

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the quarterly period ended January 31, 2018

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the transition period from _____ to _____.

Commission File No. 001-36830

KALVISTA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

55 Cambridge Parkway
Suite 901E
Cambridge, Massachusetts
(Address of principal executive offices)

20-0915291
(I.R.S. Employer Identification No.)

02142

(Zip Code)

857-999-0075

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities and Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES NO

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES NO

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company)

Smaller reporting company

Emerging growth company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES NO

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 standard provided pursuant to Section 13(a) of the Exchange Act.

As of March 1, 2018 the registrant had 10,795,895 shares of common stock, \$0.001 par value per share, issued and outstanding.

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PART I. FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

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

	January 31, 2018 (Unaudited)	April 30, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 58,678	\$ 30,950
Research and development tax credit receivable	4,989	2,250
Grants and other receivables	40	297
Prepaid expenses and other current assets	2,003	701
Total current assets	65,710	34,198
Other assets	173	50
Property and equipment, net	774	97
Total assets	<u>\$ 66,657</u>	<u>\$ 34,345</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,575	\$ 1,153
Accrued expenses	2,290	1,865
Deferred revenue - current portion	19,996	—
Capital lease liability - current portion	222	—
Total current liabilities	24,083	3,018
Long-term liabilities:		
Deferred revenue - net of current portion	13,889	—
Capital lease liability - net of current portion	117	—
Total long-term liabilities	14,006	—
Commitments and contingencies (Note 4)		
Stockholders' equity		
Common stock, \$0.001 par value		
Shares authorized: 100,000,000		
Shares issued and outstanding: 10,792,646	11	10
Additional paid-in capital	99,696	89,815
Accumulated deficit	(71,003)	(55,855)
Accumulated other comprehensive loss	(136)	(2,643)
Total stockholders' equity	28,568	31,327
Total liabilities and stockholders' equity	<u>\$ 66,657</u>	<u>\$ 34,345</u>

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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

	Three Months Ended		Nine Months Ended	
	January 31,		January 31,	
	2018	2017	2018	2017
Revenue	\$ 2,331	\$ 248	\$ 3,554	\$ 1,390
Operating Expenses:				
Research and development	4,548	3,339	12,385	9,670
General and administrative	2,129	5,026	6,905	8,973
Total operating expenses	6,677	8,365	19,290	18,643
Operating loss	(4,346)	(8,117)	(15,736)	(17,253)
Other income (expense):				
Interest income	14	7	17	31
Foreign currency exchange gain (loss)	(1,887)	(195)	(1,836)	1,511
Other income	985	661	2,407	1,310
Total other income (expense)	(888)	473	588	2,852
Net loss	\$ (5,234)	\$ (7,644)	\$ (15,148)	\$ (14,401)
Other comprehensive loss:				
Foreign currency translation adjustments	2,434	166	2,507	(2,832)
Comprehensive loss	\$ (2,800)	\$ (7,478)	\$ (12,641)	\$ (17,233)
Net loss per share to common stockholders, basic and diluted	\$ (0.49)	\$ (1.03)	\$ (1.49)	\$ (5.50)
Weighted average common shares outstanding, basic and diluted	10,788,556	7,657,874	10,168,520	3,013,073

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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

	Nine Months Ended January 31,	
	2018	2017
Cash Flows from Operating Activities		
Net loss	\$ (15,148)	\$ (14,401)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	129	29
Stock-based compensation	779	228
Foreign currency remeasurement (gain) loss	(500)	(1,464)
Changes in operating assets and liabilities:		
Research and development tax credit receivable	(2,383)	(1,303)
Prepaid expenses and other current assets	(1,206)	(689)
Grants and other receivables	281	36
Other assets	(123)	—
Accounts payable	548	(1,957)
Accrued expenses	332	(1,560)
Deferred revenue	33,804	—
Net cash provided by (used in) operating activities	<u>16,513</u>	<u>(21,081)</u>
Cash Flows from Investing Activities		
Cash acquired in transaction	—	34,139
Acquisition of property and equipment	(343)	(67)
Net cash provided by (used in) investing activities	<u>(343)</u>	<u>34,072</u>
Cash Flows from Financing Activities		
Capital lease principal payments	(101)	—
Issuance of common stock	9,100	2
Net cash from financing activities	<u>8,999</u>	<u>2</u>
Effect of exchange rate changes on cash	2,559	(1,259)
Net increase in cash and cash equivalents	<u>27,728</u>	<u>11,734</u>
Cash and cash equivalents at beginning of period	30,950	21,764
Cash and cash equivalents at end of period	<u>\$ 58,678</u>	<u>\$ 33,498</u>
Supplemental Disclosures of Non-cash Financing Activities		
Capital leases	\$ 513	\$ —
Conversion of preferred stock to common stock	\$ —	\$ 58,608

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

1. The Company

KalVista Pharmaceuticals, Inc. (“KalVista” or the “Company”) is a clinical stage pharmaceutical company focused on the discovery, development and commercialization of serine protease inhibitors as new treatments for diseases with significant unmet need. The Company’s initial focus is on developing small molecule inhibitors of plasma kallikrein for two indications: hereditary angioedema (“HAE”) and diabetic macular edema (“DME”). The strategy in HAE is to develop a portfolio of program candidates in order to create a best-in-class oral therapy. The Company intends to obtain data on multiple molecules prior to making decisions on which program, or programs, to advance into later stage trials, as well as which specific indications to pursue within HAE.

The Company also has developed KVD001, an intravitreally administered plasma kallikrein inhibitor for DME. In October 2017, the Company’s wholly-owned, U.K. based subsidiary KalVista Pharmaceuticals Limited (“KalVista Limited”) and Merck Sharp & Dohme Corp. (“Merck”) entered into an option agreement (the “Option Agreement”) under which the Company granted to Merck an option to acquire KVD001 through a period following completion of a Phase 2 clinical trial. The Company also granted to Merck a similar option to acquire investigational orally delivered molecules for DME (the “Oral DME Compounds”) that it will continue to develop as part of its ongoing research and development activities, through a period following the completion of a Phase 2 clinical trial. Under the terms of the Option Agreement, Merck paid to the Company a non-refundable upfront fee of \$37 million in November 2017. See Note 5 for further discussion of the arrangement with Merck.

In January 2018, the Company announced the initiation of a Phase 2 clinical trial for KVD001. This study is anticipated to enroll a total of 123 patients to evaluate the safety and efficacy of KVD001 in patients with DME who have received previous anti-VEGF therapy but continue to demonstrate reduced visual acuity and significant edema. The double-masked study will consist 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. The Company anticipates that data from this study will be available in the second half of 2019. Once the Company provides certain data resulting from the study to Merck pursuant to the Option Agreement, Merck will have a defined period to exercise the option on KVD001, as well as to make an additional payment to maintain the option on the Oral DME Compounds.

Also in January 2018, the Company announced the initiation of a first-in-human study for KVD900, the next program to advance to clinical trials from the Company’s HAE portfolio. The Phase 1 trial of KVD900 is dosing healthy volunteers to evaluate the safety, tolerability and exposure of the drug candidate, and a plasma-based assay will be used to assess the pharmacodynamic effect of KVD900. The Company expects to provide an update on the status and progress of the HAE portfolio, including KVD900, in mid-2018. The Company also intends to advance at least one additional HAE drug candidate to the clinic before the end of 2018.

