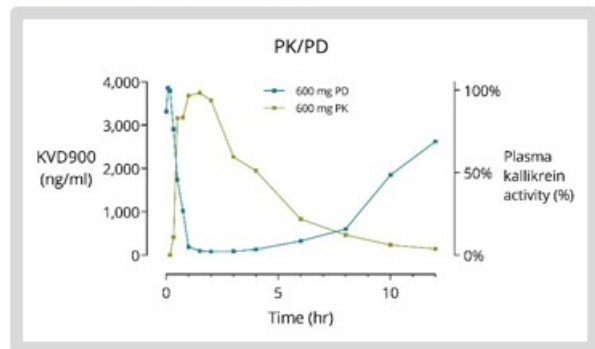
- Dose-dependent increase in exposure of both C_{max} and AUC
- Confident control of exposure with dose

- Tablet formulation shows even faster absorption than capsule



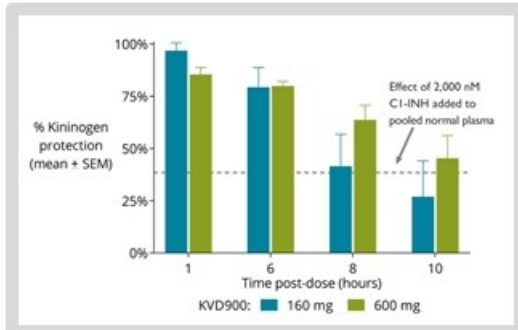
KVD900 Phase 1 Study – Single Dose PK/PD

- Strong inhibition of plasma kallikrein activity
 - 160 mg and 600 mg dose cohort shown
- Plasma activated by the addition of dextran sulfate
 - Plasma kallikrein activity monitored using a fluorescent substrate
- Rapid onset of inhibition
 - KVD900 exposure delivers potent inhibition of plasma kallikrein
 - 80% inhibition within 30 minutes
 - Complete inhibition at 45 minutes

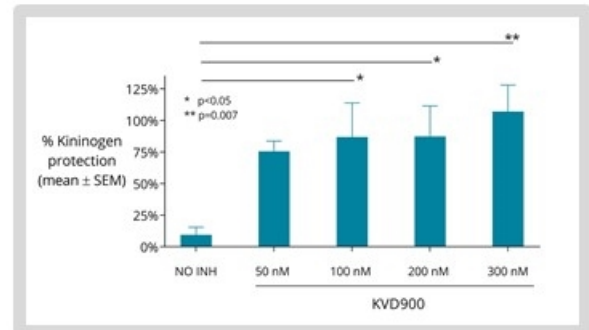


KVD900 Blocks Kininogen Cleavage

- Plasma kallikrein cleaves kininogen to release the hormone bradykinin – the mediator of edema in HAE
- Plasma kallikrein was activated in whole plasma by the addition of dextran sulfate
- KVD900 protects kininogen in both normal and HAE plasma



Plasma samples from subjects dosed with 600 mg KVD900 are protected from plasma kallikrein mediated kininogen cleavage for at least 10 hours

