

## KALYTERA THERAPEUTICS, INC.

### MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*As of August 28, 2017*

**For the three and six months ended June 30, 2017**

*This management discussion and analysis (“MD&A”) of Kalytera Therapeutics, Inc. (the “Company” or “Kalytera”) is for the three and six months ended June 30, 2017 and is performed by management using information available as of August ■, 2017. Kalytera has prepared this MD&A with reference to National Instrument 51-102 “Continuous Disclosure Obligations” of the Canadian Securities Administrators. This MD&A should be read in conjunction with the Company’s unaudited condensed consolidated interim financial statements for the three and six months ended June 30, 2017 and the related notes thereto (“Interim Financial Statements”), as well as the Company’s audited consolidated financial statements for the year ended December 31, 2016 and the related notes thereto (“Annual Financial Statements”). The Company’s Interim Financial Statements and Annual Financial Statements are prepared in accordance with International Financial Reporting Standards (“IFRS”).*

*All amounts are expressed in United States dollars unless otherwise indicated.*

*This MD&A contains certain “forward-looking statements” and certain “forward-looking information” as defined under applicable Canadian securities laws that may not be based on historical fact, including, without limitation, statements containing the words “believe”, “may”, “plan”, “will”, “estimate”, “continue”, “anticipate”, “intend”, “expect” and similar expressions. Forward-looking statements are necessarily based on estimates and assumptions made by us in light of Kalytera’s experience and perception of historical trends, current conditions and expected future developments, as well as the factors Kalytera believes are appropriate. Forward-looking statements in this MD&A include but are not limited to statements relating to:*

- *the initiation, timing, cost, progress and success of Kalytera’s research and development programs, pre-clinical studies and clinical trials;*
- *Kalytera’s ability to advance product candidates into, and successfully complete, clinical trials;*
- *Kalytera’s ability to recruit sufficient numbers of patients for Kalytera’s future clinical trials;*
- *Kalytera’s ability to achieve profitability;*
- *Kalytera’s ability to obtain funding for Kalytera’s operations, including funding for research and commercial activities;*
- *Kalytera’s ability to establish and maintain relationships with collaborators with acceptable development, regulatory and commercialization expertise and the benefits to be derived from such collaborative efforts;*
- *whether Kalytera’s third party collaborators will maintain their intellectual property rights in the technology Kalytera licenses;*
- *the implementation of Kalytera’s business model and strategic plans;*
- *Kalytera’s ability to develop and commercialize product candidates;*
- *Kalytera’s anticipated regulatory submissions and commercial activities;*
- *Kalytera’s estimates of the size and characteristics of the potential markets for its product candidates;*
- *Kalytera’s commercialization, marketing and manufacturing capabilities and strategy;*

- *Kalytera's ability to protect its intellectual property and operate its business without infringing upon the intellectual property rights of others;*
- *Kalytera's expectations regarding federal, provincial and foreign regulatory requirements;*
- *whether the Company will receive, and the timing and costs of obtaining, regulatory approvals in the U.S., Canada, the European Union and other jurisdictions;*
- *the therapeutic benefits, effectiveness and safety of Kalytera's product candidates;*
- *the rate and degree of market acceptance and clinical utility of Kalytera's future products, if any;*
- *the timing of, and Kalytera's ability and its collaborators' ability, if any, to obtain and maintain regulatory approvals for its product candidates;*
- *Kalytera's expectations regarding market risk, including interest rate changes and foreign currency fluctuations;*
- *Kalytera's ability to engage and retain the employees required to grow its business;*
- *the compensation that is expected to be paid to employees of the Company;*
- *Kalytera's future financial performance and projected expenditures;*
- *developments relating to Kalytera's competitors and its industry, including the success of competing therapies that are or may become available; and*
- *estimates of Kalytera's expenses, future revenue, capital requirements and its needs for additional financing.*

*Such statements reflect Kalytera's current views with respect to future events and are subject to risks and uncertainties and are necessarily based upon a number of estimates and assumptions that, while considered reasonable by Kalytera, are inherently subject to significant business, economic, competitive, political and social uncertainties and contingencies. Many factors could cause Kalytera's actual results, performance or achievements to be materially different from any future results, performance, or achievements that may be expressed or implied by such forward-looking statements. In making the forward looking statements included in this MD&A, the Company has made various material assumptions, including, but not limited to: (i) enrollment in, completion of and obtaining positive results from clinical trials; (ii) obtaining regulatory approvals; (iii) general business and economic conditions; (iv) the Company's ability to develop and commercialize, or otherwise monetize, its product candidates and in-license and develop new products; (v) the assumption that Kalytera's current good relationships with its collaborators, licensors and other third parties will be maintained; (vi) the availability of financing on reasonable terms; (vii) the Company's ability to attract and retain skilled staff; (viii) the products and technology offered by the Company's competitors; and (ix) the Company's ability to protect patents and proprietary rights.*

*In evaluating forward-looking statements, current and prospective shareholders should specifically consider various factors, including the risks outlined under the heading "Risk Factors" in the Company's management discussion and analysis in respect of the Annual Financial Statements that was filed on SEDAR ([www.sedar.com](http://www.sedar.com)) on May 1, 2017. Should one or more of these risks or uncertainties, or a risk that is not currently known to us materializes, or should assumptions underlying those forward-looking statements prove incorrect, actual results may vary materially from those described herein. These forward-looking statements are made as of the date of this MD&A, and Kalytera does not intend, and do not assume any obligation, to update these forward-looking statements, except as required by applicable securities laws. Investors are cautioned that forward-looking statements are not guarantees of future performance and are inherently uncertain. Accordingly, investors are cautioned not to put undue reliance on forward-looking statements.*

## OVERVIEW OF THE COMPANY

Kalytera is a clinical-stage specialty pharmaceutical company developing a portfolio of cannabinoid, cannabinoid-like, and endocannabinoid-like pharmaceutical products. Kalytera believes interest in cannabinoid therapeutics has increased significantly over the past several years as preclinical and clinical data has emerged highlighting the potential efficacy and safety benefits of cannabinoid therapeutics.

Kalytera is developing the following product candidates in the following programs: (1) cannabidiol (“**CBD**”) therapeutics; (2) proprietary CBD prodrugs; and (3) cannabinoid-like and endocannabinoid-like compounds, with an initial focus on CBD therapeutics and CBD prodrugs. Kalytera currently has no product candidate that has received regulatory approval.