The Company has devoted substantially all of its efforts to research and development, including clinical trials of its product candidates. The Company has not completed the development of any product candidates. Pharmaceutical drug product candidates, like those being developed by the Company, require approvals from the U.S. Food and Drug Administration (“FDA”) or foreign regulatory agencies prior to commercial sales. There can be no assurance that any product candidates will receive the necessary approvals and any failure to receive approval or delay in approval may have a material adverse impact on the business and financial results. The Company has not yet commenced commercial operations. The Company is subject to a number of risks and uncertainties similar to those of other life science companies developing new products, including, among others, the risks related to the necessity to obtain adequate additional financing, to successfully develop product candidates, to obtain regulatory approval of product candidates, to comply with government regulations, to successfully commercialize its potential products, to the protection of proprietary technology and to the dependence on key individuals.

The Company has funded its operations primarily through the issuance and sale of preferred stock and common stock, the share purchase transaction with Carbylan Therapeutics, Inc. (“Carbylan”), the Option Agreement, and grant income. As of January 31, 2018, the Company had an accumulated deficit of \$71.0 million and \$58.7 million of cash and cash equivalents. The Company’s working capital, primarily cash, is anticipated to fund the Company’s operations for at least the next twelve months from the date these interim condensed consolidated financial statements are issued. Accordingly, the unaudited interim condensed consolidated financial statements have been prepared on a going concern basis.

The Company will need to expend substantial resources for research and development, including costs associated with the clinical testing of its product candidates, and will need to obtain additional financing to fund its operations and to conduct trials for its product candidates. The Company will seek to finance future cash needs through equity offerings, future grants, corporate partnerships and product sales.

The Company has never been profitable and has incurred significant operating losses in each year since inception. Cash requirements may vary materially from those now planned because of changes in the Company’s focus and direction of its research and development programs, competitive and technical advances, patent developments, regulatory changes or other developments. Additional financing will be required to continue operations after the Company exhausts its current cash resources and to continue its long-term plans for clinical trials and new product development. There can be no assurance that any such financing can be obtained by the Company, or if obtained, what the terms thereof may be, or that any amount that the Company is able to raise will be adequate to support the Company’s working capital requirements until it achieves profitable operations. If adequate additional working capital is not secured when it becomes needed, the Company may be required to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible and/or suspend or curtail planned research programs. Any of these actions could materially harm the Company’s business and prospects.

The Company’s headquarters is located in Cambridge, Massachusetts, with research activities located in Porton Down, United Kingdom and Boston, Massachusetts.

2. Summary of Significant Accounting Policies

Principles of Consolidation: The accompanying unaudited interim condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary. All intercompany transactions and balances have been eliminated in consolidation.

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”) for interim financial information and in accordance with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. Such financial statements reflect all adjustments that are, in management’s opinion, necessary to present fairly, in all material respects, the Company’s consolidated financial position, results of operations, and cash flows. There were no adjustments other than normal recurring adjustments. The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the annual financial statements. These unaudited interim condensed consolidated financial results are not necessarily indicative of the results to be expected for the year ending April 30, 2018, or for any other future annual or interim period. The accompanying unaudited interim condensed consolidated financial statements should be read in conjunction with the audited financial statements as of and for the year ended April 30, 2017.

Segment Reporting: The Company’s Chief Operating Decision Maker, the CEO, manages the Company’s operations as a single operating segment for the purposes of assessing performance and making operating decisions.

Net Loss per Share Attributable to Common Stockholders: Basic and diluted net income (loss) per share is presented in conformity with the two-class method required for participating securities. Under the two-class method, basic net income (loss) per share is computed by dividing the net income (loss) attributable to common shareholders by the weighted average number of common shares outstanding during the period. Net income (loss) attributable to common shareholders is determined by allocating undistributed earnings between holders of common and convertible preferred shares, based on the contractual dividend rights contained in the Company’s preferred share agreement. Where there is an undistributed loss, no amount is allocated to the convertible preferred shares. Diluted net income (loss) per share is computed by dividing net income (loss) by the sum of the weighted average number of common shares and the number of dilutive potential common share equivalents outstanding during the period. Potential dilutive common share equivalents consist of the incremental common shares issuable upon the exercise of vested share options.

Potential dilutive common share equivalents consist of:

	January 31,	
	2018	2017
Stock Options	315,908	120,127

In computing diluted earnings per share, common share equivalents are not considered in periods in which a net loss is reported, as the inclusion of the common share equivalents would be anti-dilutive. As a result, there is no difference between the Company's basic and diluted loss per share for the periods presented.

Basic and diluted net loss per share (in thousands, except share and per share amounts)

	Three Months Ended		Nine Months Ended	
	January 31,		January 31,	
	2018	2017	2018	2017
Net loss	\$ (5,234)	\$ (7,644)	\$ (15,148)	\$ (14,401)
Less: dividend on Series A	—	91	—	935
Less: dividend on Series B	—	120	—	1,237
Loss available to common shareholders for the purpose of calculating basic and diluted net loss per share	\$ (5,234)	\$ (7,855)	\$ (15,148)	\$ (16,573)
Weighted average common shares, basic and diluted	10,788,556	7,657,874	10,168,520	3,013,073
Net loss per share, basic and diluted	\$ (0.49)	\$ (1.03)	\$ (1.49)	\$ (5.50)

The weighted average shares outstanding, reported loss per share and potential dilutive common share equivalents for the periods prior to November 21, 2016, the date of the reverse merger arising from the share purchase transaction with Carbylan, have been retrospectively adjusted to reflect historical weighted average number of common shares outstanding multiplied by the exchange ratio established in the share purchase agreement.

Fair Value Measurement: The Company classifies fair value measurements using a three level hierarchy that prioritizes the inputs used to measure fair value. This hierarchy requires entities to maximize the use of observable inputs and minimize the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows: Level 1, quoted market prices in active markets for identical assets or liabilities; Level 2, observable inputs other than quoted market prices included in Level 1, such as quoted market prices for markets that are not active or other inputs that are observable or can be corroborated by observable market data; and Level 3, unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities, including certain pricing models, discounted cash flow methodologies and similar techniques that use significant unobservable inputs.

Recently Issued Accounting Pronouncements Not Yet Adopted: In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards update ("ASU") 2014-09, "Revenue from Contracts with Customers," requiring an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The updated standard will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective and permits the use of either the retrospective or cumulative effect transition method. The Company expects to adopt the updated standard in the first quarter of fiscal 2019 using the modified retrospective method of adoption. The Company is assessing the impact that adoption of this new guidance will have on the consolidated financial statements. The Company's only significant revenue generating arrangement is the arrangement with Merck, which is currently being evaluated for the impact that the adoption of this guidance will have on the consolidated financial statements.

In February 2016, the FASB issued new lease accounting guidance in ASU No. 2016-02, "Leases" (Topic 842). Under the new guidance, lessees will be required to recognize for all leases (with the exception of short term leases) at the commencement date: (1) a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis; and (2) a right of use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. The new lease guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early application is permitted, however, the Company does not intend to early adopt. See Note 4 for additional information regarding the Company's lease obligations.