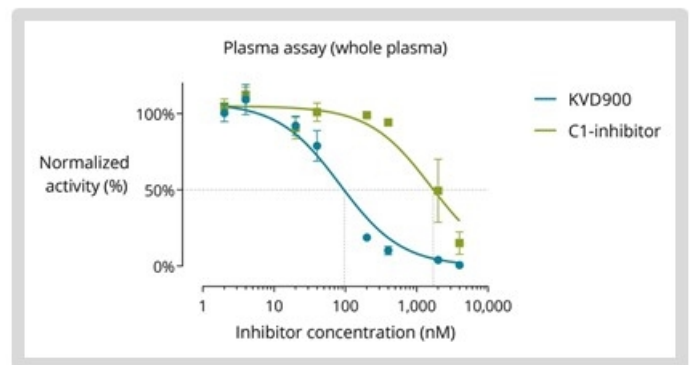


KVD900 protects HAE plasma from plasma kallikrein mediated kininogen cleavage



KVD900 Potency Compares Favorably to Berinert

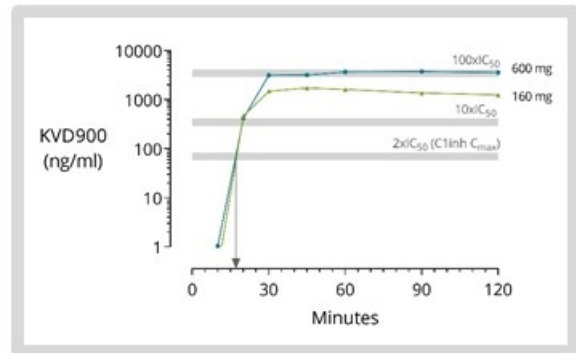
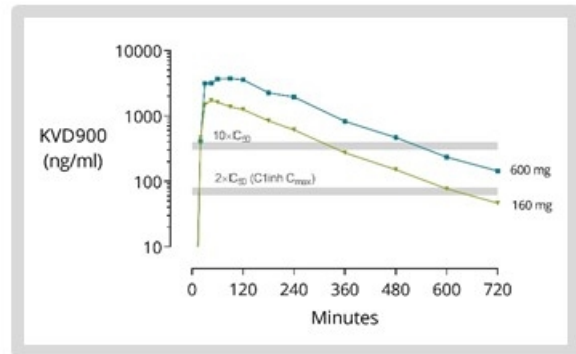
- Comparing to approved, acute C1 inhibitor treatments demonstrates the level of plasma kallikrein inhibition that delivers clinical efficacy
- C1 inhibitor potency
 - IC_{50} in whole plasma is 1700nM
 - KVD900 is 90nM
- Berinert
 - Following administration of the approved dose of 20IU/kg
 - C_{max} »3000nM (0.32mg/ml) reached within 48 minutes of dosing
 - Maximal concentration is $\approx 2x$ IC_{50}



KVD900 Displays Rapid Uptake

- Multiple dose levels achieve sufficient plasma kallikrein inhibition
 - Based on clinically efficacious doses of C1-INH
- 600 mg – exceeds 100x IC_{50} and maintains 2x IC_{50} for 12+ hours
- 160 mg – exceeds 50x IC_{50} and maintains 2x IC_{50} for 10 hours

- Onset is important for acute efficacy
- 2x IC_{50} reached around 20 minutes
 - Equivalent to C1-INH injection
- 10x IC_{50} before 30 minutes

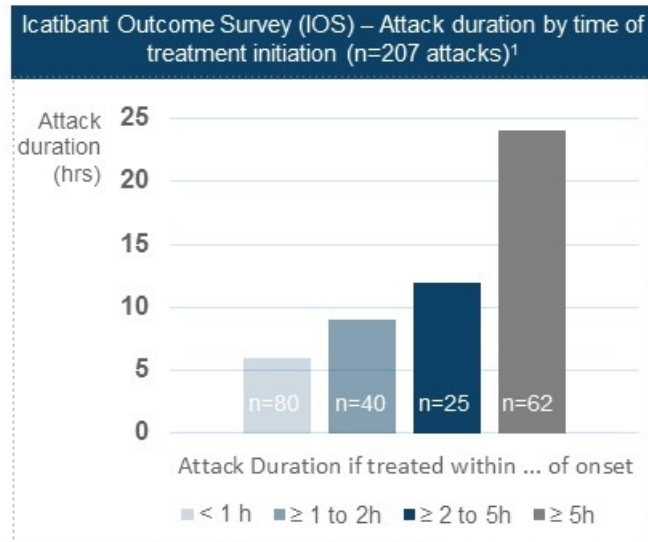


KVD900: On-Demand Treatment of Acute HAE Attacks

- Data suggests an ideal fit with best-in-class treatment for acute oral therapy
 - Rapid absorption leads to effective concentrations in 30 minutes or less, which is equivalent to injected
 - Systemic levels above effective concentration maintained for up to 10 hours
 - No SAEs or other dose limiting AEs/tolerability issues
 - No GI effects
 - Short residence time to minimize any tolerability findings or impact on other medications
- KVD900 has the potential to be a patient-friendly treatment which offers the opportunity to intervene early resulting in higher efficacy
 - Efficacy of acute injectable treatments is often undermined by late dosing
 - Early treatment has been shown to be key in maximizing treatment outcomes
 - Potential label extension for treatment on prodromal symptoms → episodic prophylaxis



Early Treatment Dramatically Reduces Attack Duration...