Kalytera’s lead clinical-stage program is focused on developing CBD formulations for both treatment and prevention of acute graft versus host disease (“**GVHD**”). Kalytera’s lead program in GVHD has recently completed three Phase 2a clinical studies evaluating the safety and efficacy of (1) short term use of CBD in the prevention of acute GVHD, (2) prolonged use of CBD in the prevention of acute GVHD, and (3) prolonged use of CBD in the of treatment steroid-refractory grades 3-4 acute GVHD. Kalytera’s GVHD program was recently acquired pursuant to Kalytera’s acquisition of Talent Biotech Ltd. (“**Talent**”), a formerly privately held, Israeli-based developer of CBD therapeutics, as announced on February 16, 2017.

With its recent acquisition of Talent, Kalytera has transitioned from a pre-clinical stage company to a clinical-stage pharmaceutical company pioneering the development of a next generation of cannabinoid therapeutics. Through its experienced leadership, drug development expertise, and intellectual property rights, Kalytera is seeking to establish a leading position in the development of cannabinoid medicines for a range of important unmet medical needs, with an initial focus on GVHD.

Over the next 15 months, Kalytera intends to advance the development of CBD therapeutics for both treatment and prevention of acute GVHD by conducting late-stage clinical studies in these indications.

Kalytera is also developing a pre-clinical stage pipeline of CBD prodrugs for the treatment of a variety of disorders. CBD prodrugs are designed to specifically modify physiochemical properties and functionality of CBD. These modifications are intended to enhance regional therapy and enable bifunctional therapy. Over the next 15 months, through Q4 2018, Kalytera also expects to advance at least one of its CBD prodrugs into Phase 1 human clinical testing.

### **Cannabidiol (“CBD”)**

CBD is a non-psychoactive cannabinoid compound that has been shown to be an effective therapeutic against a number of pharmacological targets. However, there are limitations associated with natural CBD, including its poor oral bioavailability. Kalytera is developing CBD formulations and CBD pro-drugs in an effort to overcome these limitations, and to target delivery of CBD to specific disease sites within the body. Kalytera has filed composition of matter and method of use patents covering its inventions in the six major markets (the U.S., the United Kingdom, France, Germany, Italy and Spain, as well as several other jurisdictions, including Japan, Canada, Brazil and Australia).

Kalytera will also seek to advance a portfolio of synthetic, non-psychoactive cannabinoid-like compounds. By modifying cannabinoid molecules, and molecules which regulate the endogenous cannabinoid signaling system, Kalytera will seek to improve pharmacokinetics and increase potency, potentially allowing for the development of drug candidates with improved activity.

## **CBD – In Treatment and Prevention of Graft Versus Host Disease (“GVHD”)**

GVHD is a multisystem disorder that occurs when the transplanted cells from a donor (“the graft”) recognize the transplant recipient (“the host”) as foreign. This interaction initiates an immune reaction that causes disease in the transplant recipient. This reaction can occur within days after the transplant (acute GVHD) or months to years after the transplant (chronic GVHD).

GVHD commonly occurs following hematopoietic stem cell transplantation (“HCT”), a procedure whereby the stem cells of the bone marrow or peripheral blood of a healthy donor are transplanted into a new host after chemotherapy or radiation. This is a lifesaving procedure for many diseases of the blood and bone marrow including leukemia, Hodgkin and Non-Hodgkin lymphoma, multiple myeloma, sickle cell anemia, and thalassemia. According to a report prepared by GlobalData PharmaPoint, the *Graft-Versus-Host-Disease Opportunity Analysis and Forecasts to 2023 Update (the “GlobalData Report”)*, there were over 8,000 HCT procedures in the U.S. in 2014 and the use of HCT is expected to continue to increase at a rate of 7% per year. Whereas HCT procedures can be lifesaving, they pose many dangerous side effects, including infection and GVHD.

Acute GVHD is graded from grades 1 to 4, based on the severity of symptoms, and the degree to which various organ systems are involved. In general, grade 1 can be described as mild, grade 2 can be described as moderate, grade 3 can be described as severe, and grade 4 can be described as life threatening. Patients with acute GVHD may suffer from rashes and blistering of the skin, nausea, vomiting, abdominal cramps accompanied by diarrhea, and jaundice. Generally, acute reactions are more severe and life threatening.

Acute GVHD is a major cause of morbidity and mortality following HCT. As reported in the GlobalData Report, it is estimated that even with intensive prophylaxis with immunosuppressive treatments, 30-50% of patients transplanted from fully matched sibling donors and 50-70% of patients transplanted from unrelated donors will develop some level of acute GVHD.

The first step in prevention of GVHD is the selection of donor cells that closely match the genetics of the immune system of the transplant recipient, ideally a sibling donor. From there, the patient relies on drugs that have been developed to prevent or treat GVHD. Medicinal prevention of acute GVHD is dependent on immunosuppression of the donor cells, either pharmacologically or through T-cell depletion. Common drugs include methotrexate, cyclosporine tacrolimus, sirolimus, mycophenolate mofetil and ATG. Preventive measures and clinical practices vary by institution.

Treatment of GVHD involves pharmacologic suppression of the graft’s immune cell activation and re-establishment of donor-host immune-tolerance. Most patients are prescribed corticosteroids, which directly suppress the donor’s immune cell attack on host tissue, but also raise the risk of infection and cancer relapse. As with prevention, the optimal drug strategy for GVHD is not well defined. As stated in the GlobalData Report, only 30-50% of patients with moderate to severe GVHD respond to corticosteroids, putting many at risk for fatal outcomes. Better treatment options are needed to improve the mortality and morbidity outcomes for transplant recipients.