Recently Adopted Accounting Pronouncements: In March 2016, the FASB issued ASU No. 2016-09, Compensation –Stock Compensation (Topic 718) ("ASU 2016-09") to require changes to several areas of employee share-based payment accounting in an effort to simplify share-based reporting. The update revises requirements in the following areas: minimum statutory withholding, accounting for income taxes and forfeitures. The Company adopted this standard in the quarter ended July 31, 2017, and will account for forfeitures as incurred. The adoption of this standard did not have a material impact on the unaudited interim condensed consolidated financial statements.

3. Accrued Expenses

Accrued expenses consisted of the following as of January 31, 2018 and April 30, 2017 (in thousands):

	January 31, 2018	April 30, 2017
Accrued compensation expense	\$ 1,051	\$ 1,300
Accrued research expense	753	348
Accrued professional fees	233	146
Other accrued expenses	253	71
	<u>\$ 2,290</u>	<u>\$ 1,865</u>

4. Commitments and Contingencies

Clinical Studies: The Company enters into contractual agreements with contract research organizations in connection with preclinical and toxicology studies and clinical trials. Amounts due under these agreements are invoiced to the Company on predetermined schedules during the course of the toxicology studies and clinical trials and are not refundable regardless of the outcome. The Company has a contractual obligation related to the expected future costs to be incurred to complete the ongoing toxicology studies and clinical trials. The remaining commitment, which has cancellation provisions, totals \$8.8 million at January 31, 2018.

Lease Commitments: The Company is party to several operating leases for office and laboratory space as well as a capital lease for certain lab equipment, which commenced in the three months ended October 31, 2017. The capital lease has a term of 24 months, for which the Company made a down payment of approximately \$102,000 and will make monthly lease payments of approximately \$18,000 over the term of the lease. Rent expense is reflected in general and administrative expenses and research and development expenses as determined by the underlying activities.

Future minimum lease payments under these leases as of January 31, 2018 are as follows (in thousands):

Fiscal year	Capital Leases	Operating Leases
2018	\$ 59	\$ 86
2019	234	223
2020	59	225
2021	—	228
2022 and thereafter	—	328
Total minimum lease payments	352	<u>\$ 1,090</u>
Less amounts representing interest	(13)	
Present value of minimum payments	339	
Current portion	(222)	
Long-term portion	<u>\$ 117</u>	

Contingencies: From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business activities. The Company accrues a liability for such matters when it is probable that such expenditures can be reasonably estimated. There are no contingent liabilities requiring accrual at January 31, 2018.

As a result of the terms of grant income received in prior years, upon successful regulatory approval and following the first commercial sale of certain products, the Company will be required to pay royalty fees of up to \$1.0 million within 90 days of the first commercial sale of the product subject to certain limitations, and follow on payments depending upon commercial success and type of product. Given the stage of development of the current pipeline of products it is not possible to predict with certainty the amount or timing of any such liability.

5. Merck Arrangement

On October 6, 2017, the Company's wholly-owned U.K. based subsidiary KalVista Pharmaceuticals Limited ("KalVista Limited") and Merck Sharp & Dohme Corp. ("Merck") entered into an option agreement (the "Option Agreement"). The Company is the guarantor of KalVista Limited's obligations under the Option Agreement. Under the terms of the Option Agreement, the Company, through KalVista Limited, has granted to Merck an option to acquire KVD001 through a period following completion of a Phase 2 clinical trial. The Company, through KalVista Limited, has also granted to Merck a similar option to acquire investigational orally delivered molecules for DME that the Company will continue to develop as part of its ongoing research and development activities, through a period following the completion of a Phase 2 clinical trial. The Company, through KalVista Limited, also granted to Merck a non-exclusive license to use the compounds solely for research purposes, and is required to use its diligent efforts to develop the two compounds through the completion of Phase 2 clinical trials. The Company will fund and retain control over the planned Phase 2 clinical trial of KVD001 as well as development of the investigational oral DME compounds through Phase 2 clinical trials unless Merck determines to exercise its options earlier, at which point Merck will take responsibility for all development and commercialization activities for the compounds. The Company's development efforts under the Option Agreement will be governed by a joint steering committee consisting of equal representatives from the Company and Merck.

Under the terms of the Option Agreement, Merck paid a non-refundable upfront fee of \$37 million to KalVista Limited in November 2017. If Merck exercises both options under the Option Agreement, KalVista Limited could receive up to an additional \$715 million composed of option exercise payments and clinical, regulatory, and sales-based milestone payments. In addition, the Company is eligible for tiered royalties on global net sales ranging from mid-single digits to double digit percentages. Merck may terminate the Option Agreement at any time upon written notice to the Company. KalVista Limited may terminate the Option Agreement in the event of Merck's material breach of the Option Agreement, subject to cure.

Concurrent with the Option Agreement, the Company and Merck also entered into a stock purchase agreement (the "Stock Purchase Agreement") pursuant to which Merck paid approximately \$9.1 million to purchase 1,070,589 new shares of the Company's common stock at a price of \$8.50 per share.

The Company determined that the Option Agreement and the Stock Purchase Agreement were negotiated and executed contemporaneously, and therefore should be combined as one arrangement for accounting purposes. The Company evaluated the arrangement in accordance with the provisions of ASC 605-25. The Company determined that the arrangement contains the following deliverables: (i) a non-exclusive license to use the two compounds solely for research purposes, (ii) research and development services related to the development of KVD001 through completion of a Phase 2 clinical trial, (iii) research and development services related to the development of the Oral DME Compounds, and (iv) unregistered shares of the Company's common stock.

The Company has determined that Merck's options to acquire KVD001 and the Oral DME Compounds are substantive options. Merck is not contractually obligated to exercise the options. The Company has determined that Merck's options to acquire KVD001 and the Oral DME Compounds are not priced at a significant and incremental discount. Consequently, the Company determined that Merck's options are not deliverables in the arrangement.

The Company further determined that the research license granted did not have standalone value from the respective research and development services, as the license could not be used on its own by Merck for its intended purpose of developing and commercializing KVD001 and the Oral DME Compounds on a standalone basis. As a result, the research license has been combined with the respective research and development services for KVD001 and the Oral DME Compounds as two units of accounting (the "KVD001 Unit of Accounting" and the "Oral DME Unit of Accounting"). The Company has concluded that the common stock deliverable identified at the inception of the arrangement has standalone value from the other deliverables and therefore represents a separate unit of accounting (the "Common Stock Unit of Accounting").

Therefore, the Company has identified three units of accounting under the arrangement as follows: (i) the KVD001 Unit of Accounting, (ii) the Oral DME Unit of Accounting, and (iii) the Common Stock Unit of Accounting. Allocable arrangement consideration at inception of the arrangement is comprised of the non-refundable up-front payment of \$37.0 million and the payment for the common stock of \$9.1 million. The Company allocated the \$9.1 million payment to the common stock, as this represented the fair value of the shares issued based on arms-length negotiations between the Company and Merck. The amount allocated to the common stock is recorded to stockholders' equity at the date of issuance. The Company allocated the remaining allocable consideration of \$37.0 million to the remaining units of accounting using the relative-selling price method.

