

KALYTERA THERAPEUTICS, INC.

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

As of May 1, 2017

For the year ended December 31, 2016

This management discussion and analysis (“MD&A”) of Kalytera Therapeutics, Inc. (the “Company” or “Kalytera”) is for the year ended December 31, 2016 and is performed by management using information available as of May 1, 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 audited financial statements for the year ended December 31, 2016 and the related notes thereto (“Annual Financial Statements”). The Company’s 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 this MD&A. 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 18 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, 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. Over the next 18 months, through Q4 2018, Kalytera also expects to advance at least one of its CBD prodrugs into Phase 1 human clinical testing for atopic dermatitis and acne vulgaris.

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, previously the Chief Medical Officer of Talent and Head of the Bone Marrow Transplantation Department at the Rabin Medical Center in Israel who is now Kalytera’s Senior Clinical Scientist, 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.

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.

Kalytera is planning to complete preclinical IND-enabling work for K-1032 by Q3 2017, and expects to initiate Phase 1 clinical testing of K-1032 in Atopic Dermatitis and/or Acne Vulgaris by Q4 2017.

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 pivotal registration study in each of these indications. These studies are expected to take approximately 18 months to complete.

Kalytera plans to advance the development of at least one of its patent pending CBD prodrugs for the treatment of Atopic Dermatitis and Acne Vulgaris through completion of a Phase 1 study in the next 18 months.

Corporate Developments During the Fiscal Year Ended December 31, 2016

On June 23, 2016, the Company announced the appointment of Dr. Robert S. Langer to Kalytera's Scientific Advisory Board. Dr. Langer is a David H. Koch Institute Professor at the Massachusetts Institute of Technology ("MIT"). He is a prolific biotechnologist, engineer, and inventor who is widely recognized for his contributions to the drug delivery and tissue engineering fields. His research laboratory at MIT is the largest biomedical engineering lab in the world, employing over 100 persons.

On June 29, 2016, the Company announced that it had appointed Robert Farrell, J.D. as President, Chief Operating Officer and Chief Financial Officer. Mr. Farrell has over 25 years of experience in the pharmaceutical, biotechnology, and medical device sectors. Mr. Farrell has had primary or significant responsibility for the completion of mergers & acquisitions, corporate partnerships, licensing transactions, and divestitures in both the U.S. and Europe. In addition, Mr. Farrell has many years of operational experience, including executive responsibility and responsibility for all financial operations.

On August 23, 2016, the Company announced the appointment of Andrew L. Salzman, M.D. as Kalytera's Chief Medical Officer. Dr. Salzman is a renowned physician, inventor, and biomedical entrepreneur who has brought numerous medicines from conception to clinical trials. As the founder of Inotek Pharmaceuticals (Nasdaq: ITEK), a clinical-stage developer of therapies for glaucoma and other serious eye diseases, Dr. Salzman helped raise \$92M in venture capital and concluded a \$600M licensing transaction with Genentech. Dr. Salzman is also the founder of Orphan Technologies, where he participated in the development of three novel enzyme replacement therapies for rare metabolic diseases.

On September 22, 2016, the Company completed a private placement offering of 4,666,465 units (pre-Merger: 3,022,680), each unit consisting of (i) one common share of Kalytera Therapeutics, Inc., the Delaware corporation that was previously the parent company of Kalytera's business prior to the Merger described below ("**Kalytera Delaware**") and (ii) one five year warrant to purchase a common share of Kalytera Delaware at a price of 0.65 per Common Share. As described below, in the Merger, each common share of Kalytera Delaware and each such warrant to purchase a common share of Kalytera Delaware was exchanged for current common shares of Kalytera at an exchange ratio of approximately 1.54 current common shares of the Company for each common share or warrant of Kalytera Delaware.

On October 6, 2016, the Company announced a reverse takeover transaction involving Santa Maria Petroleum Inc., a corporation with no material remaining assets or operations listed on the NEX board of the TSX Venture Exchange ("**TSX-V**") ("**Santa Maria**") and Kalytera Delaware (the "**Merger**"). In connection with the Merger, Santa Maria incorporated a subsidiary in Delaware, which then merged with Kalytera Delaware. Kalytera Delaware survived the merger, and continued its existence as a wholly-owned subsidiary of Santa Maria. The common shares held by the shareholders of Kalytera Delaware were converted and exchanged into common shares of Santa Maria based on an exchange ratio of approximately 1.54 common shares of Santa Maria for each common share of Kalytera Delaware. Further, each warrant held by warrant holders of Kalytera Delaware (except for certain broker warrants described below) were exchanged for common shares of Santa Maria based on an exchange ratio of approximately 1.54 common shares of Santa Maria for each common share of Kalytera Delaware for which such warrant was exercisable. With respect to stock options to purchase common shares of Kalytera Delaware, each option to purchase one common share of Kalytera Delaware (under Kalytera Delaware's 2015 Long-Term Incentive Plan), whether vested or unvested, was exchanged for a substantially identical option to purchase a number of common shares of Santa Maria based on the exchange ratio of approximately 1.54 common shares of Santa Maria for each common share of Kalytera Delaware.

Immediately prior to and in connection with the completion of the Merger, Santa Maria consolidated its share capital on the basis of approximately 2.3 (old) common shares for one (new) common share, and

changed its jurisdiction of organization from Ontario to British Columbia and also changed its name to Kalytera Therapeutics, Inc. (the Company). The Company is thus the same legal entity as the re-named Santa Maria, and following the Merger the Company holds all of the shares of Kalytera Delaware, which owns Kalytera's business (directly and indirectly through subsidiaries).

Also in connection with the Merger, Kalytera completed a private placement financing pursuant to which it issued subscription receipts ("**Subscription Receipts**") at a price of C\$0.40 per Subscription Receipt for gross proceeds of approximately C\$7,000,000. The Subscription Receipts were converted, for no additional consideration, into common shares of Kalytera upon completion of the Merger ("**Common Shares**") pursuant to the terms thereof. In connection with such private placement financing, certain parties including Clarus Securities Inc. and Haywood Securities were paid a commission and issued broker warrants.

Other than C\$1,000,000 which was released pursuant to an amending agreement to the subscription receipt agreement between Kalytera Delaware, Santa Maria, TSX Trust Company and Clarus Securities Inc., dated November 1, 2016 on November 4, 2016, the proceeds of the private placement financing were released immediately following the Merger upon satisfaction of the escrow release conditions as set forth in the subscription receipt agreement relating thereto, which conditions included the satisfaction of all conditions precedent to the Merger.

Also, in connection with the Merger, Kalytera completed a subsequent financing on December 12, 2016, pursuant to which 3,333,333 Subscription Receipts were issued at a price of C\$0.40 per Subscription Receipt for gross proceeds of approximately C\$1,333,333. The Subscription Receipts were converted for no additional consideration into Common Shares on a one-for-one basis upon completion of the Merger pursuant to the terms thereof, and proceeds were released to the Company upon closing of the Merger, in same manner as described above in connection with the previous financing.

On December 14, 2016, the Company announced the appointment of Andrew L. Salzman, M.D. as Kalytera's Chief Executive Officer. Dr. Salzman also serves as Chief Medical Officer and as a member of Kalytera's Board of Directors.

On December 30, 2016, the Merger was completed. In connection with the completion of the Merger, the Company (i.e. the Santa Maria entity) was up-listed from the NEX board of the TSX-V to become a Tier 1 issuer on the TSX-V. Immediately following the Merger, former Santa Maria Shareholders held approximately 23% of the outstanding Common Shares of the Company, former holders of common shares and warrants of Kalytera Delaware held just over approximately 50% of the outstanding Common Shares of the Company, and the remaining outstanding Common Shares were held by subscribers in the Subscription Receipts financings described above.