Delaying treatment dramatically extends attack duration



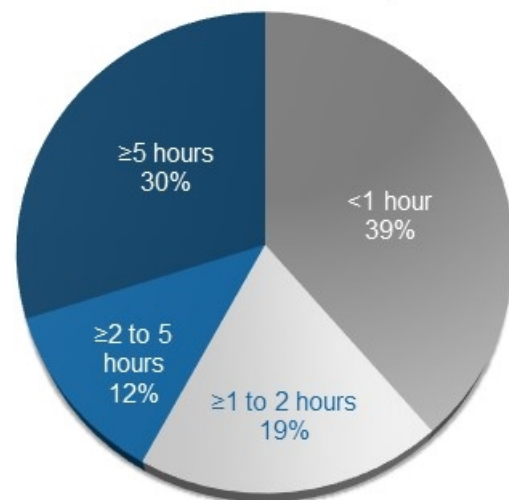
...But Majority of Patients Do Not Treat Early Enough

>60% of patients administer their therapy more than one hour after the beginning of an attack, per IOS

Key reasons why treatment is delayed:

1. Inconvenient – many therapies require medical professional training
2. Painful – both during and after administration
3. Hope – rather than treat, patients frequently will just hope for a less severe attack

Time to Treatment (n=207)

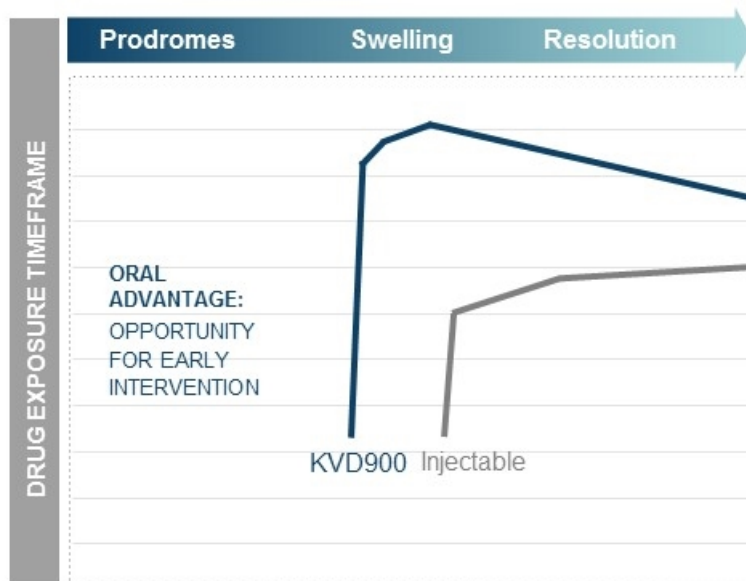


■ <1 hour ■ ≥1 to 2 hours ■ ≥2 to 5 hours ■ ≥5 hours

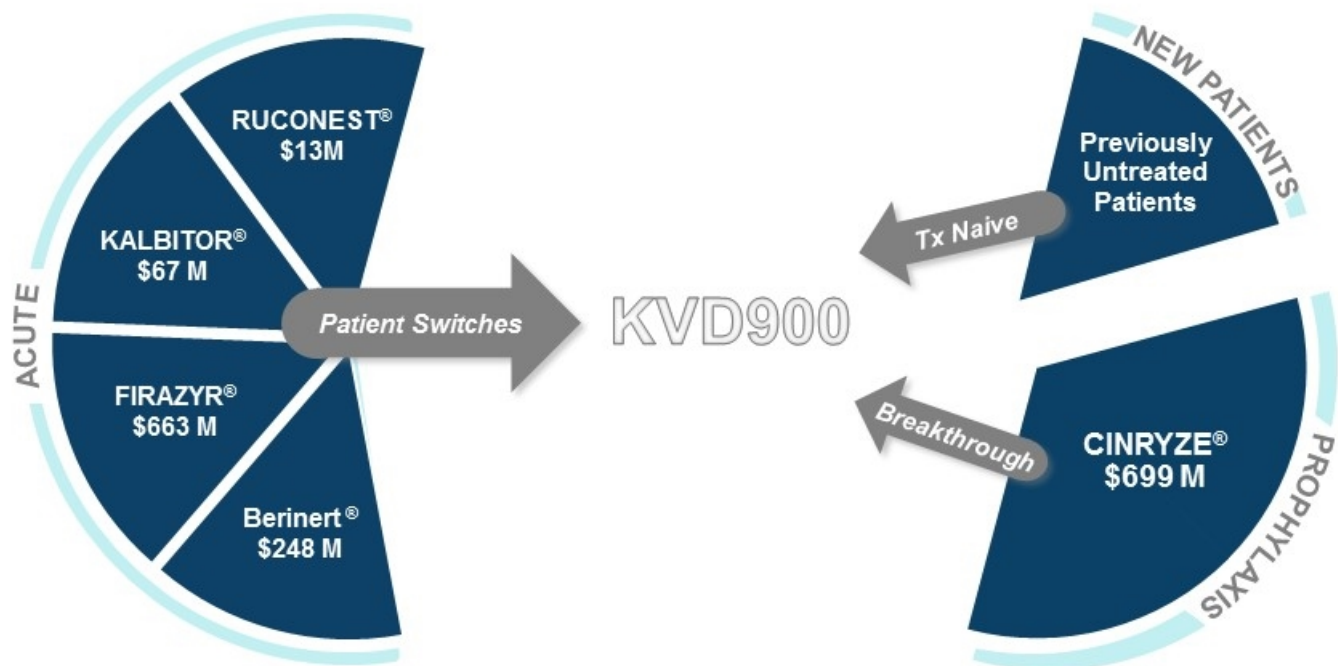


KVD900 Supports Earlier Treatment and Faster Attack Resolution

- Convenience and tolerability of KVD900 compared to other therapies will encourage earlier dosing
- Rapid absorption of KVD900 yields high exposures which compare favorably to injectable therapies
- Combination of these attributes will lead to shorter and less severe attacks and better treatment outcomes
- **Offers the potential to dramatically improve patient quality of life by providing better disease control**