The Company determined that neither vendor-specific objective evidence or third-party evidence is available for any of the units of accounting identified at arrangement inception. Accordingly, the selling price of each unit of accounting was developed using management's best estimate of selling price.

The Company developed the Best Estimate of Selling Price (“BESP”) for the KVD001 Unit of Accounting and Oral DME Unit of Accounting by applying a risk-adjusted analysis of discounted cash flows and the allocable arrangement consideration was allocated among the separate units of accounting using the relative selling price method. The amount allocated to each Unit of Accounting will be recognized as revenue on a proportional performance basis. During the three months and nine months ended January 31, 2018, the Company recognized approximately \$2.3 million and \$3.2 million, respectively, of revenue with respect to the arrangement with Merck. As of January 31, 2018, deferred revenue on the condensed consolidated balance sheet was \$33.9 million.

6. Grant Income

Grant income is primarily recognized through an agreement with the Technology Strategy Board (“TSB”), a United Kingdom government organization. The Company recognizes revenue for reimbursements of research and development costs as the services are performed up to an agreed upon threshold. The Company records these reimbursements as revenue and not as a reduction of research and development expenses, as the Company has the risks and rewards as the principal in the research and development activities. Any services performed and not yet collected upon are shown as a receivable. During the three and nine months ended January 31 2018 and 2017, revenue recognized through the TSB grant amounted to \$6,000 and \$248,000, and \$0.4 million and \$1.4 million, respectively. As of January 31, 2018, the development activities related to the TSB grant have been substantially completed and the Company does not anticipate significant further reimbursements.

The Company evaluates the terms of sponsored research agreement grants and federal grants to assess the Company’s obligations and if the Company’s obligations are satisfied by the passage of time, revenue is recognized as described above. For grants with refund provisions, the Company reviews the grant to determine the likelihood of repayment. If the likelihood of repayment of the grant is determined to be remote, the grant is recognized as revenue. If the probability of repayment is determined to be more than remote, the Company records the grant as a deferred revenue liability, until such time that the grant requirements have been satisfied.

7. Income Taxes

The 2017 Tax Act, which was signed into law on December 22, 2017, has resulted in significant changes to the U.S. corporate income tax system. These changes include a federal statutory rate reduction from 35% to 21%, the elimination or reduction of certain domestic deductions and credits, and limitations on the deductibility of interest expense and executive compensation. The 2017 Tax Act also transitions international taxation from a worldwide system to a modified territorial system and includes base erosion prevention measures on non-U.S. earnings, which has the effect of subjecting certain earnings of the Company’s foreign subsidiaries to U.S. taxation as global intangible low-taxed income (“GILTI”), as well as a base erosion and anti-abuse tax (“BEAT”) aimed at preventing the erosion of the U.S. tax base. These changes are effective beginning in the Company’s fiscal year beginning May 1, 2018.

The Company’s deferred tax assets and liabilities are measured at the enacted tax rate expected to apply when these temporary differences are expected to be realized or settled. Because of the valuation allowance provided on the Company’s domestic net deferred tax assets, the remeasurement of the deferred tax assets and liabilities to the newly enacted rate has no impact on its tax provision.

The 2017 Tax Act eliminates the deferral of U.S. income tax on the historical unrepatriated earnings by imposing the Transition Toll Tax, which is a one-time mandatory deemed repatriation tax on undistributed foreign earnings. The Transition Toll Tax is assessed on the U.S. shareholder's share of the foreign corporation's accumulated foreign earnings that have not previously been taxed. The Company does not have any unrepatriated earnings that are subject to the Transition Toll Tax.

The Company’s preliminary conclusion is that GILTI and BEAT likely will not have an impact on its tax provision. However, the Company has not yet concluded on whether the impact of GILTI and BEAT will be included in the measurement of deferred taxes or recognized as assessed as period costs.

These preliminary estimates, including the remeasurement of deferred tax assets and liabilities, are subject to the finalization of management’s analysis related to certain matters, such as developing interpretations of the provisions of the 2017 Tax Act, changes to certain estimates, and amounts related to the earnings and profits of foreign subsidiaries that might arise upon filing of the Company’s tax returns. The final determination of the Transition Toll Tax and the remeasurement of deferred assets and liabilities will be completed as additional information becomes available, but not later than one year from the enactment of the 2017 Tax Act.

Item 2. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion in conjunction with our unaudited interim condensed financial statements and related notes included elsewhere in this report. This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties. All statements other than statements of historical facts contained in this report are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “may,” “could,” “will,” “would,” “should,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “intend,” “predict,” “seek,” “contemplate,” “potential” or “continue” or the negative of these terms or other comparable terminology. These forward-looking statements, include, but are not limited to, the success, cost and timing of our product development activities and clinical trials as well as other activities we may undertake. Any forward-looking statements in this Quarterly Report on Form 10-Q reflect our current views with respect to future events or our future financial performance, are based on assumptions, and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under “Risk Factors” in our Annual Report on Form 10-K or described elsewhere in this Quarterly Report on Form 10-Q. These forward-looking statements speak only as of the date hereof. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future. Unless the context indicates otherwise, in this Quarterly Report on Form 10-Q, the terms “KalVista,” “Company,” “we,” “us” and “our” refer to KalVista Pharmaceuticals, Inc. and, where appropriate, its consolidated subsidiary.

Management Overview

We are a clinical stage pharmaceutical company focused on the discovery, development and commercialization of serine protease inhibitors as new treatments for diseases with significant unmet need. Our initial focus is on developing small molecule inhibitors of plasma kallikrein for two indications: hereditary angioedema (“HAE”) and diabetic macular edema (“DME”). Our strategy in HAE is to develop a portfolio of program candidates in order to create a best-in-class oral therapy. We intend to obtain data on multiple molecules prior to making decisions on which program, or programs, to advance into later stage trials, as well as which specific indications to pursue within HAE.

We also have developed KVD001, an intravitreally administered plasma kallikrein inhibitor for DME. In October 2017, our wholly-owned, U.K. based subsidiary KalVista Pharmaceuticals Limited (“KalVista Limited”) and Merck Sharp & Dohme Corp. (“Merck”) entered into an option agreement (the “Option Agreement”) under which we granted to Merck an option to acquire KVD001 through a period following completion of a Phase 2 clinical trial. We also granted to Merck a similar option to acquire investigational orally delivered molecules for DME (the “Oral DME Compounds”) that we will continue to develop as part of our ongoing research and development activities, through a period following the completion of a Phase 2 clinical trial.

Under the terms of the Option Agreement, Merck paid us a non-refundable upfront fee of \$37 million in November 2017. If Merck exercises both options under the Option Agreement, we could receive up to an additional \$715 million composed of option exercise payments and clinical, regulatory, and sales-based milestone payments. In addition, we are eligible for tiered royalties on global net sales ranging from mid-single digits to double digit percentages. Concurrent with the Option Agreement, we and Merck also entered into a stock purchase agreement (the “Stock Purchase Agreement”) pursuant to which Merck paid approximately \$9.1 million to purchase 1,070,589 new shares of our common stock.