Corporate Developments Subsequent to December 31, 2016

On January 13, 2017, the Company announced that it had entered into a binding letter of intent to acquire all of the issued and outstanding securities of Talent, a privately held, Israeli-based developer of CBD therapeutics. Under the terms of the letter of intent, Kalytera made a non-refundable payment of US\$1,000,000 to Talent shareholders. Talent was advancing a Phase 2 clinical program investigating the use of CBD to prevent and treat GVHD.

On January 18, 2017, the Company announced preliminary results of a 12 patient Phase 2a study evaluating the safety and efficacy of prolonged use of CBD in the prevention of graft versus host disease GVHD. Preliminary results of the study demonstrate that only 15% of patients in the CBD treatment group

developed grades 2-4 GVHD, as compared to a 60-70% incidence predicted by historical data used as a control. The study was conducted by Talent.

On February 7, 2017, the Company closed the first tranche of a private placement offering of Common Shares. The first tranche closing consisted of the issuance of 29,833,300 Common Shares at a price of C\$0.45 per Common Share, for gross proceeds of C\$13,424,985.

On February 16, 2017, the Company announced the closing of the acquisition of Talent. The consideration for the acquisition included a combination of cash, securities, and future contingent payments to Talent shareholders. To date, Kalytera has made cash payments to Talent shareholders totaling US\$10,000,000, and in addition, the Company has issued 17,301,208 Common Shares to Talent's former shareholders, which securities will be 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.

On February 17, 2017, the Company closed the second tranche of a private placement offering of common shares. The second tranche closing consisted of the issuance of 3,500,033 Common Shares at a price of C\$0.45 per Common Share, for gross proceeds of C\$1,575,015. Together with the closing of the first tranche, an aggregate of 33,333,333 Common Shares were issued for aggregate gross proceeds of C\$15,000,000. Clarus Securities Inc., as lead agent, together with Haywood Securities Inc. and Canaccord Genuity Corp., acted as agents for the Company in connection with the first tranche and the second tranche of the offering. A portion of the proceeds of the private placement offering were used to fund the acquisition of Talent.

On February 22, 2017, the Company announced results from a Phase 2a study evaluating the safety and efficacy of CBD for the treatment of acute (grades 3-4) GVHD. In this study, ten patients with acute (grades 3-4) GVHD that was refractory to standard treatment with high-dose steroids, were administered daily doses of CBD for up to three months. Nine of the ten patients enrolled in the study responded to treatment; seven achieved complete remission, and two achieved a near-complete response.

On March 17, 2017, the Company announced the appointment of Pini Ben-Elazar to the Company's board of directors. Mr. Ben-Elazar was nominated by the selling shareholders of Talent in accordance with the terms of the Company's acquisition of Talent. Mr. Ben-Elazar is the Chief Executive Officer of Mor.

On April 17, 2017, the Company announced that it had applied for a \$5 million grant from the Israel Innovation Authority to fund development of its portfolio of CBD prodrugs. These grants are bearing royalties from sales of the sponsored products, up to 100% of the grants received, linked to the U.S. dollar and interest at the rate of LIBOR. The obligation to pay these royalties is contingent upon actual sales of products and in the absence of such sales no payment is required.

OVERALL PERFORMANCE

Since its inception in July 2014, Kalytera has accumulated a deficit of \$13,076,844 as at December 31, 2016. The Company did not generate any revenue from product sales during 2016. 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 which 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 equity financings and 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.

SELECTED ANNUAL FINANCIAL INFORMATION

The following table sets forth selected financial information for the fiscal year ended December 31, 2016 ("**Fiscal 2016**"), comparable fiscal year ended December 31, 2015 ("**Fiscal 2015**"), and the fiscal period from July 18, 2014 (date of inception) to December 31, 2014 ("**Fiscal 2014**"). The selected financial information set out below has been derived from the Annual Financial Statements and accompanying notes, in each case prepared in accordance with IFRS. The Fiscal 2014 Annual Financial Statements have been audited by Kalytera's former auditors, Turner, Stone & Company LLP and the Fiscal 2015 and Fiscal 2016 Annual Financial Statements have been audited by Kalytera's auditors, Kost Forer Gabbay & Kasierer, a member of Ernst & Young Global. The selected financial information set out below may not be indicative of the Company's future performance. The following discussion should be read in conjunction with the Annual Financial Statements.

	Fiscal 2016	Fiscal 2015	Fiscal 2014
Net loss for the fiscal period	\$11,554,265	\$1,403,927	\$118,652
Basic and diluted loss per share	\$0.39	\$0.07	\$0.01
Total assets	\$4,813,831	\$641,353	\$127,270
Total non-current financial liabilities	-	-	-
Cash dividends declared per Common Share	-	-	-

Revenues

Kalytera did not generate any revenue from product sales in Fiscal 2016. The time in which Kalytera will become profitable depends on a variety of factors as set out in "Risk Factors - Kalytera has not generated any revenue to date and may never be profitable".

Grant Revenue

Kalytera Therapeutics Israel, Ltd. ("**Kalytera Israel**") is a wholly-owned subsidiary of Kalytera Delaware which was incorporated on September 4, 2016 and is situated in Israel. Kalytera Israel was incorporated to oversee the administration of research and development activities of Kalytera to be conducted in Israel. A variety of ongoing grant and support programs offered by the Israeli Innovation Authority (the "**IIA**") provide financial and developmental resources to companies providing industrial research and development within Israel. The goal of the IIA is to assist in the development of technology in Israel as a means of fostering economic growth, encouraging technological innovation and entrepreneurship, leveraging Israel's scientific potential, enhancing the knowledge base of industry in Israel, stimulating

high value-added R&D and encouraging R&D collaboration both nationally and internationally. Grants are available in amounts ranging from 20% to 50% of the approved budget. Kalytera expects to generate cash inflows in the form of grant awards.

In particular, on April 17, 2017, Kalytera announced that it had applied for a \$5 million grant from the IIA to fund development of its portfolio of CBD prodrugs. Kalytera expects to receive a decision on the grant application in the third quarter of 2017. If approved, the grant is expected to be in the form of a conditional, non-recourse loan to be paid back from future royalties.

The amounts actually spent for any specific purpose may vary significantly, and will depend on a number of factors including, but not limited to, the pace of progress of Kalytera's commercialization and development efforts, actual needs with respect to product testing, research and development, market conditions, and change in or revisions to marketing strategies, as well as any legal or regulatory changes which may ensue.

Discussion of Operations

Kalytera recorded a net loss of \$11,554,265 (\$0.39 per Common Share) in Fiscal 2016 and \$1,403,927 (\$0.07 per Common Share) in Fiscal 2015. The increase in net loss was primarily due to higher operating expenditures as the Company built its corporate infrastructure, completed the Merger and expanded its operations necessary to invent and patent the Company's CBD prodrugs. The Company achieved a number of corporate milestones in Fiscal 2016 as detailed earlier in this MD&A (see "*Corporate Developments During the Fiscal Year Ended December 31, 2016*"). These milestones include completing the private placement offering of units of Kalytera Delaware in September 2016, the listing of the Company's Common Shares on the TSX-V pursuant to the Merger, and closing the private offerings of Subscription Receipts.

Specifically, the increased loss of \$10,150,338 between the two fiscal periods was due to an increase of \$6,923,036 in expenses recorded in connection with the reverse merger, an increase of \$2,675,658 in general and administrative expenses and an increase of \$993,564 in research and development expenses.