In 2015, Professor Moshe Yeshurun, Kalytera’s Chief Medical Officer (“CMO”), and previously the CMO of Talent and Head of the Bone Marrow Transplantation Department at the Rabin Medical Center in Israel, published the results of a Phase 2a clinical trial evaluating the safety and efficacy of CBD in the prevention of acute GVHD. These results were published in *Biology of Blood and Marrow Transplantation*, 21 (2015) 1770-1775. As reported in this peer-reviewed article, 48 patients undergoing matched unrelated donor transplantation received oral CBD a week before and 30 days after HCT. The incidence of acute grades 2-4 GVHD among these patients was 12%, compared to a rate of 48% in 102

consecutive patients evaluated previously at the same unit at Beilinson Hospital in Petach Tikvah, Israel. Based on the promising results of that study, a subsequent Phase 2a clinical study was undertaken to evaluate the efficacy of prolonged administration of CBD following HCT. In that study, which enrolled 12 patients, participants were provided daily doses of CBD seven days prior to transplantation and for 100 days following the procedure. With a median follow-up of 8.5 months following transplantation, 85% of patients in the study did not develop significant (grades 2-4) acute GVHD, despite the fact that the majority of the patients in the study (10) received stem cells from unrelated donors, including five patients who received stem cells from non-fully matched donors. Only 15% of these patients developed grades 2-4 GVHD, versus the predicted incidence of 60% in the scientific literature, potentially representing a more than four-fold reduction. In a further Phase 2a study, Professor Yeshurun established that treatment of grades 3-4 steroid-refractory acute GVHD with oral CBD resulted in a complete response in 7 of 10 patients and a very good partial response in 2 of 10 patients. These findings contrast with the historical data seen in Dr. Yeshurun's unit at Beilinson Hospital, where since 2006, among 32 consecutive patients presenting with grades 3-4 acute GVHD, those with grade 3 GVHD had a mortality rate of 33%, and those with grade 4 GVHD had a 100% mortality rate.

Kalytera intends to carry out additional studies in GVHD to advance this program towards regulatory approval and market authorization. These additional clinical studies may support U.S. Food and Drug Administration (“**FDA**”) Breakthrough Therapy and Fast Track Designations, which could accelerate the regulatory approval process.

Kalytera, through its wholly-owned subsidiary Talent, has the right to pursue the commercialization and development of CBD for the prevention and treatment of GVHD as the licensee under a world-wide exclusive license of certain technology (the “**Mor License**”) with Mor Research Applications Ltd. (“**Mor**”). Under the Mor License, Kalytera (through Talent) has been granted exclusive rights under certain applications of Mor for method of use patents for certain CBD formulations, and all documentation relating thereto or created in connection therewith, in the field of cannabidiol compositions in the prevention and treatment of the acute and chronic forms of GVHD. Under the Mor License, Mor is entitled to royalties equal to a low single-digit percentage of the Net Sales (as defined in the Mor License) of products covered by the Mor License received by or on behalf of Talent (or in the case of certain sublicenses that may be granted by Talent), a low single-digit percentage of Net Sales of products covered by the Mor License actually received by the sublicensee. Under the Mor License, Talent is required to achieve certain clinical and regulatory milestones on timelines agreed with Mor, failing which Mor will have the right to terminate the Mor License following the expiry of all applicable cure periods.

## **CBD Prodrugs**

Kalytera is also developing a pre-clinical stage pipeline of CBD prodrugs for the treatment of a variety of disorders, with an initial focus on atopic dermatitis and acne vulgaris. CBD prodrugs are designed to specifically modify physiochemical properties and functionality of CBD. These modifications are intended to enhance regional therapy and enable bifunctional therapy. Kalytera anticipates that, based on preclinical animal studies conducted by Kalytera to date, its prodrug pipeline will be well tolerated.

Prodrugs are covalently-modified derivatives of a pharmacologically active agent and must undergo transformation *in vivo* in order to release the active agent.

Kalytera's product candidate portfolio includes a number of proprietary, synthetic, non-psychoactive CBD prodrugs, all of which remain in preclinical testing. Kalytera's CBD prodrugs are designed to improve the bioavailability of CBD, as well as to permit targeted delivery of CBD to specific disease sites within the body.

Kalytera has invented and applied for composition of matter patent protection for four CBD prodrugs: K-1012, K-1022, K-1032, and K-1052.

These programs have not advanced beyond the preclinical research stage, and are currently on hold, though Kalytera may pursue further development in the future.

### ***K-1032***

K-1032 is a prodrug invented by Kalytera, intended for the treatment of chronic inflammatory skin diseases, such as Atopic Dermatitis and Acne Vulgaris. K-1032 is the L-valine-ester derivative of CBD. Acne Vulgaris is a chronic inflammatory disease of the sebaceous-pilosebaceous unit and is the most common skin disease, affecting 45 million people in the USA, according to the American Academy of Dermatology. Progressive acne is closely linked to activation of inflammation.

Despite the existence of numerous topical products and systemic drugs that have been applied to treat acne, all possess significant side effects or have limited efficacy. Therefore, Kalytera believes there remains an unmet need for an effective, safe, and well-tolerated treatment for Atopic Dermatitis and Acne Vulgaris.

### ***K-1012***

K-1012 is a patent pending prodrug invented by Kalytera, intended for the treatment of Acute Respiratory Distress Syndrome (“ARDS”). Designed as a bi-phosphate derivative of CBD, K-1012 is intended to be administered intratracheally via a formulation expected to increase the bioavailability of CBD.

Direct exposure to the lungs is a prerequisite in ARDS therapy, thus Kalytera has developed an aerosolized formulation. In contrast to CBD, K-1012 is soluble in aqueous solution, allowing the development of an isotonic solution for an aerosolized formulation. Due to the fixed negative charge of the phosphate groups at physiological pH, K-1012 is predicted to be entrapped in the lung lumen until undergoing cleavage by various intraluminal phosphatases. Given the increased levels of lung alkaline phosphatase (“ALP”) in the bronchoalveolar fluid as a result of pulmonary damage, Kalytera predicts ALP will liberate bioactive CBD in ARDS disease models. Progressive ARDS is closely linked to activation of inflammation. The benefits of CBD are expected to be augmented via regional targeting of K-1012 to the lung by means of the phosphate additions.

*In vivo* efficacy studies conducted by Kalytera in rodent models of *E. coli* LPS induced ARDS have been utilized to determine appropriate dosing and exposure time. Kalytera expects to carry out detailed ADME/PK analysis in rats as well as a non-clinical safety assessment of K-1012 in rats and dogs that are expected to include safety pharmacology and toxicologic IND-enabling studies.

Kalytera believes that no effective therapy currently exists for ARDS, thus there remains an urgent need for a new first-line therapeutic to improve the survival of patients suffering from ARDS. If successful, the development of K-1012 would provide the first pharmacological treatment for patients with ARDS.