In January 2018, we announced the initiation of a Phase 2 clinical trial for KVD001. This study is anticipated to enroll a total of 123 patients to evaluate the safety and efficacy of KVD001 in patients with DME who have received previous anti-VEGF therapy but continue to demonstrate reduced visual acuity and significant edema. The double-masked study will consist of two active arms receiving either 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. We anticipate that data from this study will be available in the second half of 2019. Once we provide certain data from the study to Merck pursuant to the Option Agreement, Merck will have a defined period to exercise the option on KVD001, as well as to make an additional payment to maintain the option on the Oral DME Compounds.

Also in January 2018, we announced the initiation of a first-in-human study for KVD900, the next program to advance to clinical trials from our HAE portfolio. The Phase 1 trial of KVD900 is dosing healthy volunteers to evaluate the safety, tolerability and exposure of the drug candidate, and a plasma-based assay will be used to assess the pharmacodynamic effect of KVD900. We expect to provide an update on the status and progress of the HAE portfolio, including KVD900, in mid-2018. We also intend to advance at least one additional HAE drug candidate to the clinic before the end of 2018.

We have devoted substantially all of our efforts to research and development, including clinical trials of our product candidates. We have not completed the development of any product candidates. Pharmaceutical drug product candidates, like those being developed by us, require approvals from the FDA or foreign regulatory agencies prior to commercial sales. There can be no assurance that any product candidates will receive the necessary approvals and any failure to receive approval or delay in approval may have a material adverse impact on our business and financial results. We are subject to a number of risks and uncertainties similar to those of other life science companies developing new products, including, among others, the risks related to the necessity to obtain adequate additional financing, to successfully develop product candidates, to obtain regulatory approval of product candidates, to comply with government regulations, to successfully commercialize our potential products, to the protection of proprietary technology and to our dependence on key individuals.

Our headquarters is located in Cambridge, Massachusetts, with research activities located in Porton Down, United Kingdom and Boston, Massachusetts.

Financial Overview

Revenue

Our revenue consists primarily of a portion of the upfront fees from the Option Agreement, which is recognized as revenue on a proportional performance basis as the related research and development activities are conducted.

We have received grant income to support our research and development activities primarily through an agreement with the Technology Strategy Board (“TSB”), a United Kingdom government organization. Under the terms of the grant the TSB had authorized a total amount of up to \$7.3 million over the lifetime of the agreements between us and TSB, to accelerate the development of the oral drug program. As of January 31, 2018, the development activities related to the TSB grant have been substantially completed and we do not anticipate any significant further reimbursements.

Research and Development Expenses

Research and development expenses primarily consist of costs associated with our research activities, including the preclinical and clinical development of product candidates. We contract with clinical research organizations to manage our clinical trials under agreed upon budgets for each study, with oversight by our clinical program managers. We account for all goods and services, including non-refundable advance payments, as expenses, and all research and development costs are expensed as incurred.

We expect to continue to incur substantial expenses related to development activities for the foreseeable future as we conduct clinical development, manufacturing and toxicology studies. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials, additional drug manufacturing requirements, and later stage toxicology studies such as carcinogenicity studies. The process of conducting preclinical studies and clinical trials necessary to obtain regulatory approval is costly and time consuming. The probability of success for each product candidate is affected by numerous factors, including preclinical data, clinical data, competition, manufacturing capability and commercial viability. Accordingly, we may never succeed in achieving marketing approval for any of our product candidates.

Completion dates and costs for clinical development programs as well as our research program can vary significantly for each current and future product candidate and are difficult to predict. As a result, we cannot estimate with any degree of certainty the costs associated with development of our product candidates at this point in time. We anticipate making determinations as to which programs and product candidates to pursue and how much funding to direct to each program and product candidate on an ongoing basis in response to the scientific success of early research programs, results of ongoing and future clinical trials, our ability to enter into collaborative agreements with respect to programs or potential product candidates, as well as ongoing assessments as to the commercial potential of each current or future product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of the costs associated with general management, obtaining and maintaining our patent portfolio, professional fees for accounting, auditing, consulting and legal services, and general overhead expenses.

We expect ongoing general and administrative expenses to increase in the future as we expand our operating activities, maintain and expand the patent portfolio and incur additional costs associated with the management of a public company and maintaining compliance with exchange listing and requirements of the Securities and Exchange Commission. These potential increases will likely

include management costs, legal fees, accounting fees, directors' and officers' liability insurance premiums, and expenses associated with investor relations, among others.

Other Income

Other income consists of bank interest, research and development tax credits from the United Kingdom government's tax incentive programs set up to encourage research and development in the United Kingdom and realized and unrealized exchange rate gains/losses on cash held in foreign currencies.

Income Taxes

We historically have incurred net losses and have no corporation tax liabilities. We file U.S. Federal tax returns, as well as certain state returns. We also file returns in the United Kingdom. Under the U.K. government's research and development tax incentive scheme, we have incurred qualifying research and development expenses and filed claims for research and development tax credits in accordance with the relevant tax legislation. The research and development tax credits are paid out to us in cash and reported as other income. Because of the operating losses and the full valuation allowance provided on all deferred tax assets, including the net operating losses, no tax provision has been recognized in the periods presented.

Results of Operations

Comparison of three months ended January 31, 2018 and 2017

The following table sets forth the key components of our results of operations for the three months ended January 31, 2018 and 2017 (in thousands):

	Three Months Ended January 31,		Increase (decrease)
	2018	2017	
Revenue	\$ 2,331	\$ 248	\$ 2,083
<u>Operating expenses</u>			
Research and development expenses	4,548	3,339	1,209
General and administrative expenses	2,129	5,026	(2,897)
<u>Other income (expense)</u>			
Interest, exchange rate gain (loss) and other income	(888)	473	(1,361)

Revenue. Revenue was \$2.3 million in the three months ended January 31, 2018 compared to \$0.2 million for the same period in the prior year. The increase of \$2.1 million was due primarily to \$2.3 million of revenue from the Option Agreement recognized in the three months ended January 31, 2018 compared to the same period in the prior year, which was offset by a decrease in grant revenue of \$0.2 million. We expect that our reported revenues will increase in future periods as the proceeds from the Option Agreement are recognized as services are performed.

Research and Development Expenses. Research and development expenses were \$4.5 million for the three months ended January 31, 2018 compared to \$3.3 million for the same period in the prior year, primarily due to an increase in early stage research activities and the initiation of a Phase 2 clinical trial for KVD001. The impact of exchange rates on research and development expenses was an increase to expenses of approximately \$0.4 million in the three months ended January 31, 2018 compared to the same period in the prior year.

Research and development expenses by major programs or categories were as follows (in thousands):

	Three Months Ended January 31, 2017	
	2018	2017
Intravitreal	\$ 697	\$ 80
Clinical stage oral programs	762	528
Additional oral programs	537	854
Early stage research activities	2,552	1,877
Total	\$ 4,548	\$ 3,339

Expenses for the intravitreal program were \$0.7 million for the three months ended January 31, 2018 compared to \$0.1 million for the same period in the prior year due to the initiation of a Phase 2 clinical trial for KVD001 in the three months ended January 31, 2018. We anticipate that expenses will continue to increase as the clinical trial for KVD001 progresses this year.