In addition, the Company recorded financial income, net of \$441,920, of which \$628,765 was in respect of revaluation of warrants. The following table provides an overview of the financial results in Fiscal 2016 as compared to those in Fiscal 2015:

	Fiscal 2016	Fiscal 2015
Research and development expenses	\$1,622,322	\$628,758
General and administrative expenses	3,450,827	775,169
Expenses in connection with reverse merger	6,923,036	-
Total operating expenses and loss before other income	11,996,185	1,403,927
Other expense	186,845	-
Revaluation of warrants (income)	(628,765)	-
Net loss	\$11,554,265	\$1,403,927

Research and Development Expenses

Kalytera incurred total research and development expenses of \$1,622,322 in Fiscal 2016 as compared to \$628,758 in Fiscal 2015. The increase in research and development expenses by \$993,564 was primarily due to an increase in sponsored research costs as well as costs incurred relating to the invention of the Company's patent pending CBD prodrugs. The CBD prodrug formulation optimization and prototype

development, contributed to the increased research and development costs. These compared to pre-clinical development work conducted in the preceding year.

The increase in patent costs for the year was related to the invention and development of the Company's CBD prodrugs. The following table summarizes the Company's research and development expenditures in Fiscal 2016 and Fiscal 2015:

	Fiscal 2016	Fiscal 2015
Professional and consulting fees	\$ 128,785	\$ 49,667
Share-based payments	56,748	-
Subcontract research costs	1,031,083	421,402
Subcontract development costs	404,294	157,689
Travel and accommodation	1,412	-
Total	\$1,622,322	\$628,758

General Administration Expenses

General administration expenses were \$3,450,827 in Fiscal 2016 as compared to \$775,169 in Fiscal 2015. The increase of \$2,675,658 in general administration expenses was primarily due to the Company's expanded business operations and the completion of the Merger. Specifically, the variance of \$1,138,809 was attributable to legal expenses relating to financing rounds during the fiscal year, the merger and business development activities, \$1,093,444 was attributed to increase in business development related costs, \$197,906 was attributed to increase in personnel related expenses, and other administration overhead also rose by \$245,500.

Personnel related expenses included consulting and management fees, salaries and benefits, and share-based payments increased by \$683,932, \$162,657 and \$223,438 in Fiscal 2016, respectively, as compared to those in Fiscal 2015. Kalytera added new personnel to support its expanded operations resulting in higher personnel costs.

Business development related costs included travel expenses, which were higher by \$70,115 and \$122,175 in Fiscal 2016, respectively, as compared to those in Fiscal 2015. These expenses were primarily related to the attendance at medical and financial conferences, corporate communication, business development and investor relations.

Other administration overhead comprised office related expenses, public listing related expenditures, as well as legal and professional fees. These expenses increased by \$1,248,972 in Fiscal 2016, as compared to those in Fiscal 2015. Specifically, office related expenses increased by \$77,610, public listing related costs rose by \$69,000, and legal and professional fees increased by \$1,248,972. Legal and professional fees vary depending on the timing of business transactions and corporate development activities and increased in Fiscal 2016 as compared to those in 2015 mainly because of merger and business development activities.

The Company secured its TSX-V listing in December 2016 pursuant to the Merger. Public listing related costs were comprised of initial listing expenses, and regulatory and transfer agent fees. None of these costs were incurred in Fiscal 2015 given that the Company did not start its TSX-V listing process until Fiscal 2016.

The following table summarizes the Company's general administration expenditures in Fiscal 2016 and Fiscal 2015:

	Fiscal 2016	Fiscal 2015
Advertising and promotion	\$ 122,175	\$ -
Consulting and management fees	876,030	192,098
Depreciation and amortization	19,123	877
Legal and professional fees	1,558,339	309,367
Listing expenses	69,000	-
Office and other expenses	115,807	38,197
Regulatory and transfer agent fees	4,511	5,000
Salaries and benefits	162,657	-
Share-based payments	389,271	165,833
Travel and accommodation	133,914	63,797
Total	\$ 3,450,827	\$ 775,169

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:

	Quarter Ended			
	Quarter Ended			
	31-Dec-16	30-Sep-16	30-Jun-16	31-Mar-16
	Unaudited	Unaudited	Unaudited	Unaudited
	("Q4 2016")	("Q3 2016")	("Q2 2016")	("Q1 2016")
Research and development expenses	717,184	326,846	453,034	125,259
General and administrative expenses	2,081,344	807,840	317,255	244,388
Expenses in connection with reverse merger	6,923,036	-	-	-
Finance income, net	(441,919)	-	-	-
Net loss for the period	(9,279,645)	(1,134,686)	(770,289)	(369,647)
Basic and diluted loss per common share	(0.26)	(0.10)	(0.02)	(0.01)

	Quarter Ended			
	Quarter Ended			
	31-Dec-15	30-Sep-15	30-Jun-15	31-Mar-15
	Unaudited	Unaudited	Unaudited	Unaudited
	("Q4 2015")	("Q3 2015")	("Q2 2015")	("Q1 2015")
Research and development expenditures	109,356	370,314	7,540	141,548
General administration expenditures	421,260	138,562	127,382	87,965
Net loss for the period	(530,616)	(508,876)	(134,922)	(229,513)
Basic and diluted loss per common share	(0.01)	(0.02)	(0.02)	(0.02)

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

- In general, research and development expenditures trended upwards as Kalytera advanced its product development of KAL671 and KAL436/439, as well as the invention of the Company's patent pending CBD prodrug.. These expenditures fluctuated more significantly in certain quarters due to the costs associated with the invention of the CBD prodrugs.
- In general, general administration expenses also trended upwards as the Company added personnel and built its corporate infrastructure to support its expanded operations. These expenditures fluctuated more significantly in certain quarters due to the costs associated with the TSX-V listing in Q4 2016 pursuant to the Merger.

Fourth Quarter

Kalytera recorded a net loss of \$(9,279,644) (\$0.26 per Common Share) in Q4 2016 as compared to \$(530,616) (\$0.01 per Common Share) in Q4 2015. The increase of \$8,749,028 in net loss was attributable mainly to expenses recorded in connection with the merger as discussed under the general administration expenses section above, increase in research and development expenditures of \$607,828 and increase in general and administrative expenses of \$1,660,228, offset by \$441,919 financial income, net of which \$628,765 was in respect of revaluation of warrants

Research and development expenditures increased to \$607,828 in Q4 2016 from \$109,356 in Q4 2015 due primarily to an increase in sponsored research costs as well as costs incurred relating to the invention of the Company's CBD prodrugs.

The following table provides a detailed breakdown of Kalytera's research and development expenditures in Q4 2016, as compared to those in Q4 2015:

	<u>Q4 2016</u>	<u>Q4 2015</u>
Professional and consulting fees	39,849	23,098
Share-based payments	31,972	-
Subcontract research costs	469,242	56,534
Subcontract development costs	174,709	29,724
Travel and accommodation	1,412	-
Total	\$717,184	\$109,356

General administration expenditures increased in Q4 2016 to \$2,081,344 from \$421,260 in Q4 2015 due primarily to legal and professional expenses. Kalytera was in the midst of its application for a new TSX-V listing in Q4 2016. These activities resulted in higher listing expenses and legal and professional fees in Q4 2016. The Company also recruited new directors and officers in Q4 2016 as part of its going public preparation; this resulted in higher share-based payments in Q4 2016.

The following table provides a detailed breakdown of Kalytera's general administration expenditures in Q4 2016, as compared to those in Q4 2015:

	Q4 2016	Q4 2015
Advertising and promotion	\$67,750	\$-
Consulting and management fees	556,169	45,750
Depreciation and amortization	18,373	877
Legal and professional fees	864,218	222,611
Listing expenses	21,255	-
Office and other expenses	74,190	15,242
Regulatory and transfer agent fees	1,087	5,000
Salaries and benefits	87,483	-
Share-based payments	364,495	124,135
Travel and accommodation	26,324	7,645
Total	\$2,081,344	\$421,260

LIQUIDITY AND CAPITAL RESOURCES

The Company's operational activities during Fiscal 2016 were financed mainly by capital resources carried forward from the preceding year, and through a private placement financing that closed in September 2016. At December 31, 2016, the Company's cash and cash equivalents increased to \$673,208 from \$622,229 at December 31, 2015. Working capital at December 31, 2016 increased to \$2,922,957 as compared to \$422,390 at December 31, 2015. The increase in the Company's working capital was due to the completion of the Merger and the financing activities.