### ***K-1022***

K-1022 is a patent pending prodrug invented by Kalytera, intended for the treatment of Ulcerative Colitis or Crohn’s Disease, chronic conditions characterized by inflammation of the colonic mucosa extending from the rectum proximally to varying portions of the large intestine. The increase in pro-inflammatory factors promotes inflammation and facilitates damage to intestinal tissues. Understanding the pathophysiology of colitis has provided us an opportunity to identify potential new targets for this disease.

Designed as a bi-sulfate derivative of CBD with a formulation that Kalytera designed, K-1022 is intended to be administered orally to maximize the anti-inflammatory effect of CBD. The rationale for constructing a sulfate-derivatized prodrug of CBD (K-1022) lies in expected augmented delivery to the colon, where K-1022 is expected to be converted to the active compound via the activity of colon-specific microbial sulfatases. In contrast to CBD, the disulfated derivative is water soluble, enhancing the probability of developing a successful oral formulation of K-1022. Given the safety profile and anti-inflammatory properties of CBD, it is expected that K-1022 could potentially serve as a potent and tolerated treatment for UC.

*In vivo* efficacy studies conducted by Kalytera have been used to determine suitable dosing and exposure time. Kalytera is currently performing detailed ADME/PK analysis in rats, as well as non-clinical safety assessment of K-1022 in rats and dogs that are expected to include safety pharmacology and toxicology studies, to complete IND-enabling studies.

K-1022, by virtue of the favorable safety profile of CBD, is intended to occupy a position as a first-line therapeutic for UC, if development is completed successfully.

### **K-1052**

K-1052 is a patent pending prodrug invented by Kalytera, intended for the treatment of sepsis-induced Acute Renal Failure (“**ARF**”) and Traumatic Brain Injury (“**TBI**”). Designed as an inducible Nitric Oxide Synthase (“**iNOS**”) inhibitor derivative of CBD, Kalytera is developing K-1052 to improve the long-term outcome of ARF and TBI patients.

As defined by the National Institute of Diabetes and Digestive and Kidney Diseases (the “**NIDDKD**”), ARF is a syndrome characterized by rapid loss of kidney function, specifically the glomerular filtration rate, measured by increases in serum creatinine and limited or lack of urine output. ARF is a common complication of acute illness. Despite advances in treatment and prevention, ARF continues to be associated with high rates of mortality and morbidity, particularly for patients admitted to the intensive care unit. Various types of injury lead to ARF. Common to all these injuries is an inflammatory response due to the kidney insult.

According to data and statistics compiled by the National Center for Health Statistics of the U.S. Center for Disease Control, TBI is a highly complex multi-factorial disorder, which involves primary and secondary injury cascades that underlie delayed neuronal dysfunction and death. Following head injury, TBI is a consequence of neuroinflammation caused by an increase in reactive oxygen species production and a concomitant increase in levels of inflammatory cytokines.

Kalytera anticipates that a combination of CBD and a potent iNOS inhibitor, joined together in a single prodrug form, will yield an effective therapy for diseases where inflammation and iNOS-derived nitric oxide play prominent roles. Kalytera’s formulation would be administered intravenously to hospitalized patients, in order to avoid first-pass metabolism of CBD and to improve the pharmacokinetic (“**PK**”) profile.

### **Cannabinoid-Like and Endocannabinoid-Like Compounds**

Kalytera has also investigated endocannabinoid-like compounds, KAL671 and KAL 436/439, to assess their potential in treatment of bone disease and disorders. These programs have not advanced beyond the preclinical research stage, and are currently on hold, though Kalytera may pursue further development in the future.

### **Clinical Development Timeline**

In order to obtain regulatory approval in treatment of acute grades 3 and grade 4 GVHD, and prophylaxis of GVHD, the Company will be required to carry out at least one Phase 2 pharmacodynamics (“PK”) and safety/dosing study, to be followed by a Phase 3 pivotal registration study in each of these indications. These studies are expected to take approximately 18 months to complete.

### **Corporate Developments During the Three Months Ended June 30, 2017**

On April 17, 2017, the Company announced that it had applied for a \$5 million grant from the Israel Innovation Authority (“IIA”) to fund development of its portfolio of CBD prodrugs. This grant application was subsequently denied by the IIA due to the Company’s lack of a plan to hire Israeli employees in connection with the research and development work that the Company conducts in Israel. The Company intends to amend its application to include a plan to hire 3-5 employees in Israel. The amended plan will then be resubmitted to the IIA by January 2018.

On April 25, 2017, the Company announced that it has developed the multi-center location component of the plan for the proposed clinical trials to evaluate cannabidiol (“CBD”) for the prevention and treatment of GvHD. Kalytera is developing this clinical trial plan with the intent of obtaining FDA and EMEA approval for commercialization. Kalytera expects to finalize and publish the details of its clinical trial plan in 2017. The plan will include the clinical trial designs, the anticipated timelines for initiation and completion, as well as the principal endpoints. The trials are intended to build on the encouraging data seen in the recently completed Phase 2a Clinical Trial.

On May 26, 2017, David Stefansky and Jerome Zeldis resigned as members of the Company’s board of directors. Ron Erickson was appointed the interim Chairman.

On June 21, 2017, Andrew L. Salzman, M.D. resigned as CEO and CMO and as a member of the Company’s Board of Directors. Robert Farrell, J.D., President and CFO of Kalytera assumed the role of CEO. Concurrently, the Company expanded its management team with three appointments, David Bassa, who joined the Company as COO; Dr. Moshe Yeshurun, who joined the Company as CMO; and Dr. Sari Prutchi-Sagiv, who joined the Company as Chief Scientific Officer. Each of Mr. Bassa, Dr. Prutchi-Sagiv and Dr. Yeshurun each previously held senior management positions at Talent. As part of the Talent team, they were instrumental in the development and advancement of the GvHD program, helping to conduct clinical studies in Israel that demonstrated promising results in the prevention and treatment of GvHD.