Expenses for the clinical stage oral programs were \$0.8 million in the three months ended January 31, 2018 compared to \$0.5 million for the same period in the prior year due to the commencement of the first-in-human study for KVD900 in the three months ended January 31, 2018. We anticipate that expenses will continue to increase as the first-in-human studies continue this year.

Expenses for the additional oral programs were \$0.5 million in the three months ended January 31, 2018 compared to \$0.9 million for the same period in the prior year due to KVD900 entering the clinical stage of development in the three months ended January 31, 2018. We anticipate that expenses will continue to increase as the level of activity increases in our additional oral programs this year.

Expenses for early stage research activities were \$2.6 million for the three months ended January 31, 2018 compared to \$1.9 million for the same period in the prior year due to increased headcount and additional projects compared to the same period in the prior year. We anticipate that expenses will continue to increase as multiple candidates are assessed in discovery and advanced into early stage development.

General and Administrative Expenses. General and administrative expenses were \$2.1 million for the three months ended January 31, 2018 compared to \$5.0 million for the same period in the prior year. The decrease of \$2.9 million was substantially due to a \$2.1 million decrease in professional fees and \$0.7 million of severance and payroll expenses related to the share purchase transaction with Carbylan Therapeutics, Inc. (“Carbylan”) in the prior year. We expect to continue to incur increasing expenses related to our operations as a public company.

Other Income (Expense). Other income (expense) was \$(0.9) million for the three months ended January 31, 2018 compared to \$0.5 million for the same period in the prior year. The decrease of \$1.4 million was primarily due to an increase in foreign currency exchange rate losses of \$1.7 million from cash held in USD accounts in our U.K. subsidiary which was offset by \$0.3 million in income from research and development tax credits.

Comparison of nine months ended January 31, 2018 and 2017

The following table sets forth the key components of our results of operations for the nine months ended January 31, 2018 and 2017 (in thousands):

	Nine Months Ended January 31,		Increase (decrease)
	2018	2017	
Revenue	\$ 3,554	\$ 1,390	\$ 2,164
<u>Operating expenses</u>			
Research and development expenses	12,385	9,670	2,715
General and administrative expenses	6,905	8,973	(2,068)
<u>Other income (expense)</u>			
Interest, exchange rate gain (loss) and other income	588	2,852	(2,264)

Revenue. Revenue was \$3.6 million in the nine months ended January 31, 2018 compared to \$1.4 million for the same period in the prior year. The increase of \$2.2 million was due primarily to \$3.2 million of revenue recognized from the Option Agreement, which is being recognized as services are being performed, that was offset by a decrease in grant income of \$1.0 million related to a reduction in activity related to the TSB and another grant compared to the same period in the prior year.

Research and Development Expenses. Research and development expenses were \$12.4 million for the nine months ended January 31, 2018 compared to \$9.7 million for the same period in the prior year. The increase of \$2.7 million was primarily due to an increase of \$2.9 million in early stage research activities and an increase of \$1.0 million in the intravitreal program, partially offset by a decrease of \$1.5 million in the additional oral programs. The impact of exchange rates on research and development expenses was an increase to expenses of approximately \$0.4 million in the nine months ended January 31, 2018 compared to the same period in the prior year.

Research and development expenses by major programs or categories were as follows (in thousands):

	Nine Months Ended January 31,	
	2018	2017
Intravitreal	\$ 1,462	\$ 488
Clinical stage oral programs	2,920	2,592
Additional oral programs	733	2,210
Early stage research activities	7,270	4,380
Total	\$ 12,385	\$ 9,670

Expenses for the intravitreal program were \$1.5 million for the nine months ended January 31, 2018 compared to \$0.5 million for the same period in the prior year due to the the initiation of a Phase 2 clinical trial for KVD001. We anticipate that expenses will continue to increase as the clinical trial for KVD001 progresses this year.

Expenses for the clinical stage oral programs were \$2.9 million in the nine months ended January 31, 2018 compared to \$2.6 million for the same period in the prior year due to the commencement of the first-in-human study for KVD900 in the nine months ended January 31, 2018. We anticipate that expenses will continue to increase as the first-in-human study continues this year.

Expenses for the additional oral programs were \$0.7 million in the nine months ended January 31, 2018 compared to \$2.2 million in the same period in the prior year due to KVD900 entering the clinical stage of development in the nine months ended January 31, 2018. We anticipate that expenses will continue to increase as the level of activity increases in our additional oral programs this year.

Expenses for the early stage research activities were \$7.3 million for the nine months ended January 31, 2018 compared to \$4.4 million for the same period in the prior year due to increased headcount and additional projects compared to the same period in the prior year. We anticipate that research and development expenses will continue to increase as multiple candidates are assessed in discovery and advanced into early stage development.

General and Administrative Expenses. General and administrative expenses were \$6.9 million for the nine months ended January 31, 2017 compared to \$9.0 million for the same period in the prior year. The decrease of \$2.1 million was substantially due to a decrease of \$3.5 million of professional fees and \$0.7 million of severance payments related to the share purchase transaction with Carbylan in the prior year, offset by an increase of \$1.4 million in payroll related expenses, an increase of \$0.5 million in stock-based compensation and an increase of \$0.2 million in other administrative expenses related to being a public company. We expect to continue to incur increasing expenses related to our operations as a public company.

Other Income. Other income was \$0.6 million for the nine months ended January 31, 2018 compared to \$2.9 million for the same period in the prior year. The decrease of \$2.3 million was primarily due to an increase of \$3.3 million in foreign currency exchange rate losses from cash held in USD accounts in our U.K. subsidiary, offset by a \$1.1 million increase in income from research and development tax credits.

Liquidity and Capital Resources

We have funded operations primarily through the issuance and sale of preferred stock and common stock, the share purchase transaction with Carbylan, the Option Agreement, and grant income. As of January 31, 2018, we have received cumulative equity

funding totaling \$67.7 million, \$37.1 from the Option Agreement, grant income of \$9.1 million and have an accumulated deficit of \$71.0 million. Our working capital, primarily cash, is anticipated to fund our operations for at least the next twelve months from the date these unaudited interim condensed consolidated financial statements are issued. Accordingly, the unaudited interim condensed consolidated financial statements have been prepared on a going concern basis.

We will need to expend substantial resources for research and development, including costs associated with the clinical testing of our product candidates and will need to obtain additional financing to fund our operations and to conduct trials for our product candidates. We will seek to finance future cash needs through equity offerings, future grants, corporate partnerships and product sales.

We have never been profitable and have incurred significant operating losses in each year since inception. Cash requirements may vary materially from those now planned because of changes in our focus and direction of our research and development programs, competitive and technical advances, patent developments, regulatory changes or other developments. Additional financing will be required to continue operations after we exhaust our current cash resources and to continue our long-term plans for clinical trials and new product development. There can be no assurance that any such financing can be obtained by us, or if obtained, what the terms thereof may be, or that any amount that we are able to raise will be adequate to support our working capital requirements until we achieve profitable operations. If adequate additional working capital is not secured when it becomes needed, we may be required to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible and/or suspend or curtail planned research programs. Any of these actions could materially harm our business and prospects.