Subsequent to December 31, 2016, the Company completed 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 and completed closing of the acquisition of Talent. 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 will be 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, in addition to the private placement financing completed in February 2017, will fund the Company's operations until the fourth quarter of 2017. Management plans to raise additional capital through equity financing in the near term to finance its working capital requirements and clinical development of its lead product programs, CBD in the treatment and prophylaxis 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 programs, CBD in the treatment and prophylaxis of GVHD.

Sources and Uses of Cash	Fiscal 2016	Fiscal 2015
Cash used in operating activities	(\$1,635,964)	(\$1,131,658)
Cash used in investing activities	-	(20,000)
Cash provided by financing activities	1,686,943	1,646,617
Net (decrease) increase in cash and cash equivalents	\$50,979	\$494,959

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 \$1,635,964 in Fiscal 2016 from \$1,131,658 in Fiscal 2015. This increase was primarily due to increase in other payables and accrued expenses.

Cash provided by financing activities increased by \$40,326 in Fiscal 2016 as compared to Fiscal 2015. This was due to the completion of financing rounds in the first and third quarters of 2016 and the completion of the financing round in December 2016, in conjunction with the merger.

OUTSTANDING SHARE CAPITAL

As of April 28, 2017, there were 129,235,073 Common Shares issued and outstanding, and other securities convertible into Common Shares as summarized in the following table:

	Number Outstanding as of April 28, 2017
Common Shares issued and outstanding	129,235,073
Options ⁽¹⁾	10,408,434
2016 Broker Warrants ⁽²⁾	1,318,334
2017 Broker Warrants ⁽³⁾	2,333,333

Notes:

(1) Of the 10,408,434 options outstanding, 2,129,530 are vested and exercisable at a weighted average price of C\$0.79 per Common Share. The remaining 5,536,608 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

[a] Transactions with related parties

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:

	Fiscal 2016	Fiscal 2015
Board Member Fees	172,000	20,000
Officer Salaries & Benefits	155,067	-
Officer Consulting Fees	423,409	140,140
Share based payments	19,940	20,871
TOTAL	770,416	181,011

On October 21, 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, (the Company’s CEO and CMO), and certain of his family members, related primarily to its CBD therapeutic and CBD prodrug programs. Pursuant to the Master Service Agreement, Luria is providing certain research and development services related to the Company and/or products and/or related technology. 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.

During 2016, the Company and Luria entered into a total of 10 SOWs under which Luria agreed to provide services to the Company. The Company's Governance Committee has finally approved two of these SOWs and is currently reviewing the remainder in connection with the Governance Committee's implementation of the procedure described above. These SOWs require that Luria provide services to the Company to for various projects, including:

- A review of medical literature to identify opportunities for development of CBD pharmaceuticals
- Invention of a novel CBD formulations and pro-drugs
- Preparation and submission of grant applications and patent applications
- Animal model studies in specific disease settings

The Company's total future financial obligations under these SOWs is approximately \$1,079,425, for future services.

As of December 31, 2016, the Company included in its accounts payable and accrued liabilities \$540,256.

[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.

Compensation awarded to key management is listed below:

	Fiscal 2016	Fiscal 2015
Base Salaries	300,000	-
Consulting fees	876,030	192,098
Share-based payments	132,110	129,605

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 December 31, 2016 and 2015 consist of the following:

	December 31, 2016	December 31, 2015
<i>Financial assets</i>		
Cash and cash equivalents	673,208	622,229
Amounts receivable	4,140,623	-
<i>Financial Liabilities</i>		
Accounts payable and accrued liabilities	1,897,875	35,052

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 December 31, 2016, the Company had working capital of \$2,922,957 (December 31, 2015 – \$422,390).

[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 period ended December 31, 2016 and 2015, 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 December 31, 2016 and 2015.

=As at December 31, 2016 and 2015, the Company had the following assets and liabilities denominated in NIS:

	December 31, 2016 NIS	December 31, 2015 NIS
Cash	-	-
Other receivables and prepaid expenses	82,296	-
Total	82,296	-

Based on the above net exposure as at December 31, 2016, assuming that all other variables remain constant, a 5% appreciation or deterioration of the NIS against the US dollar would result in a change of \$1,078 in the Company's net loss and comprehensive loss in US dollars.

RISK FACTORS

An investment in the Common Shares involves a high degree of risk. Kalytera operates in a dynamic and rapidly changing industry that involves numerous risks and uncertainties. The risks described below are not the only risks facing the company. Additional risks and uncertainties not currently known or that are currently deemed to be immaterial may also materially and adversely affect Kalytera's business operations. If any of these risks actually occur, Kalytera's business, financial condition, operating results or cash flows could be materially adversely affected. This could cause the trading price of the Common Shares to decline.

Risks Related to Kalytera's Financial Condition and Capital Requirements

Kalytera is an early clinical stage pharmaceutical company and has a limited operating history on which to assess the prospects for its business, has incurred significant losses since the date of its inception, and anticipates that it will continue to incur significant losses until it is able to successfully commercialize its product candidates.

Kalytera is subject to all of the business risks and uncertainties associated with any early-stage enterprise, including under-capitalization, cash shortages, limitations with respect to personnel, financial and other resources, and lack of revenues.

Kalytera has incurred significant operating losses since inception and substantially all losses have resulted from expenses incurred in connection with research and development and general and administrative costs associated with operations. Kalytera may not be able to achieve or maintain profitability and may continue to incur significant losses in the future. In addition, Kalytera expects to continue to increase operating expenses as Kalytera implements initiatives to continue to grow its business. If Kalytera cannot produce revenue to offset these expected increases in costs and operating expenses, Kalytera will not be profitable. There is no assurance that Kalytera will generate revenue and be successful in achieving a return on shareholders' investments and the likelihood of success must be considered in light of the early stage of operations.

Kalytera expects that it will need to raise substantial additional funding before it expects to become profitable. This additional financing may not be available on acceptable terms, or at all. Failure to raise such capital could result in the delay or indefinite postponement of current business objectives or Kalytera going out of business.

Kalytera is in the development and early operations stage. Kalytera will likely operate at a loss until its business becomes established and therefore may require additional financing in order to fund its ongoing and future operations and its intended development plans. The failure to raise such capital could result in the delay or indefinite postponement of current business objectives or the Company going out of business. Kalytera's ability to secure any required financing to sustain its operations will depend in part upon prevailing capital market conditions, as well as its business success. There can be no assurance that Kalytera will be successful in its efforts to secure any additional financing or additional financing on terms satisfactory to the management. If additional funds are raised through issuances of equity or convertible debt securities, existing shareholders could suffer significant dilution, and any new equity securities issued could have rights, preferences and privileges superior to those of holders of common shares. In addition, from time to time, Kalytera may enter into transactions to acquire assets or the shares of other corporations. These transactions may be financed wholly or partially with debt, which may temporarily increase Kalytera's debt levels above industry standards. Kalytera's articles do not limit the amount of indebtedness that Kalytera may incur. The level of Kalytera's indebtedness from time to time could impair its ability to obtain additional financing in the future on a timely basis to take advantage of business opportunities that may arise.

Kalytera has not generated any revenue to date and may never be profitable.