Opportunity: Share Capture and Growth of \$2B Market



22 '2017 Revenues from Shire full-year results, February 14, 2018



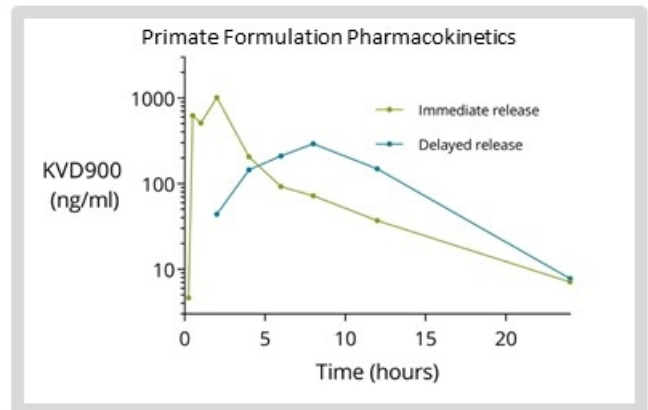
KVD900 Next Steps

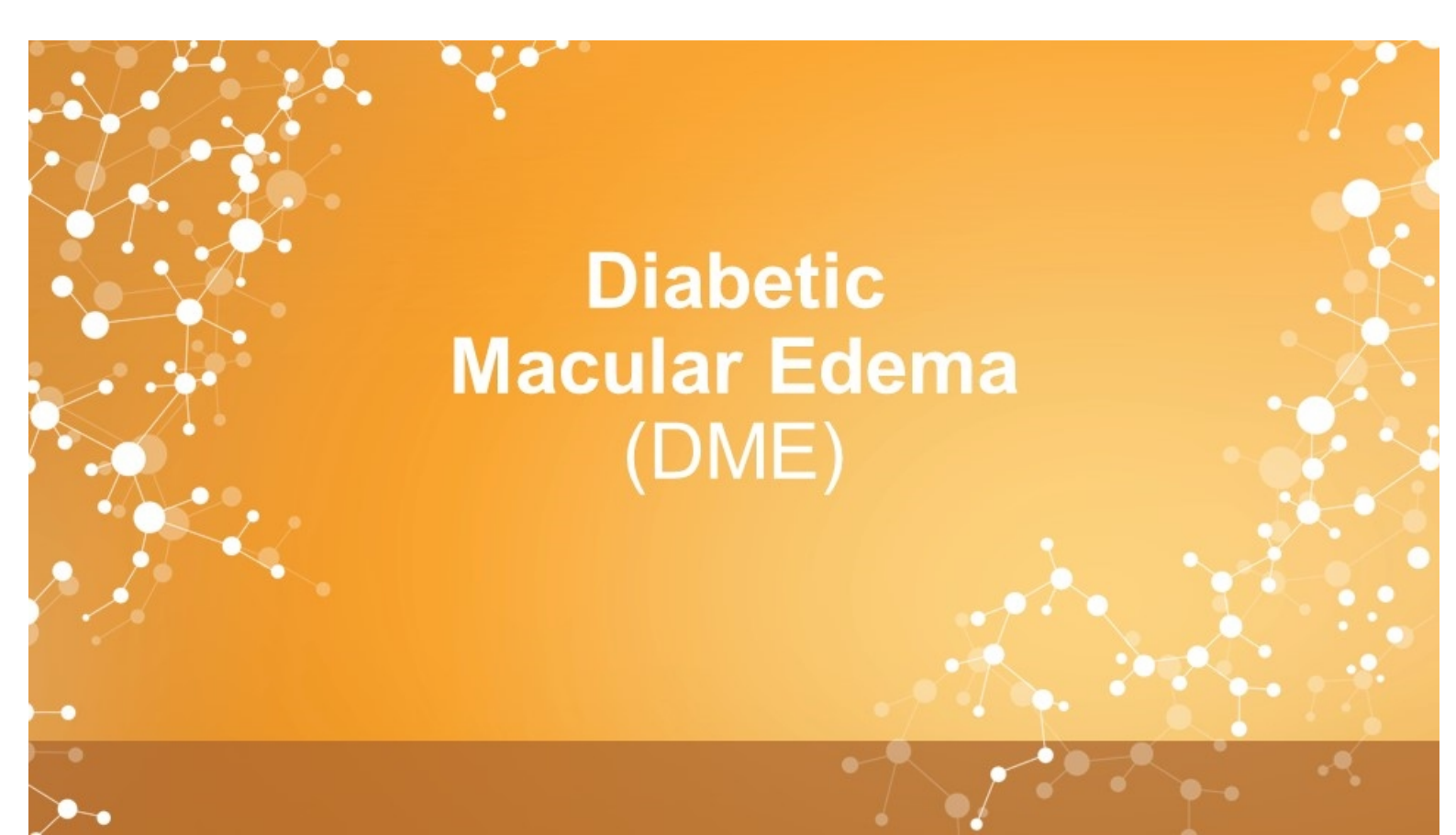
- Food effect cohort will be completed before we begin the Phase 2
- Moving into single dose Phase 2 efficacy study
 - Investigation of PK/PD in HAE patients and efficacy in acute treatment of attacks
 - Anticipated to begin recruitment before YE 2018
 - Expected completion mid-2019
 - Enables regulatory interactions to establish phase 3 requirements
- Potential to move directly to pivotal trials
- Fast Track and Orphan Drug applications in 2019
- Well defined regulatory pathway for treatment of acute attacks



Continued Focus on Our Portfolio Strategy

- KalVista remains focused on delivering oral plasma kallikrein inhibitors for:
 1. prophylactic treatment of HAE
 2. DME
- Formulation development suggests that it is feasible to modulate the release profile of KVD900 for potential prophylactic use
 - Dosing of delayed release tablets to monkeys moves T_{max} to 8 hours
- We intend to advance one additional molecule to the clinic in 2018
- Active preclinical program pursuing at least one additional compound to be clinic-ready in 2019





Diabetic Macular Edema (DME)

Diabetic Macular Edema: Over \$1 Billion Market

- Retinal swelling due to leaky blood vessels in the macula – a leading cause of blindness
- Approximately 900,000 patients in the United States have active DME and are at serious risk of vision loss – affects over 16% of diabetes patients¹
- Standard of care is anti-VEGF injected into the eye – currently there are no oral treatments for DME
- Up to 40% of patients do not adequately respond and continue to have impaired visual function and macular edema – significant unmet clinical need
- Plasma kallikrein has been identified as a potential VEGF-independent mediator of DME
- KalVista developed KVD001 as an IVT therapy, and is also working to develop an orally delivered plasma kallikrein inhibitor therapy for DME
 - The basis of Merck collaboration announced in October 2017