### **OVERALL PERFORMANCE**

Since its inception in July 2014, Kalytera has accumulated a deficit of \$16,602 as at June 30, 2017. The Company did not generate any revenue from product sales during the six months ended June 30, 2017. Kalytera expects its operating losses to continue in the next fiscal year as it invests in its product development programs, with primary focus for the next two years on development of Kalytera’s lead product development program in the treatment and prophylaxis of GVHD. This product development program was initiated by Talent, a privately held, Israeli-based developer of CBD therapeutics that was acquired by Kalytera in February 2017.

The Company has funded its operations with proceeds from equity financings, and expects to seek additional funding through debt and equity financings, as well as partnership collaborations to finance its product development, and corporate growth. However, if Kalytera’s product development activities do not show positive progress, or if capital market conditions in general or with respect to the life sciences



sector or development stage companies such as Kalytera are unfavorable, its ability to obtain additional funding will be adversely affected.

## Q2 Discussion

The following table summarizes selected unaudited consolidated financial data for the quarters ended June 30, 2017 and 2016, prepared in accordance with IFRS:

	<b><u>Quarter Ended</u></b>
	<b><u>30-June-17</u></b>
	<b>Unaudited</b>
	<b>("Q2 2017")</b>
Research and development expenses	1,024
General and administrative expenses	890
Finance income, net	10
Net loss for the period	1,904
Basic and diluted loss per common share	(0.01)
	<b><u>30-June-16</u></b>
	<b>Unaudited</b>
	<b>("Q2 2016")</b>
Research and development expenses	715
General and administrative expenses	415
Net loss for the period	1,130
Basic and diluted loss per common share	(0.04)

Variations in the Company's net losses and expenses for the periods above resulted primarily from the following factors:

- In general, research and development ("R&D") expenditures trended upwards during Q2 2017 as Kalytera advanced its lead product development program in prevention and treatment of GvHD. This increase in R&D spending was partially offset by a reduction in R&D work related to the Company's product development programs with KAL671 and KAL436/439, as well as the Company's CBD prodrugs.
- In general, general and administration expenses also trended upwards as the Company built its corporate infrastructure to support its expanded operations relating to the Company's lead product development program in prevention and treatment of GvHD.

Kalytera recorded a net loss of \$(1,904 (\$0.01 per Common Share)) in Q2 2017 as compared to \$(1,130 (\$0.04 per Common Share)) in Q2 2016. The increase of \$774 in net loss was attributable mainly to increase in research and development expenditures of \$309, increase in general and administrative expenses of \$475 and an increase of \$10 in financial income, net.

Research and development expenditures increased to \$1,024 in Q2 2017 from \$715 in Q2 2016 due primarily to an increase in subcontract research and development costs, and an addition of research employees in Q2 2017.

The following table provides a detailed breakdown of Kalytera's research and development expenditures in Q2 2017, as compared to those in Q2 2016:

	<u>Q2 2017</u>	<u>Q2 2016</u>
Salaries and benefits	\$ 371	\$ -
Share-based payments	(11)	14
Subcontract research costs	17	701
Subcontract development costs	478	-
Laboratory supplies	162	-
Travel	7	-
<b>Total</b>	<b>\$1,024</b>	<b>\$715</b>

General administration expenditures increased in Q2 2017 to \$890 from \$415 in Q2 2016 due primarily to higher legal and professional expenses.

The following table provides a detailed breakdown of Kalytera's general administration expenditures in Q2 2017, as compared to those in Q2 2016:

	<u>Q2 2017</u>	<u>Q2 2016</u>
Consulting and management fees	\$ 121	\$65
Audit fees	61	5
Insurance	73	8
Legal and professional fees	75	155
Investor relations	149	12
Office and other expenses	182	37
Board member fees	64	45
Salaries and benefits	118	-
Share-based payments	22	63
Travel and accommodation	25	25
<b>Total</b>	<b>\$890</b>	<b>\$415</b>

### Year to Date Discussion

The following table summarizes selected unaudited consolidated financial data for the six months ended June 30, 2017 and 2016, prepared in accordance with IFRS:

	<u>Year-to-Date</u>
	<u>30-June-17</u>
	<u>Unaudited</u>
	<u>Year-to-Date</u>
Research and development expenses	1,428
General and administrative expenses	2,099
Finance income, net	2
Net loss for the period	3,525
Basic and diluted loss per common share	(0.03)
	<u>30-June-16</u>

	<b>Unaudited Year-to-Date</b>
Research and development expenses	871
General and administrative expenses	779
Net loss for the period	1,650
Basic and diluted loss per common share	(0.06)

Variations in the Company's net losses and expenses for the periods above resulted primarily from the following factors:

- In general, research and development ("R&D") expenditures trended upwards during the six months ended June 30, 2017, as Kalytera advanced its lead product development program in prevention and treatment of GvHD. This increase in R&D spending was partially offset by a reduction in R&D work related to the Company's product development programs with KAL671 and KAL436/439, as well as the Company's CBD prodrugs.
- In general, general and administration expenses also trended upwards as the Company built its corporate infrastructure to support its expanded operations relating to the Company's lead product development program in prevention and treatment of GvHD.

Kalytera recorded a net loss of \$(3,525) (\$0.03 per Common Share) in the six months ended June 30, 2017, as compared to \$(1,650) (\$0.06 per Common Share) in the six months ended June 30, 2016. The increase of \$1,875 in net loss was attributable mainly to increase in research and development expenditures of \$557, increase in general and administrative expenses of \$1,320 and an increase of \$8 in financial income, net.

Research and development expenditures increased to \$1,428 in the six months ended June 30, 2017 from \$871 in the six months ended June 30, 2016 due primarily to an increase in subcontract research and development costs, and an addition of research employees in the six months ended June 30, 2017.

The following table provides a detailed breakdown of Kalytera's research and development expenditures in the six months ended June 30, 2017, as compared to those in the six months ended June 30, 2016:

	<b>Six Months Ended June 30</b>	
	<b>2017</b>	<b>2016</b>
Salaries and benefits	\$ 469	\$ -
Share-based payments	1	33
Subcontract research costs	85	251
Subcontract development costs	645	587
Laboratory supplies	221	-
Travel	7	-
<b>Total</b>	<b>\$1,428</b>	<b>\$871</b>

General administration expenditures increased in the six months ended June 30, 2017, to \$2,099 from \$779 in the six months ended June 30, 2016 due primarily to higher legal and professional expenses.