The ability to generate revenue depends upon the ability to obtain regulatory approval for, and successfully commercialize, product candidates that Kalytera develops or acquires in the future. As of the date of this MD&A, there is no expectation to generate revenue in the foreseeable future.

There is no assurance that Kalytera can generate revenues even if regulatory approvals are achieved for its product candidates. The ability to generate revenue depends on a number of factors, including:

- successful completion of development activities, including the additional preclinical studies and planned clinical trials for the product candidates;
- completion and submission of New Drug Applications to the FDA and Marketing Authorization Applications to the European Medicines Agency;
- obtaining regulatory approval from the FDA and European Medicines Agency for indications for which there is a commercial market;
- obtaining regulatory approval from Health Canada;
- completion and submission of applications to, and obtaining regulatory approval from, other foreign regulatory authorities;
- raising substantial additional capital to fund operations;
- manufacturing or acquiring CBD and approved products and in commercial quantities and on commercially reasonable terms;
- developing a commercial organization, or finding suitable partners, to market, sell and distribute approved products in the markets in which Kalytera have obtained commercialization rights;
- achieving acceptance among patients, clinicians and advocacy groups for any developed products;
- obtaining coverage and adequate reimbursement from third parties, including government payors; and
- setting a commercially viable price for any approved products.

Kalytera may not receive the government grants Kalytera applied for and even if it does, its government grants could subject the Company to audits and could require the Company to repay substantial amounts of funds awarded.

Kalytera Israel has submitted to the Israeli Innovation Authority an application for a \$5 million grant to fund development of its portfolio of CBD prodrugs on which Kalytera expects to receive a decision in the third quarter of 2017. As of the date hereof, Kalytera has not received any research grants and there can be no assurance that Kalytera will receive any grant funds, including those that have been applied for. If grant funds are received, Kalytera may be subject to routine audits by government agencies. As part of an audit, these agencies may review Kalytera's performance, cost structures and compliance with applicable laws, regulations, policies and standards and the terms and conditions of the grant. If any of Kalytera's expenditures are found to be unallowable or allocated improperly or if Kalytera has otherwise violated terms of the grant, the expenditures may not be reimbursed and/or Kalytera may be required to repay funds already disbursed. Accordingly, if grants funds are received and there is an audit, such an audit could result in a material adjustment to Kalytera's results of operations and financial condition.

Kalytera may be exposed to the financial risk related to the fluctuation of foreign exchange rates.

Kalytera may maintain cash and other financial instruments, or may incur revenues and expenditures in currencies other than the United States dollar. Significant changes in the currency exchange rates between

the United States dollar relative to these foreign currencies, which may include but are not limited to Canadian dollars, Israeli new shekel (NIS), Euros, and British pounds, could have an effect on Kalytera's results of operations, financial position or cash flows. Kalytera has not hedged its exposure to currency fluctuations.

Risks Related to Kalytera's Regulatory Requirements

Kalytera's activities are subject to regulation by governmental authorities, particularly in the United States, Israel and other jurisdictions where Kalytera intends to test and, if approved, market its product candidates.

Achievement of Kalytera's business objectives is contingent, in part, upon compliance with regulatory requirements enacted by governmental authorities and obtaining all regulatory approvals, where necessary, for the testing, manufacture, management, packaging/labelling, advertising, transportation, storage, possession, disposal, production, distribution, sale, import and export of its products. Kalytera cannot predict the outcome of the FDA, European Medicines Agency or Health Canada's regulatory approval process. Similarly, Kalytera cannot predict the time required to secure all appropriate regulatory approvals for its products, or the extent of testing and documentation that may be required by governmental authorities. Any delays in obtaining, or failure to obtain regulatory approvals, or revocation or suspension of approvals, may significantly delay or impact the development of markets, products and sales initiatives and could have a material adverse effect on Kalytera's business, results of operations and financial condition.

There is the possibility that the product candidates may contain controlled substances as defined in the *U.S. Controlled Substances Act* of 1970 or the Canadian *Controlled Drugs and Substances Act*. Containing a controlled substance would subject the product candidates to a high degree of regulation, in respect of obtaining approval to sell the product candidates and in respect of ongoing compliance if a product candidate is approved for sale.

Kalytera will incur ongoing costs and obligations related to regulatory compliance. Failure to comply with regulations may result in additional costs for corrective measures, penalties or restrictions of its operations. Canadian legislation imposes criminal penalties for non-compliance with drug regulatory requirements. In addition, changes in regulations, more vigorous enforcement thereof or other unanticipated events could require extensive changes to the Company's operations, increased compliance costs or give rise to material liabilities, which could have a material adverse effect on its business, results of operations and financial condition.

Kalytera's ability to successfully produce the product candidates is dependent on extensive ongoing regulatory compliance and reporting requirements by the Drug Enforcement Agency, FDA, European Medicines Agency, Health Canada, other foreign regulatory authorities and provincial, state and local regulatory authorities ("**Reporting Requirements**").

Failure to comply with the requirements and terms of the Reporting Requirements could have a material adverse impact on Kalytera's business, financial condition and operating results. There is no assurance that continuous regulatory approval will be given for the testing, manufacture, management, packaging/labelling, advertising, transportation, storage, possession, disposal, production, distribution, sale, import and export of the product candidates. Should regulatory approval not be continued, Kalytera's business, financial condition and operating results would be materially adversely affected.

The commercial medical marijuana industry is a new industry and Kalytera anticipates that such regulations will be subject to change as the U.S. federal government monitors licensed producers in action.

Kalytera's operations are subject to a variety of laws, regulations, guidelines and policies relating to the testing, manufacture, import, export, management, distribution, packaging/labelling, advertising, sale, transportation, storage and disposal of the product candidates but also including laws and regulations relating to drugs, controlled substances, health and safety, the conduct of operations and the protection of the environment. While to the knowledge of management, Kalytera is currently in compliance with all such laws, any changes to such laws, regulations, guidelines and policies due to matters beyond its control may cause adverse effects to its operations.

On October 19, 2015, the Liberal Party of Canada (the "**Liberal Party**") was elected and obtained a majority government in Canada. The Liberal Party have made electoral commitments to legalize, regulate and tax recreational cannabis use in Canada. On April 20, 2016, the Liberal Party made a commitment to introduce legislation to meet their electoral commitments by the spring of 2017. On June 30, 2016, the Government of Canada issued a news release indicating that it had launched the Task Force on Marijuana Legalization and Regulation and a public consultation for the creation of a new legislative system with respect to the legalization of marijuana. The new release included a discussion paper entitled "Toward the Legalization, Regulation and Restriction of Access to Marijuana" (the "**Discussion Paper**"), which sets out the objectives of the new system and identified specific issues and options for which the Government of Canada was seeking comment. The public consultation remained open until August 29, 2016. The task force provided a report to the Government of Canada regarding the design of a new legislative system on November 30, 2016 entitled "A Framework for the Legalization and Regulation of Cannabis in Canada". On April 13, 2017, proposed legislation referred to as the "Cannabis Act" providing for the legalization and regulation of cannabis in Canada was introduced in the Canadian House of Commons by the federal government. The federal government has indicated that it intends to bring the proposed Cannabis Act into force by July 1, 2018. The current version of the proposed Cannabis Act may change during consultation and the legislative process. Draft regulations under the Cannabis Act have not yet been published and, when they are, are subject to consultation and change. Laws of the provincial and territorial governments relating to the sale and distribution of cannabis products may be enacted but are not yet published. The impact of this potential development at this time is unknown and a regulatory change for cannabis may not be implemented at all, but if implemented may impact the medical marijuana market. Further, it is unclear whether the product candidates would be regulated under this new legislative system, or whether they would be subject to other drug legislation in Canada such as the Canadian *Controlled Drugs and Substances Act*.