Cash Flows

The following table shows a summary of the net cash flow activity for the nine months ended January 31, 2018 and 2017 (in thousands):

	Nine Months Ended January 31,	
	2018	2017
Cash flows provided by (used in) operating activities	\$ 16,513	\$ (21,081)
Cash flows (used in) provided by investing activities	(343)	34,072
Cash flows provided by financing activities	8,999	2
Effect of exchange rate changes on cash	2,559	(1,259)
Net increase in cash and cash equivalents	<u>\$ 27,728</u>	<u>\$ 11,734</u>

Net cash provided by (used in) operating activities

Net cash provided by operating activities of \$16.6 million for the nine months ended January 31, 2018 consisting primarily of a net loss of \$15.1 million, favorable adjustments from non-cash items of \$0.4 million and favorable net working capital movements of \$31.3 million, which consisted primarily of a \$33.8 million increase in deferred revenue related to the Option Agreement, partially offset by an increase in the research and development tax credit receivable of \$2.4 million and an increase in prepaids and other current assets of \$1.2 million. Net cash used in operating activities was \$21.1 million for the nine months ended January 31, 2017 consisting primarily of a net loss of \$14.4 million, an adjustment of foreign currency remeasurement gains of \$1.5 million, and adverse working capital movements of \$5.5 million consisting primarily of an increase in the research and development tax credit receivable of \$1.3 million a decrease in accounts payable of \$2.0 million and a decrease in accrued expenses of \$1.6 million.

Net cash used in (provided by) investing activities

Net cash used in investing activities for the nine months ended January 31, 2018 was \$0.3 million compared to \$34.1 million provided by investing activities during the same period in the prior year and primarily consisted of the acquisition of laboratory equipment and capital expenditures related to the offices in Cambridge, Massachusetts and Porton Down, United Kingdom. We expect to incur additional capital expenditures in the remainder of this fiscal year related primarily to the build out of our new administrative and research facility in Porton Down, United Kingdom. Cash provided by investing activities for the nine months ended January 31, 2017 was primarily due to the cash obtained in the share purchase agreement with Carbylan.

Net cash provided by financing activities

The increase in net cash provided by financing activities during the nine months ended January 31, 2018 compared to the same period in the prior year was \$9.0 million due to the sale and issuance of common stock to Merck in October 2017.

Operating Capital Requirements

To date, we have not generated any product sales revenues and we do not have any products that have been approved for commercialization. We do not expect to generate significant revenue unless and until we obtain regulatory approval for, and commercialize, one of our current or future product candidates. We anticipate that we will continue to incur losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, product candidates, and begin to commercialize any approved products. We are subject to all of the risks inherent in the development of new therapeutic products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. As a result of the completion of the share purchase transaction with Carbylan in November 2016, we incur additional costs associated with operating as a public company. We currently anticipate that, based upon our operating plans, existing capital resources, the additional funding secured through the share purchase transaction and the Option Agreement, we have sufficient funding to operate for at least the next twelve months.

Until such time, if ever, as we can generate substantial revenues, we expect to finance our cash needs through a combination of equity or debt financings, collaborations, strategic partnerships or licensing arrangements. To the extent that additional capital is raised through the sale of stock or convertible debt securities, the ownership interest of existing stockholders will be diluted, and the terms of these newly issued securities may include liquidation or other preferences that adversely affect the rights of common stockholders. Debt financing, if available, may involve agreements that include increased fixed payment obligations and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, selling or licensing intellectual property rights and other operating restrictions that could adversely impact our ability to conduct business. Additional fundraising through collaborations, strategic partnerships or licensing arrangements with third parties may require us to relinquish valuable rights to product candidates, including other technologies, future revenue streams or research programs, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate product development or future commercialization efforts or grant rights to develop and commercialize our other product candidates even if we would otherwise prefer to develop and commercialize such product candidates internally.

Contractual Obligations and Commitments

We enter into contracts in the normal course of business with contract research organizations and clinical trial sites for the conduct of clinical trials, preclinical and clinical studies, professional consultants and other vendors for clinical supply manufacturing or other services. These contracts generally provide for termination on notice, and therefore are cancelable contracts and not included in the table of contractual obligations and commitments. We are party to several operating leases for office and laboratory space as well as a capital lease for certain laboratory equipment as of January 31, 2018. See the minimum lease payments schedule in Note 4 to these unaudited interim condensed consolidated financial statements.

Off-Balance Sheet Arrangements

At January 31, 2018 we were not a party to any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with U.S. GAAP. The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of our financial statements and the reported revenue and expenses during the reported periods. We evaluate these estimates and judgments, including those described below, on an ongoing basis. We base our estimates on historical experience, known trends and events, contractual milestones and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. See Note 2 to the unaudited interim condensed consolidated financial statements in Part I, Item 1 of this Quarterly Report on Form 10-Q for a description of our significant accounting policies and assumptions used in applying those policies. While the accounting policies and estimates that we deem to be critical are discussed in more detail in the Annual Report on Form 10-K filed on July 27, 2017, the following accounting policies have become critical since the filing of our Annual Report.

Revenue Recognition

We recognize revenue from research and development arrangements and grant income. Revenue is realized or realizable and earned when all of the following criteria are met: (i) persuasive evidence of an arrangement exists; (ii) delivery has occurred or services have been rendered; (iii) the seller's price to the buyer is fixed or determinable; and (iv) collectability is reasonably assured.

Grant income is received for the development and commercialization of product candidates through sponsored research arrangements with non-profit organizations and from federal research and development grant programs. Revenue is recognized as qualifying research and development costs are incurred. The existing grant program is sponsored by the U.K. government and is substantially complete, with no significant further reimbursements anticipated.

For arrangements that involve the delivery of more than one element, such as the Option Agreement, each product, service and/or right to use assets is evaluated to determine whether it qualifies as a separate unit of accounting. This determination is based on whether the deliverable has "stand-alone value" to the customer. The consideration that is fixed or determinable is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. The estimated selling price of each deliverable is determined using the following hierarchy of values: (i) vendor-specific objective evidence of fair value, (ii) third-party evidence of selling price and (iii) best estimate of selling price ("BESP"). The BESP reflects our best estimate of what the selling price would be if the deliverable was regularly sold by us on a stand-alone basis. The consideration allocated to each unit of accounting is recognized as the related goods or services are delivered, limited to the consideration that is not contingent upon future deliverables. Analyzing the arrangement to identify deliverables requires the use of judgment, and each deliverable may be an obligation to deliver services, a right or license to use an asset, or another performance obligation.

Commencing in October 2017, we began recognizing revenue under the Merck arrangement. We determined that the research license granted did not have standalone value from the respective research and development services, as the license could not be used on its own by Merck for its intended purpose of developing and commercializing KVD001 and the Oral DME Compounds on a standalone basis. As a result, the research license has been combined with the respective research and development services for KVD001 and the Oral DME Compounds as two units of accounting (the "KVD001 Unit of Accounting" and the "Oral DME Unit of Accounting"). We allocated the allocable consideration of \$37.0 million to these two units of accounting using the relative-selling price method.