The following table provides a detailed breakdown of Kalytera's general administration expenditures in the six months ended June 30, 2017, as compared to those in the six months ended June 30, 2016:

	<b>Six Months Ended June 30</b>	
	<b>2017</b>	<b>2016</b>
Consulting and management fees	\$ 389	\$111
Audit fees	78	-
Insurance	102	12
Legal and professional fees	604	285
Investor relations	213	-
Office and other expenses	253	59
Board member fees	125	90
Salaries and benefits	211	-
Share-based payments	49	166
Travel and accommodation	75	56
<b>Total</b>	<b>\$2,099</b>	<b>\$779</b>

### QUARTERLY FINANCIAL INFORMATION

The following table summarizes selected unaudited consolidated financial data for each of the last eight fiscal quarters, prepared in accordance with IFRS:

	<b>Quarter Ended</b>			
	<b>30-Jun-17</b>	<b>31-Mar-17</b>	<b>31-Dec-16</b>	<b>30-Sep-16</b>
	<b>Unaudited</b>	<b>Unaudited</b>		<b>Unaudited</b>
	<b>("Q2 2017")</b>	<b>("Q1 2017")</b>	<b>("Q4 2016")</b>	<b>("Q3 2016")</b>
Research and development expenses	1,024	404	717	327
General and administrative expenses	890	1,209	2,081	686
Expenses in connection with reverse merger	-	-	6,923	-
Finance expense (income), net	(10)	8	(442)	-
Net loss for the period	(1,904)	(1,621)	(9,280)	(1,013)
Basic and diluted loss per common share	(0.01)	(0.02)	(0.26)	(0.10)

	<b>30-Jun-16</b>	<b>31-Mar-16</b>	<b>31-Dec-15</b>	<b>30-Sep-15</b>
	<b>Unaudited</b>	<b>Unaudited</b>		<b>Unaudited</b>
	<b>("Q2 2016")</b>	<b>("Q1 2016")</b>	<b>("Q4 2015")<sup>3</sup></b>	<b>("Q3 2015")</b>
			.	
			.	
Research and development expenditures	715	157	109	370
General administration expenditures	415	392	421	139
Net loss for the period	(1,130)	(549)	(531)	(509)
Basic and diluted loss per common	(0.04)	(0.02)	(0.01)	(0.02)

share

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Variations in the Company's net losses and expenses for the periods above resulted primarily from the following factors:

- In general, research and development ("R&D") expenditures trended upwards during Q2 2017 as Kalytera advanced its lead product development program in prevention and treatment of GvHD. This increase in R&D spending was partially offset by a reduction in R&D work related to the Company's product development programs with KAL671 and KAL436/439, as well as the Company's CBD prodrugs.
- In general, general and administration expenses also trended upwards as the Company built its corporate infrastructure to support its expanded operations relating to the Company's lead product development program in prevention and treatment of GvHD.

### **LIQUIDITY AND CAPITAL RESOURCES**

The Company's operational activities during the second quarter of 2017 were financed mainly from the proceeds of a brokered private placement financing in Canada in February 2017 of 33,333,333 Common Shares at a price of C\$0.45 per Common Share for aggregate gross proceeds of C\$15 million. At June 30, 2017, the Company's cash and cash equivalents increased to \$1,466 from \$673 at December 31, 2016. Working capital at June 30, 2017 decreased to (\$83) as compared to \$2,917 at December 31, 2016. The decrease in the Company's working capital was due to the acquisition of Talent Biotechs Ltd. during the first quarter of 2017, offset by an inflow of funds from financing rounds in December 2016 and in February 2017, as well as research and development expenditures as the Company advanced its lead product development program in prevention and treatment of GvHD.

The Company completed the acquisition of Talent in February 2017. The consideration for the acquisition of Talent included a combination of cash, securities, and future contingent payments to Talent shareholders. To date, Kalytera has made cash payments to Talent former shareholders totaling US\$10,000,000, and in addition, the Company has issued 17,301,208 Common Shares to former Talent shareholders, which securities are subject to a contractual hold period expiring December 30, 2017. Subject to the completion of certain milestones in relation to the development and commercialization of the GVHD program, the Company will pay up to US\$20,000,000 in aggregate future contingent payments. The Company will also issue to former Talent shareholders an additional 2,883,535 Common Shares upon the completion of the first Phase 2b clinical study, and a further additional 2,883,535 Common Shares upon the issuance of the first patent by the USPTO or EU with respect to certain assets of Talent acquired in connection with the acquisition. The former shareholders of Talent will also receive additional earn-out payments equal to 5% of the aggregate annual net sales of all products covered by patent rights included in the business of Talent.

Kalytera, through its acquisition of Talent, has the right to pursue the commercialization and development of CBD for the prevention and treatment of GVHD as exclusive licensee under the Mor License. Under the Mor License, Mor is entitled to royalties equal to a low single-digit percentage of the Net Sales (as defined in the Mor License) of products covered by the Mor License received by or on behalf of Talent (or in the case of certain sublicenses that may be granted by Talent), a low single-digit percentage of Net Sales of products covered by the Mor License actually received by the sublicensee.

Although it is difficult to predict future liquidity requirements, management believes that the current working capital will fund the Company's operations until the fourth quarter of 2017. Management plans

to raise additional capital through debt or equity financing in the near term to finance its working capital requirements and clinical development of its lead product program in the prevention and treatment of GvHD. The Company's future cash requirements may vary materially from those expected now due to a number of factors, including costs associated with product development and strategic opportunities. As a result, it may be necessary to raise additional funds sooner than currently expected. These funds may come from sources such as entering into strategic collaboration arrangements, the issuance of shares from treasury, or alternative sources of financing. However, there can be no assurance that the Company will successfully raise funds to continue the development of its lead product program, CBD in the treatment and prophylaxis of GVHD.

## Sources and Uses of Cash – Q2

<b>Sources and Uses of Cash</b>	<b>Quarter Ended</b>	
	<b>June 30, 2017</b>	<b>June 30, 2016</b>
Cash used in operating activities	(\$1,670)	(\$557)
Cash used in investing activities	-	-
Cash provided by financing activities	-	-
Net decrease in cash and cash equivalents	(\$1,670)	(\$557)

Cash used in operating activities was comprised of net loss, add-back of non-cash expenses, and net change in non-cash working capital items. Cash used in operating activities increased to \$1,670 in the quarter ended June 30, 2017 from \$557 in the quarter ended June 30, 2016. This increase was due to increase in the volume of operations.