Kalytera's product candidates may contain controlled substances, the use of which may generate public controversy.

Since Kalytera's product candidates may contain controlled substances, their regulatory approval may generate public controversy. Political and social pressures and adverse publicity could lead to delays in approval of, and increased expenses for, Kalytera's product candidates. These pressures could also limit or restrict the introduction and marketing of its product candidates. Adverse publicity from cannabis misuse or adverse side effects from cannabis or other cannabinoid products may adversely affect the commercial success or market penetration achievable by Kalytera's product candidates. The nature of Kalytera's business attracts a high level of public and media interest, and in the event of any resultant adverse publicity, its reputation may be harmed.

Risks Related to the Development of Kalytera's Product Candidates

The results of the preclinical testing and clinical trials are uncertain and a product candidate can fail at any stage of clinical development.

Prior to obtaining regulatory approval for sale of the product candidates, Kalytera must conduct preclinical testing and clinical trials. The historic failure rate for product candidates is high due to scientific feasibility, safety, efficacy, changing standards of medical care and other variables.

The testing process can take many years and may include post-marketing studies and surveillance, which would require the expenditure of substantial resources. As a result, Kalytera cannot assure that clinical trials will begin or be completed on schedule, as the commencement and completion of clinical trials can be delayed for various reasons. A clinical trial may be suspended or terminated by Kalytera, the FDA, Institutional Review Board, ethics committees, data safety monitoring boards or other foreign or U.S. regulatory authorities overseeing the clinical trial at issue due to a number of factors, including, among others: failure to conduct the clinical trial in accordance with regulatory requirements; inspection of clinical trial sites by regulatory authorities which requires corrective action by Kalytera, including the imposition of a clinical hold; unforeseen safety issues; adverse side effects or lack of effectiveness of the product candidates; and changes in government regulations or administrative actions.

Conducting clinical trials outside the United States could negatively impact Kalytera. Risks inherent in conducting international clinical trials include: foreign regulatory requirements that could burden or limit the ability to conduct clinical trials; administrative burdens of conducting clinical trials under multiple foreign regulatory schema; foreign currency fluctuations which could negatively impact Kalytera's financial condition; manufacturing, customs, shipment and storage requirements; cultural differences in medical practice and clinical research; and diminished protection of intellectual property. There is no assurance that the FDA will accept data from clinical trials conducted in other jurisdictions. If the FDA does not accept the data, the result would be an increase in clinical trials which would be costly, time-consuming and delay Kalytera's development plan.

Kalytera relies on contract research organizations, clinical data management organizations and consultants to design, conduct, supervise and monitor preclinical studies due to a lack of internal resources to perform these functions.

Outsourcing these functions involves risk that third party providers may not perform to the Company's standards, may not produce results in a timely manner or may fail to perform at all. If any contract research organization fails to comply with applicable regulatory requirements, the clinical data generated in the clinical trial may be deemed unreliable to regulatory authorities. Additional clinical trials may be required before approval of marketing applications will be given. Kalytera cannot provide assurance that all third party providers will meet the regulatory requirements for clinical trials. Failure of third party providers to meet regulatory requirements could result in repeat preclinical and clinical trials, which would delay the regulatory approval process or termination of preclinical and clinical trials. Reliance on third party providers could result in a material adverse effect on Kalytera's costs and results of operations.

Kalytera may encounter significant setbacks in in clinical trials after achieving positive results in preclinical and early clinical development.

The results of Kalytera's preclinical testing may not necessarily be predictive of the results from the planned additional clinical trials in humans. Significant setbacks can be caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in clinical trials, including adverse events. Preclinical and clinical data is susceptible to varying interpretations and analyses,

and there is the potential that product candidates that performed satisfactorily in preclinical studies and clinical trials fail to obtain U.S. Food and Drug Administration and European Medicines Agency approval. Failure to produce positive results in clinical trials of the product candidates could result in a material adverse effect to Kalytera's development timeline, regulatory approval, commercialization prospects and business and financial prospects.

There is a risk of product failure if Kalytera's product candidates prove to be unsafe, ineffective or inadequate for clinical development or commercialization.

Kalytera will focus its financial and managerial resources on research programs relating to its product candidates. Kalytera may forego or delay pursuit of opportunities with other product candidates that could potentially prove to have commercial potential. Kalytera's resource allocation decisions could result in failure to capitalize on viable commercial products or profitable market opportunities.

If product development is successful and regulatory approval is obtained, Kalytera's ability to generate revenue depends on the acceptance of the product candidates by physicians and patients. Factors which affect market acceptance include the indication statement and warnings approved by regulatory authorities on the product label, continued demonstration of efficacy and safety in commercial use, physicians' willingness to prescribe the product candidates, reimbursement from third-party payors such as government healthcare systems and insurance companies, the price of the product, the nature of any post-approval risk management plans mandated by regulatory authorities, competition, and marketing and distribution support. Factors preventing market acceptance of the product candidates could have a material adverse effect on Kalytera's business, results of operations and financial condition.

Kalytera's ability to generate revenue is based on its ability to market the product candidates in multiple jurisdictions where Kalytera has limited experience. This risk could have a material adverse effect on Kalytera's business, results of operations and financial condition.

Kalytera may not be successful in its efforts to identify, license or discover additional product candidates.

Although a substantial amount of Kalytera's effort will focus on the continued clinical testing, potential approval and commercialization of its existing product candidates, the success of its business also depends in part upon its ability to identify, license or discover additional product candidates. Kalytera's research programs or licensing efforts may fail to yield additional product candidates for clinical development for a number of reasons, including but not limited to the following:

- Kalytera's research or business development methodology or search criteria and process may be unsuccessful in identifying potential product candidates;
- Kalytera may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates;
- Kalytera's product candidates may not succeed in preclinical or clinical testing;
- Kalytera's potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval;
- competitors may develop alternatives that render Kalytera's product candidates obsolete or less attractive;

- product candidates Kalytera develops may be covered by third parties' patents or other exclusive rights;
- the market for a product candidate may change during Kalytera's program so that such a product may become unreasonable to continue to develop;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

If any of these events occur, Kalytera may be forced to abandon its development efforts for a program or programs, or Kalytera may not be able to identify, license or discover additional product candidates, which would have a material adverse effect on its business and could potentially cause Kalytera to cease operations. Research programs to identify new product candidates require substantial technical, financial and human resources. Kalytera may focus its efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

Even if Kalytera is able to commercialize its product candidates, the products may not receive coverage and adequate reimbursement from third-party payors, which could harm its business.

The availability of reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments. Sales of Kalytera's product candidates, if approved, will depend substantially on the extent to which the costs of these product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only to limited levels, Kalytera may not be able to successfully commercialize its product candidates it develops. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow Kalytera to establish or maintain pricing sufficient to realize a sufficient return on its investment.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or Medicare Modernization Act, established the Medicare Part D program and provided authority for limiting the number of drugs that will be covered in any therapeutic class thereunder. The Medicare Modernization Act, including its cost reduction initiatives, could decrease the coverage and reimbursement rate that Kalytera receives for any of its approved products. Furthermore, private payors often follow Medicare coverage policies and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS, as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors tend to follow CMS to a substantial degree.

The intended use of a drug product by a physician can also affect pricing. For example, CMS could initiate a National Coverage Determination administrative procedure, by which the agency determines which uses of a therapeutic product would and would not be reimbursable under Medicare. This determination process

can be lengthy, thereby creating a long period during which the future reimbursement for a particular product may be uncertain.

Outside the United States, particularly in member states of the European Union, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations or the successful completion of health technology assessment procedures with governmental authorities can take considerable time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Certain countries allow companies to fix their own prices for medicines, but monitor and control company profits. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, Kalytera or its collaborators may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of its product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of any product candidate approved for marketing is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, Kalytera's business, financial condition, results of operations or prospects could be adversely affected.