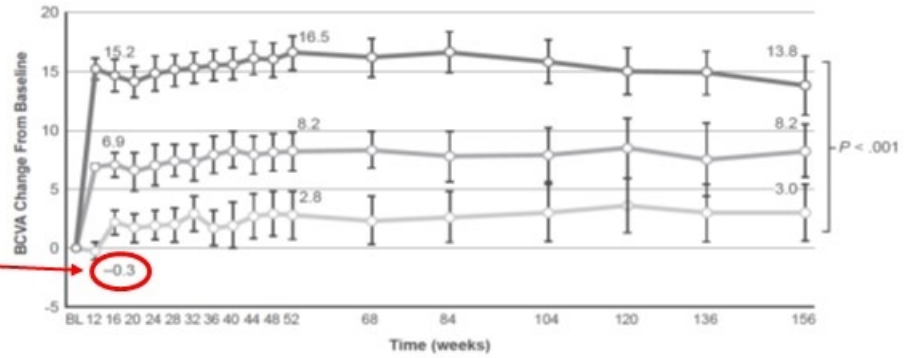


40% anti-VEGF Patients Not Adequately Treated

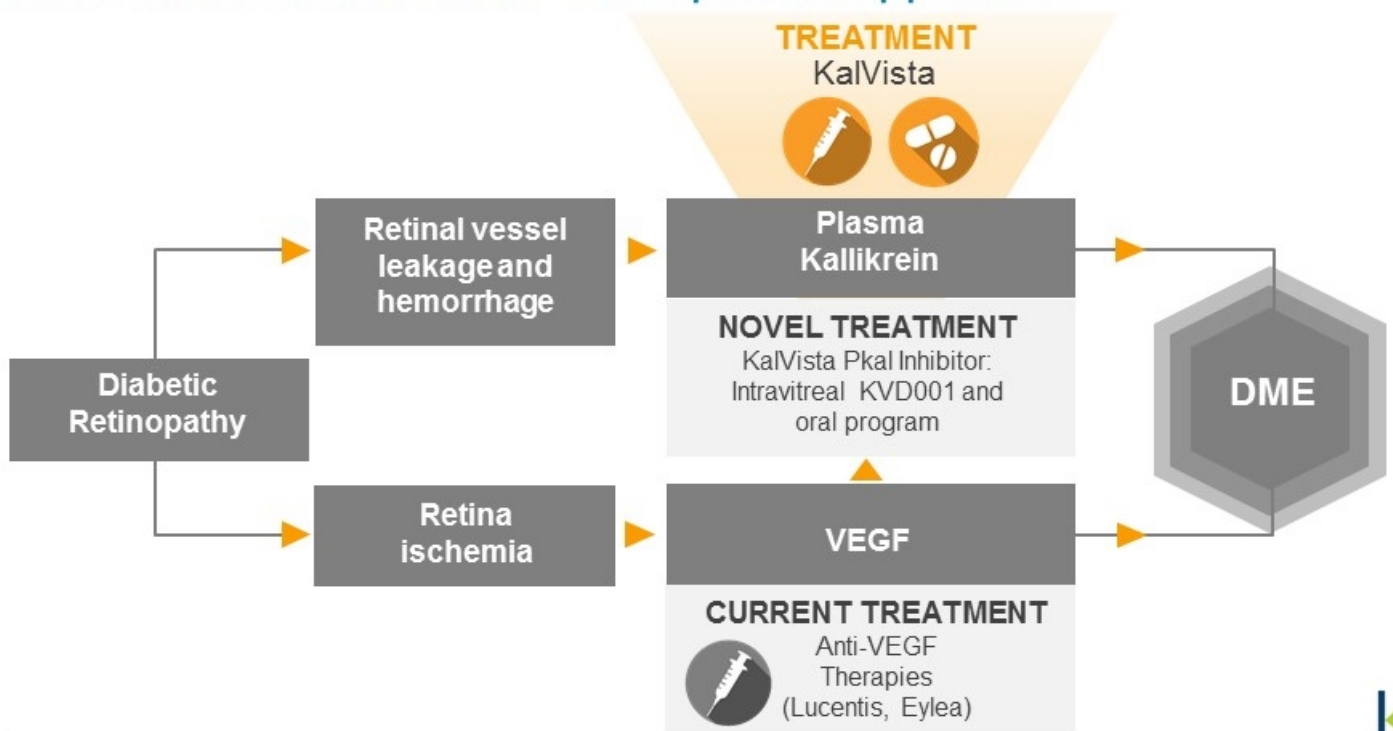
- Large well controlled trial (DRCR Protocol I) of anti-VEGF treatment in DME patients evaluated 854 eyes
- 40% of eyes showed -0.3 letters of improvement in mean BCVA after 3 injections