No cash was used in investing activities in the quarters ended June 30, 2017 and 2016.

No cash was provided by financing activities in the quarters ended June 30, 2017 and 2016.

## Sources and Uses of Cash – Year to Date

<b>Sources and Uses of Cash</b>	<b>Six Months Ended June 30</b>	
	<b>2017</b>	<b>2016</b>
Cash used in operating activities	(\$3,800)	(\$894)
Cash used in investing activities	(\$10,000)	-
Cash provided by financing activities	\$14,593	-
Net decrease in cash and cash equivalents	(\$793)	(\$894)

Cash used in operating activities was comprised of net loss, add-back of non-cash expenses, and net change in non-cash working capital items. Cash used in operating activities increased to \$3,800 in the six months ended June 30, 2017 from \$894 in the six months ended June 30, 2016. This increase was due to increase in the volume of operations.

Cash used in investing activities increased to \$10,000 in the six months ended June 30, 2017, as compared to nil in the six months ended June 30, 2016. This was due to the completion of the acquisition of Talent Biotech Ltd. in February 2017.

Cash provided by financing activities increased to \$14,593 in the six months ended June 30, 2017, as compared to \$230 in the six months ended June 30, 2016. This was due to the completion of financing

round in the first quarter of 2017 and the receipt of funds from a financing round in December 2016, in the first quarter of 2017.

### OUTSTANDING SHARE CAPITAL

As of August 28, 2017, there were 129,235,053 Common Shares issued and outstanding, and other securities convertible into Common Shares as summarized in the following table:

	<b>Number Outstanding as of August 28, 2017</b>
Common Shares issued and outstanding	129,235,053
Options <sup>(1)</sup>	6,481,033
2016 Broker Warrants <sup>(2)</sup>	1,318,334
2017 Broker Warrants <sup>(3)</sup>	2,333,333

Notes:

(1) Of the 6,481,033 options outstanding, 3,101,484 are vested and exercisable at a weighted average price of C\$0.79 per Common Share. The remaining 3,379,549 options are not vested and have a weighted average price of C\$0.72 per Common Share.

(2) Each 2016 Broker Warrant entitles the holder to acquire one Common Share at a price of C\$0.40 per Common Share.

(3) Each 2017 Broker Warrant entitles the holder to acquire one Common Share at a price of C\$0.45 per Common Share.

### OFF-BALANCE SHEET ARRANGEMENTS

The Company has no undisclosed off-balance sheet arrangements that have or are reasonably likely to have, a current or future effect on its results of operations, financial condition, revenues or expenses, liquidity, capital expenditures or capital resources that is material to investors.

### RELATED PARTY TRANSACTIONS

Related parties include members of the Board and officers of the Company, and enterprises controlled by these individuals. The following fees and expenses were incurred in the normal course of business:

	<b>Q2 2017</b>	<b>Q2 2016</b>	<b>Six Months Ended June 30, 2017</b>	<b>2016</b>
Board Member Fees	50	10	110	10
Officer Salaries & Benefits	81	-	163	-
Share based payments	21	34	45	96
Research and development	238	137	306	838
Administrative services	49	25	218	40
<b>TOTAL</b>	<b>439</b>	<b>206</b>	<b>842</b>	<b>984</b>

In October, 2016, the Company entered into a Master Service Agreement with Luria Scientific Industries (“**Luria**”). Luria is a division of Salzman Capital Ventures, Ltd., an Israeli corporation that is wholly-

owned by Dr. Andrew Salzman and certain of his family members, related primarily to its CBD therapeutic and CBD prodrug programs.

From October 2016, until June 21, 2017, the date on which Dr. Andrew Salzman resigned his positions as an officer and director of the Company, the transactions between the Company and Luria were characterized as related party transactions. After Dr. Salzman's resignation on June 21, 2017, this was no longer the case.

Pursuant to the Master Service Agreement, Luria provides certain research and development ("R&D") services, and general and administrative ("G&A") services to the Company. For each task to be performed by Luria, the Company and Luria sign an applicable statement of work (each a "**SOW**"). Each SOW includes, among other things, a description of the tasks to be performed, the deliverables and documentation, if any, to be produced by Luria (collectively "**Deliverables**"), acceptance criteria for each Deliverable, a schedule of performance, a schedule of payments, as well as other terms and conditions pertaining to the specific project. Each SOW is deemed to incorporate all of the terms and conditions of the Master Service Agreement. Each SOW becomes effective once it has been signed and dated by the appropriate authorized signatories on behalf of both Luria and the Company, provided, however, that the Governance Committee has implemented a policy that for any SOW requiring payment by the Company to Luria of an amount or amounts in excess of \$10,000, the prior written approval of the Company's Governance Committee must first be obtained before any such SOW may be signed by the Company.

In order for any such SOW requiring payment by the Company to Luria of an amount or amounts in excess of USD \$10,000 to be approved by the Governance Committee, the following standard procedure must be followed:

- All goods and services that are expected to cost more than \$10,000 must be pre-approved by all members of the Governance Committee by a Statement of Work ("**SOW**").
- The SOW must be presented to the Governance Committee, and shall include comparable market cost information for similar a type of work.
- The Company's CFO will review the SOW prior to its submission to the Governance Committee.
- The Governance Committee will provide a written approval, rejection or make modifications.

As at June 30, 2017, the Company and Luria had two SOWs that were in effect, under which Luria agreed to provide both R&D and G&A services to the Company. The Company's Governance Committee has approved these two SOWs. These two SOWs specify the hourly rates that will be charged by Luria to the Company for each of certain Luria personnel that will be engaged in providing such R&D and G&A services.

The Company's future financial obligations under these two SOWs is expected to be approximately \$150 per month, with approximately \$105 being charged for R&D services, and approximately \$45 being charged for G&A services.

The Company is in the process of hiring personnel not affiliated with Luria to provide G&A services to the Company. The Company expects to hire these personnel during Q3 2017, and, as a result, Luria is not expected to provide G&A services to the Company by the end of Q3 2017.



The Company is also in the process of hiring personnel not affiliated with Luria to provide R&D services to the Company. The Company expects to hire these personnel during Q3 and Q4 2017, and, as a result, there is expected to be a reduction in R&D services provided by Luria to the Company by year-end 2017.