Kalytera faces an inherent risk of exposure to product liability claims, regulatory action and litigation if its products are alleged to have caused significant loss or injury.

If Kalytera obtains regulatory approval for its product candidates, as a manufacturer and distributor of products designed to be ingested by humans, Kalytera faces an inherent risk of exposure to product liability claims, regulatory action and litigation if its products are alleged to have caused significant loss or injury. In addition, the manufacture and sale of marijuana products involve the risk of injury to consumers due to tampering by unauthorized third parties or product contamination. Previously unknown adverse reactions resulting from human consumption of marijuana products alone or in combination with other medications or substances could occur. Kalytera may be subject to various product liability claims, including, among others, that its products caused injury or illness, include inadequate instructions for use or include inadequate warnings concerning possible side effects or interactions with other substances. A product liability claims or regulatory action against Kalytera could result in increased costs, could adversely affect its reputation with its clients and consumers generally, and could have a material adverse effect on its results of operations and financial condition. There can be no assurances that Kalytera will be able to obtain or maintain product liability insurance on acceptable terms or with adequate coverage against potential liabilities. Such insurance is expensive and may not be available in the future on acceptable terms, or at all. The inability to obtain sufficient insurance coverage on reasonable terms or to otherwise protect against potential product liability claims could prevent or inhibit the commercialization of products.

Risks Related to Kalytera's Business Operations

Kalytera may not be able to maintain its required supply of skilled labor, equipment, parts and components.

Kalytera's ability to compete and grow will be dependent on it having access, at a reasonable cost and in a timely manner, to skilled labor, equipment, parts and components. No assurances can be given that Kalytera will be successful in maintaining its required supply of skilled labor, equipment, parts and components.

Kalytera relies on third parties to supply and manufacture the materials for the research and development of the product candidates. Kalytera cannot provide assurance that the supply of research and development, preclinical and clinical development drugs and other materials will not be limited, interrupted, restricted in certain geographic regions, be of satisfactory quality or be delivered in a timely manner.

Manufacturers of therapeutic products and their facilities are subject to review and periodic inspections by the FDA, the European Medicines Agency and other comparable regulatory authorities for compliance with regulations. Manufacturers of controlled substances must obtain and maintain necessary Drug Enforcement Agency and state registrations and registrations with applicable foreign regulatory authorities. Manufacturers of controlled substances must establish and maintain processes to ensure compliance with Drug Enforcement Agency and state registrations and requirements of applicable foreign regulatory authorities governing, among other things, the storage, handling, security, record keeping and reporting for controlled substances. If there are issues with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or Kalytera, including requiring a recall or withdrawal of the product from the market or suspension of manufacturing. The occurrence of problems with a facility may inhibit Kalytera's ability to commercialize the product candidates and may otherwise have a material adverse effect on its business, financial condition and results of operations.

Failure to obtain import and export licenses or delays or disruption to transportation systems could cause partial or total loss of revenue.

Kalytera's shipment, import and export of its product candidates and the active pharmaceutical ingredients used to manufacture its product candidates requires import and export licenses. The import and export process requires the issuance of import and export licenses by the relevant controlled substance authority in both the importing and exporting country. The granting and maintenance of these licenses is uncertain. Any failure to obtain or maintain an import or export license would have a material adverse effect on its business, results of operations or financial condition.

In the event licenses are granted, Kalytera will depend on fast and efficient courier services to distribute its product. Any prolonged disruption of this courier service may result in the product batches being stored outside required temperature ranges. Inappropriate storage may damage the product shipment resulting in delays in clinical trials or, upon commercialization, a partial or total loss of revenue from one or more shipments of active pharmaceutical ingredients or the product candidates. A delay in a clinical trial or, upon commercialization, a partial or total loss of revenue from delays in shipment could have a material adverse effect on its business, results of operations or financial condition. Rising costs associated with the courier services used by Kalytera to ship its products may also adversely impact its business and its ability to operate profitably.

Kalytera currently have no sales, marketing and distribution capabilities to commercialize the product candidates.

If the product candidates are approved by regulatory bodies, Kalytera will need to acquire sales, marketing and distribution capabilities to commercialize the product candidates. This process is expensive and time-consuming. If Kalytera is not successful in commercializing any product candidate approved, either through internal processes or through third parties, its business, financial condition and results of operations could be materially adversely affected.

Increased competition by larger and better financed competitors could materially and adversely affect Kalytera's business, financial condition and results of operations.

There is potential that Kalytera will face intense competition from other companies, some of which can be expected to have longer operating histories and more financial resources and manufacturing and marketing experience than Kalytera.

There currently are public companies working in the cannabis therapeutic area. These companies may have an advantage in marketing approved products and may obtain regulatory approval of the product candidates before Kalytera is able to. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in more concentrated resources among a smaller number of competitors. To remain competitive, Kalytera will require a continued level of investment in research and development, marketing, sales and client support. Kalytera may not have sufficient resources to maintain research and development, marketing, sales and client support efforts on a competitive basis which could materially and adversely affect its business, financial condition and results of operations.

Kalytera may become party to litigation from time to time in the ordinary course of business which could adversely affect its business.

Should any litigation in which Kalytera becomes involved be determined against it, such a decision could adversely affect its ability to continue operating and the market price for the common shares and could use significant resources. Even if Kalytera is involved in litigation and win, litigation could redirect significant portion of Kalytera's resources. Litigation may also create a negative perception of Kalytera's brand.

Inability to acquire and retain patients as clients may limit Kalytera's ability to produce desirable and effective product.

Kalytera's success depends on its ability to attract and retain patients as clients. There are many factors which could impact Kalytera's ability to attract and retain clients, including but not limited to its ability to continually produce desirable and effective product and the continued growth in the aggregate number of patients selecting the product candidates as a treatment option. Kalytera's failure to acquire and retain patients as clients would have a material adverse effect on its business, operating results and financial condition.

Kalytera is exposed to the risk of employee fraud and other misconduct.

Employee fraud includes intentional failure to comply with regulations, intentional failure to provide accurate information to regulatory authorities and intentional failure to comply with manufacturing standards. Other misconduct includes failure to report financial information accurately, failure to disclosure unauthorized activities to us, and the improper use of information obtained in the course of clinical trials. Employee misconduct resulting in legal action, significant fines or other sanctions could result in a material adverse effect to Kalytera's business, results of operations or financial condition.

Kalytera manages its business through a small number of employees and key consultants. Kalytera depends on them even more than similarly-situated companies.

Kalytera's success is dependent upon the ability, expertise, judgment, discretion and good faith of its senior management. While employment agreements are customarily used as a primary method of retaining the services of key employees, these agreements cannot assure the continued services of such employees. Any loss of the services of such individuals, or an inability to attract, retain and motivate sufficient numbers of

qualified senior management could have a material adverse effect on Kalytera's business, operating results or financial condition.

Kalytera does not currently carry "key person" insurance on the lives of members of management.

Kalytera will need to expand its organization and Kalytera may experience difficulties in recruiting needed additional employees and consultants, which could disrupt its operations.

As Kalytera's development and commercialization plans and strategies develop and because Kalytera is so leanly staffed, it will need additional managerial, operational, sales, marketing, financial, legal and other resources. The competition for qualified personnel in the pharmaceutical field is intense. Due to this intense competition, Kalytera may be unable to attract and retain qualified personnel necessary for the development of its business or to recruit suitable replacement personnel.