Protocol I analysis of ranibizumab treated eyes (n=340 at 12 wks)

Mean Change: 12 weeks	Eyes
15.2 letters	37% (126 of 340)
6.9 letters	23% (79 of 340)
-0.3 letters	40% (135 of 340)

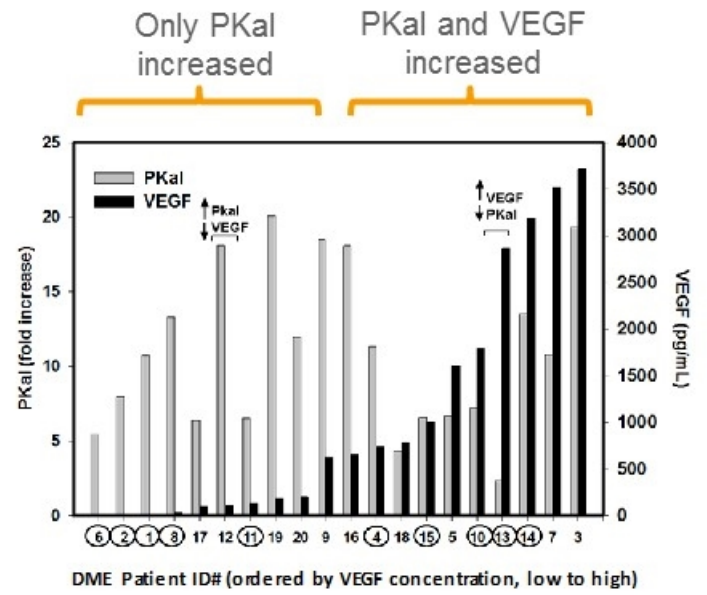


KalVista Offers a Novel Therapeutic Approach



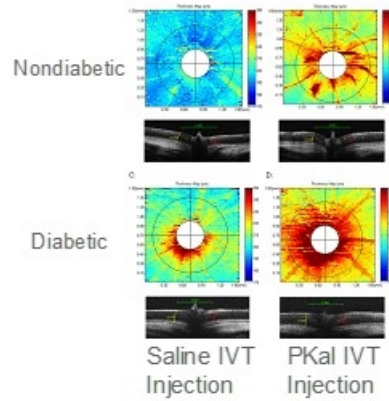
Plasma Kallikrein Elevated in DME Vitreous

- Vitreous samples from patients with DME show increased Pk_{al} levels
- Significant population has elevated Pk_{al} and low VEGF
 - Patients who may respond well to Pk_{al} inhibition and poorly to anti-VEGF treatment
 - Clear medical need
- Presence of Pk_{al} in addition to VEGF suggests potential utility in broader population



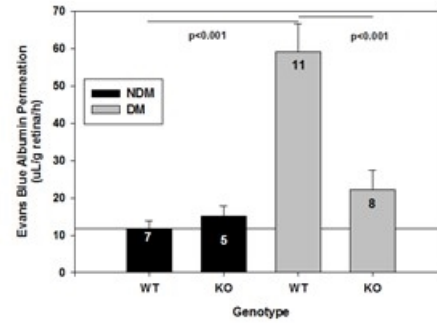
Plasma Kallikrein-Mediated Retinal Edema

- Injection of Pk1 into vitreous causes retinal edema
- Effect of Pk1 is enhanced in diabetic animals
 - Diabetes sensitizes eye to effect of Pk1



Clermont et al, Diabetes 2011

- Induction of diabetes in animals increases retinal leakage
- Knock-out of Pk1 is strongly protective against diabetes-induced retinal leakage