Neither vendor-specific objective evidence or third-party evidence is available for any of the units of accounting identified at arrangement inception. Accordingly, the selling price of each unit of accounting was developed using management's best estimate of selling price ("BESP"). BESP for the KVD001 Unit of Accounting and the Oral DME Unit of Accounting were determined by applying a risk-adjusted analysis of discounted cash flows and the allocable arrangement consideration was allocated among the separate units of accounting using the relative selling price method.

The amount allocated to the KVD001 Unit of Accounting and the Oral DME Unit of Accounting will be recognized as revenue on a proportional performance basis as the research and development activities are conducted through completion of the respective Phase 2 clinical trials. If the period over which revenue is attributed changes or the estimates of proportional performance change, the reported revenue could be materially impacted.

Recently Issued Accounting Pronouncements

See discussion in Note 2 to these unaudited interim condensed consolidated financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Interest Rate Risk

We have exposure to market risk in interest income sensitivity, which is affected by changes in the general level of interest rates. However, because of the short-term nature of the bank deposit arrangements and the very low interest rates prevailing in the United Kingdom and the United States, a sudden change in market interest rates would not be expected to have a material impact on our financial condition and/or results of operations. We do not believe that our cash or cash equivalents have significant risk of default or illiquidity.

Foreign Exchange Rate Risk

We maintain cash balances primarily in both U.S. Dollars (“USD”) and British Pound Sterling (“GBP”) to fund ongoing operations. Cash and cash equivalents as of January 31, 2018 was \$58.7 million and consisted of readily available checking and bank deposit accounts held primarily in both USD and GBP. As of January 31, 2018, 89% of cash and cash equivalents were held in USD and 11% in GBP. We currently incur significant expenses in GBP and convert USD as needed to fund those expenses. We do not believe our cash and cash equivalents are exposed to significant exchange rate risk, though we do not currently engage in exchange rate hedging or other similar activities. A 10% change in the exchange rate would result in a net gain or loss of approximately \$2.8 million.

Effects of Inflation

We do not believe that inflation and changing prices had a significant impact on the results of operations for any periods presented herein.

ITEM 4. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(b) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of January 31, 2018. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of January 31, 2018.

Changes in Internal Controls over Financial Reporting

There have been no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended January 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II

OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we may become involved in various lawsuits and legal proceedings which arise in the ordinary course of business. We are currently not aware of any such legal proceedings or claims that we believe will have a material adverse effect on our business, financial condition or operating results.

Item 1A. RISK FACTORS

There have been no material changes to the risk factors described in the section captioned “Part I, Item 1A, Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended April 30, 2017, except as described below. In addition to the other information set forth in this report, you should carefully consider the factors discussed in the section captioned “Part I, item 1A, Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended April 30, 2017, which could materially affect our business, financial condition, or future results. The risks described here and in our Annual Report on form 10-K are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may have a material adverse effect on our business, financial condition, or operating results.

We may face operational disruptions due to lack of adequate facilities.

We are highly dependent upon our U.K. facility to conduct our scientific research. Our lease on that facility expired on November 30, 2017, and we currently continue to occupy the facility on a month-to-month basis with our landlord, whose master lease on the facility expired on December 22, 2017. Although we believe the risk of being forced to vacate our current facility without the ability to move to a new one is low, we have not yet signed a lease for the new facility to which we plan to move our operations in mid-2018. If we are forced to vacate our current spaces in advance of our move to a new facility, or if we are unable to obtain a lease for our planned new facility, it could cause a severe disruption to our scientific activities that could materially endanger our business and future prospects.

Comprehensive tax reform bills could increase the tax burden on any orphan drug programs we may have in the future and adversely affect our business and financial condition.

The U.S. government has recently enacted comprehensive tax legislation that includes significant changes to the taxation of business entities. These changes include, among others, (i) a permanent reduction to the corporate income tax rate, (ii) a partial limitation on the deductibility of business interest expense, (iii) a shift of the U.S. taxation of multinational corporations from a tax on worldwide income to a territorial system (along with certain rules designed to prevent erosion of the U.S. income tax base) and (iv) a one-time tax on accumulated offshore earnings held in cash and illiquid assets, with the latter taxed at a lower rate.

Notwithstanding the reduction in the corporate income tax rate, the overall impact of this tax reform is uncertain, and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law. This quarterly report does not discuss any such tax legislation or the manner in which it might affect purchasers of our common stock. We recommend our stockholders consult with their legal and tax advisors with respect to any such legislation and the potential tax consequences of investing in our common stock.

Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Not applicable.

Item 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Item 5. OTHER INFORMATION

Not applicable.

Item 6. EXHIBITS

Exhibits

- 31.1 [Certification of Principal Executive Officer Required Under Rule 13a-14\(a\) of the Securities Exchange Act of 1934, as amended.](#)
- 31.2 [Certification of Principal Financial Officer Required Under Rule 13a-14\(a\) of the Securities Exchange Act of 1934, as amended.](#)
- 32.1 [Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a-14\(b\) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. 1350.](#)
- 101.INS* XBRL Instance Document
- 101.SCH* XBRL Taxonomy Extension Schema Document
- 101.CAL* XBRL Taxonomy Extension Calculation Linkbase Document
- 101.DEF* XBRL Taxonomy Extension Definition Linkbase Document
- 101.LAB* XBRL Taxonomy Extension Labels Linkbase Document
- 101.PRE* XBRL Taxonomy Extension Presentation Linkbase Document

SIGNATURES

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 thereunto duly authorized.

KALVISTA PHARMACEUTICALS, INC.

Date: March 16, 2018

By: /s/ T. Andrew Crockett

T. Andrew Crockett
Chief Executive Officer
(Principal Executive Officer)

Date: March 16, 2018

By: /s/ Benjamin L. Palleiko

Benjamin L. Palleiko
Chief Financial Officer
(Principal Financial and Accounting Officer)

**CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, T. Andrew Crockett, certify that:

1. I have reviewed this quarterly report on Form 10-Q of KalVista Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2018

/s/ T. Andrew Crockett

T. Andrew Crockett
Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Benjamin L. Palleiko, certify that:

1. I have reviewed this quarterly report on Form 10-Q of KalVista Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 16, 2018

/s/ Benjamin L. Palleiko

Benjamin L Palleiko
Chief Financial Officer
(Principal Financial and Accounting Officer)

**CERTIFICATION PURSUANT TO SECTION 906 OF
THE SARBANES-OXLEY ACT OF 2002 (18 U.S.C. SECTION 1350)**

In connection with the accompanying Quarterly Report of KalVista Pharmaceuticals Inc. (the "Company") on Form 10-Q for the fiscal quarter ended January 31, 2018 (the "Report"), I, T. Andrew Crockett, as Chief Executive Officer of the Company, and Benjamin L. Palleiko, as Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 16, 2018

/s/ T. Andrew Crockett
T. Andrew Crockett
Chief Executive Officer
(Principal Executive Officer)

Dated: March 16, 2018

/s/ Benjamin L. Palleiko
Benjamin L. Palleiko
Chief Financial Officer
(Principal Financial and Accounting Officer)