As of June 30, 2017, the Company included in its accounts payable and accrued liabilities \$162 payable to Luria.

## **[b] Key management compensation**

Key management includes members of the Board and executive officers of the Company.

On May 18, 2015, Kalytera entered into a Consulting Agreement with Sutherland Paige & Associates, Inc., a company owned by Seth Yakatan, a director of the Company, providing for Seth Yakatan to serve as the interim-CEO and a member of Kalytera's board of directors (the "**Yakatan Consulting Agreement**"). Pursuant to the Yakatan Consulting Agreement, Seth Yakatan received US\$20,000 upon signing, an additional US\$20,000 within sixty (60) days of signing and was paid US\$5,000 per month. On June 1, 2016, the Yakatan Consulting Agreement was amended. Following the amendment, Seth Yakatan received US\$7,500 per month for his services, and US\$500 per month for use of office space and for furnishing the Company with a corporate address and certain corporate services.

On December 14, 2016, Seth Yakatan resigned as interim-CEO, however he has continued to receive US\$7,500 per month for his services as a member of the Company's board of directors, and US\$500 per month for use of office space.

On May 26, 2017, David Stefansky and Jerome Zeldis resigned as members of the Company's board of directors. Ron Erickson was appointed the interim Chairman.

On June 21, 2017, Dr. Andrew Salzman resigned his management positions of CEO and CMO, and also resigned as a member of the Company's board of directors. Robert Farrell, J.D. was appointed as interim CEO, and Dr. Moshe Yeshurun was appointed CMO.

**Compensation awarded to key management is listed below:**

	<b>Q2 2017</b>	<b>Q2 2016</b>	<b>Six Months Ended June 30,</b>	
			<b>2017</b>	<b>2016</b>
Base Salaries	129	-	285	-
Consulting fees	-	-	-	-
Share-based payments	8	34	19	96

## **PROPOSED TRANSACTIONS**

There are at present no transactions outstanding that have been proposed but not approved by either the Company or regulatory authorities.

## **CHANGES IN OR ADOPTION OF ACCOUNTING POLICIES**

### **New Standards Recently Adopted**

The IASB has issued the following major standards that are not yet effective: IFRS 9, "Financial Instruments", IFRS 15, "Revenue from Contracts with Customers", and IFRS 16, "Leases". IFRS 9 and

IFRS 15 are effective for periods commencing from January 1, 2018, and IFRS 16 is effective for periods commencing from January 1, 2019. At this stage, these standards are not expected to have a significant impact on the Company.

## FINANCIAL INSTRUMENTS AND RISKS

The Company's financial instruments at June 30, 2017 and December 31, 2016 consist of the following:

	June 30, 2017	December 31, 2016
<b><i>Financial assets</i></b>		
Cash and cash equivalents	1,466	673
Amounts receivable	92	4,141
<b><i>Financial Liabilities</i></b>		
Accounts payable and accrued liabilities	1,641	1,897

The Company has designated its cash and cash equivalents as fair value through profit or loss, which is measured at fair value. Amounts receivable are classified as loans and receivables, which are measured at amortized cost. Accounts payable and accrued liabilities are classified as other financial liabilities, which are measured at amortized cost.

### Fair value

The fair value of the Company's financial instruments is approximated by their carrying value due to their short-term nature.

IFRS 13 establishes a fair value hierarchy for financial instruments measured at fair value that reflects the significance of inputs used in making fair value measurements as follows:

Level 1 – quoted prices in active markets for identical assets or liabilities;

Level 2 – inputs other than quoted prices included in Level 1 that are observable for the asset or liabilities, either directly (i.e. as prices) or indirectly (i.e. from derived prices); and

Level 3 – inputs for the asset or liability that are not based upon observable market data. The fair value of cash and cash equivalents is based on Level 1 inputs.

### [a] Credit risk

Credit risk is the risk of a financial loss to the Company if a counterparty to a financial instrument fails to meet its contractual obligations. Credit risk arises for the Company from its cash on deposits and amounts receivable. The Company has adopted practices to mitigate against the deterioration of principal, to enhance the Company's ability to meet its liquidity needs, and to optimize yields within those parameters.

### [b] Liquidity risk

Liquidity risk is the risk that the Company will not be able to meet its obligations as they come due. The Company's exposure to liquidity risk is dependent on its purchasing commitments and obligations and its ability to raise funds to meet commitments and sustain operations. The Company manages liquidity risk

by continuously monitoring its actual and forecasted working capital requirements, and actively managing its financing activities. As of June 30, 2017, the Company had working capital of (\$83) (December 31, 2016 – \$2,917).

[i] Interest rate risk

Interest rate risk is the risk that the future cash flows of a financial instrument will fluctuate because of changes in the market interest rates. During the three and six month periods ended June 30, 2017 and 2016, fluctuations in the market interest rates had no significant impact on its interest income.

[ii] Currency risk

The Company is exposed to the financial risk related to the fluctuation of foreign exchanges rates. The Company has a portion of its operating expenses in Canadian dollars and in Israeli new shekels (NIS). The Company has not entered into foreign exchange derivative contracts. A significant change in the currency exchange rate between the Canadian dollar or the NIS relative to the U.S. dollar could have an effect on the Company's results of operations, financial position or cash flows.

The Company did not record material balances in Canadian dollars as of June 30, 2017 and December 31, 2016.

As at June 30, 2017 and December 31, 2016, the Company had the following assets and liabilities denominated in NIS:

	<b>June 30, 2017</b>	<b>December 31, 2016</b>
	<b>NIS</b>	<b>NIS</b>
Cash	1,748	-
Other receivables and prepaid expenses	321	82
Other payable and accrued expenses	(1,243)	-
<b>Total</b>	<b>826</b>	<b>82</b>

Based on the above net exposure as at June 30, 2017, assuming that all other variables remain constant, a 5% appreciation or deterioration of the NIS against the US dollar would result in a decrease of \$41 or an increase of \$41, respectively, in the Company's net loss and comprehensive loss in US dollars.

### **ADDITIONAL INFORMATION**

Additional information about the Company, including the Interim Financial Statements and the Annual Financial Statements, is available on SEDAR at [www.sedar.com](http://www.sedar.com).