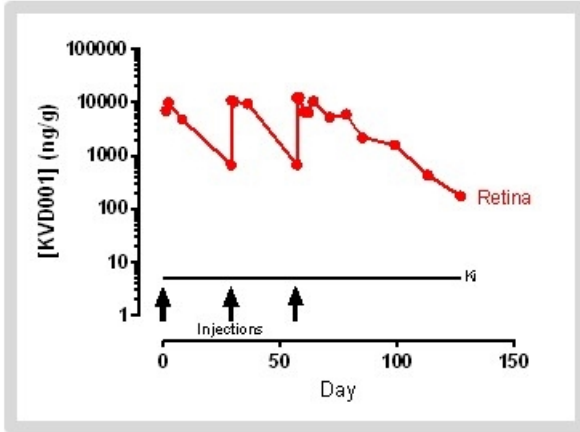


Kita et al, Diabetes 2015



KVD001 Preclinical Profile

- KVD001 is a potent inhibitor of human plasma kallikrein with a K_i of 9 nM
- Highly selective against related proteases
 - Selective against a broad panel of other enzymes



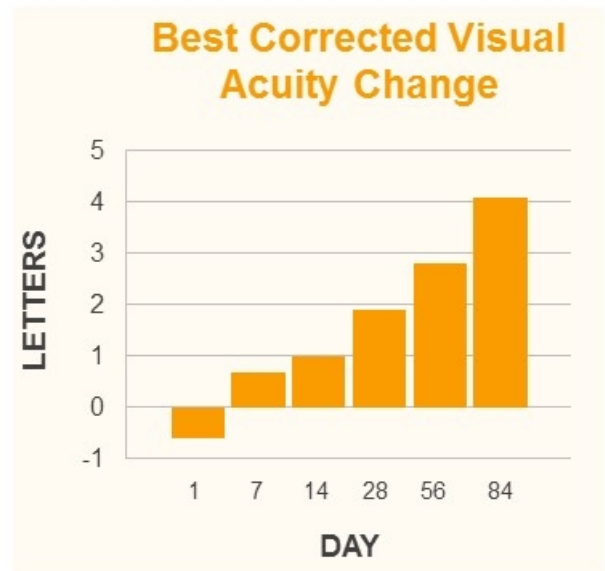
Enzyme (Human)	Fold selectivity
Tissue Kallikrein	>500
Factor VIIa	>500
Factor Xa	>500
Factor XIa	>500
Factor XIIa	>500
Plasmin	200
Thrombin	>500
Trypsin	>500

- IVT administration to rabbits at clinically relevant doses
 - Highest exposure in the retina
 - Exposure maintained well above K_i for 10+ weeks
 - Half-life of 5-10 days comparable to anti-VEGFs



Phase 1 Trial Results

- KVD001: IVT first-in-class plasma kallikrein inhibitor for DME
- Open label, single ascending dose Phase 1 trial in 14 DME patients complete
 - All patients had previously received anti-VEGF treatment
 - Well tolerated
 - Signal of improved visual acuity following single dose
- Duration of animal exposure consistent with signal of improvement



Mean change in visual acuity following a single dose of KVD001
N=14



Option Agreement With Merck on DME Programs

- In October 2017, KalVista and Merck announced a collaboration for KVD001, KalVista's intravitreal DME program, as well as future orally-delivered plasma kallikrein inhibitors for DME developed by KalVista
- Merck has two options, to acquire KVD001 and/or oral DME assets until a specified time following certain data on each
- Until the options are exercised, KalVista retains full ownership and control of the assets
 - KalVista to execute and fund the Phase 2 KVD001 trial and other activities
 - Merck pays all costs post-exercise
- \$37 million upfront payment to KalVista
- \$715 million in potential additional milestone payments
- Tiered sales royalties on global net sales
- Merck acquired a 9.9% stake in KalVista in a concurrent PIPE



KVD001 Phase 2 Enrollment on Track

- Approximately 123 patients who have discontinued treatment with anti-VEGF therapy and who still have significant edema and reduced visual acuity
- Sham-controlled, double-masked clinical trial will evaluate two doses
- Efficacy endpoints include best corrected visual acuity (BCVA), central subfield thickness (CST), and the diabetic retinopathy severity scale (DRSS)



Company Achievements and Milestones

HAE portfolio update	✓
KVD001 enrollment update	✓
KVD900 Phase 2 clinical trial initiates	Late 2018
KVDXXX regulatory filing	YE 2018
KVD900 Phase 2 completed	Mid-2019
KVD001 Phase 2 data	H2 2019





KalVista
Pharmaceuticals

NASDAQ: KALV