Kalytera's management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these growth activities. Kalytera may not be able to effectively manage the expansion of its operations, which may result in weaknesses in its infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Kalytera's expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If Kalytera's management is unable to effectively manage its growth, its expenses may increase more than expected, its ability to generate and/or grow revenue could be reduced and Kalytera may not be able to implement its business strategy. Kalytera's future financial performance and its ability to commercialize product candidates and compete effectively will depend, in part, on its ability to effectively manage any future growth.

Kalytera may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and health information privacy and security laws. If Kalytera is unable to comply, or have not fully complied, with such laws, Kalytera could face substantial penalties.

If Kalytera obtains FDA approval for any of its product candidates and begin commercializing those products in the United States, its operations may be directly or indirectly through its customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act and physician sunshine laws and regulations. These laws may impact, among other things, Kalytera's proposed sales, marketing and education programs. In addition, Kalytera may be subject to patient privacy regulation by both the federal government and the states in which Kalytera conducts its business. The laws that may affect its ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent;

- the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology and Clinical Health Act, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- the federal physician sunshine requirements under the Affordable Care Act requires manufacturers of drugs, devices and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, other healthcare providers and teaching hospitals and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers, state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of Kalytera's business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the Affordable Care Act, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. Moreover, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

If Kalytera's operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, it may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment and the curtailment or restructuring of its operations, any of which could adversely affect its ability to operate its business and its results of operations.

If Kalytera fails to comply with environmental, health and safety laws and regulations, Kalytera could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of its business.

Kalytera's research and development activities and its third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials, including the components of its product candidates and other hazardous compounds. Kalytera and its manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use

are stored at Kalytera's and its manufacturers' facilities pending their use and disposal. Kalytera cannot eliminate the risk of contamination, which could cause an interruption of its commercialization efforts, research and development efforts, business operations and environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although Kalytera believes that the safety procedures utilized by its third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, Kalytera cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, Kalytera may be held liable for any resulting damages and such liability could exceed its resources and state or federal or other applicable authorities may curtail its use of certain materials and/or interrupt its business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. Kalytera cannot predict the impact of such changes and cannot be certain of its future compliance. Kalytera does not currently carry biological or hazardous waste insurance coverage.

Security breaches and other disruptions could compromise Kalytera's information, expose Kalytera to liability and harm its reputation and business.

In the ordinary course of its business Kalytera collects and stores sensitive data, including intellectual property, personal information and its proprietary business information. The secure maintenance and transmission of this information is critical to its operations and business strategy. Kalytera relies on commercially available systems, software, tools and domestically available monitoring to provide security for processing, transmitting and storing this sensitive data.

Hackers may attempt to penetrate Kalytera's computer systems, and, if successful, misappropriate personal or confidential business information. In addition, an associate, contractor or other third-party with whom s do business may attempt to circumvent Kalytera's security measures in order to obtain such information, and may purposefully or inadvertently cause a breach involving such information. While Kalytera continues to implement additional protective measures to reduce the risk of and detect cyber incidents, cyber-attacks are becoming more sophisticated and frequent, and the techniques used in such attacks change rapidly.

Also, Kalytera's information technology networks and infrastructure may still be vulnerable to damage, disruptions or shutdowns due to attack by hackers or breaches, employee error or malfeasance, power outages, computer viruses, telecommunication or utility failures, systems failures, natural disasters, terrorism or other catastrophic events. Any such compromise could disrupt Kalytera's operations, damage its reputation and subject Kalytera to additional costs and liabilities, any of which could adversely affect its business.

There are risks associated with having Kalytera's operations located in Israel.

Kalytera has operations located in Israel. In addition, certain of Kalytera's officers and directors are residents of Israel. Accordingly, political, economic and military conditions in Israel and the surrounding region may directly affect its business.

Kalytera's operations could be disrupted by the absence of a significant number of its officers, directors, employees and consultants related to military service.

Kalytera's employees and consultants in Israel, including members of its senior management, may be obligated to perform one month, and in some cases longer periods, of military reserve duty until they reach the age of 40 (or older, for citizens who hold certain positions in the Israeli armed forces reserves) and, in

the event of a military conflict or emergency circumstances, may be called to immediate and unlimited active duty. In the event of severe unrest or other conflict, individuals could be required to serve in the military for extended periods of time. In response to increases in terrorist activity, there have been periods of significant call-ups of military reservists. It is possible that there will be similar large-scale military reserve duty call-ups in the future. Such disruption could materially adversely affect Kalytera's business and operations. Additionally, the absence of a significant number of the employees of Kalytera's Israeli suppliers and contractors related to military service or the absence for extended periods of one or more of their key employees for military service may disrupt their operations.

Risks Related to Kalytera's Intellectual Property

If Kalytera or its licensors are unable to obtain and maintain effective patent rights for its product candidates, Kalytera may not be able to compete effectively in its markets. If Kalytera is unable to protect the confidentiality of its trade secrets or know-how, such proprietary information may be used by others to compete against Kalytera.

- Kalytera's success depends in large part on its and its licensors' ability to obtain and maintain patent and other intellectual property protection in the United States, Canada and in other countries with respect to its proprietary technology and new product candidates.
- Kalytera has sought to protect its proprietary position by filing patent applications in the United States and in other countries, with respect to its novel technologies and product candidates, which are important to its business. Patent prosecution is expensive and time consuming, and Kalytera may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that Kalytera will fail to identify patentable aspects of its research and development output before it is too late to obtain patent protection.
- Kalytera cannot offer any assurances about which, if any, patent applications will issue, the breadth of any such patent or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Any successful opposition to its patents after issuance could deprive Kalytera of rights necessary for the successful commercialization of any new product candidates that it may develop.
- Also, there is no guarantee that the patent registration applications that were submitted by Kalytera or its licensors with regard to its technologies will result in patent registration. In the event of failure to complete patent registration, Kalytera's developments will not be proprietary, which might allow other entities to manufacture its product candidates and compete with them.

Further, there is no assurance that all potentially relevant prior art relating to Kalytera's or its licensors' patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover Kalytera's product candidates, third parties may challenge their validity, enforceability, or scope, which may result in such patents being narrowed, found unenforceable or invalidated. Furthermore, even if they are unchallenged, Kalytera's or its licensors' patent applications and any future patents may not adequately protect its intellectual property, provide exclusivity for its new product candidates, or prevent others from designing around its claims. Any of these outcomes could impair Kalytera's ability to prevent competition from third parties, which may have an adverse impact on its business.

Kalytera has entered into an exclusive license agreement with Mor which provides Kalytera with exclusive worldwide licenses to certain intellectual property related to its CBD therapeutic program for the treatment and prevention of GVHD. To the extent the licensed or future licensed patents are found to be invalid or unenforceable, or patent applications are rejected, Kalytera may be limited in its ability to compete and market its product candidates, which would materially adversely affect its future revenue, financial condition and results of operations. Further, the Mor license is terminable by the licensor in certain circumstances (such as the failure of Kalytera to achieve certain milestone objectives on agreed timelines), in which event Kalytera may also be limited in its ability to compete and market its product candidates as described above.. Moreover, fluctuating currency rates may create inconsistencies in the royalty payments Kalytera is obligated to make under its license.

If Kalytera cannot obtain and maintain effective patent and other intellectual property rights for its product candidates, Kalytera may not be able to compete effectively, and its business and results of operations would be harmed.

Kalytera may not be able to identify infringements of its or its licensors' patents and accordingly the enforcement of its intellectual property rights may be difficult.

The drug substance in some of Kalytera's product candidates is repurposed, which means that it is available in other pharmaceutical products for the purpose of treating indications that are different from the indications for its product candidates. It is possible that if Kalytera receives regulatory approval to market and sell its drug candidates, some patients that receive a prescription could be sold the same drug substance but not its product candidate. It would be difficult, if not impossible for Kalytera to identify such instances that may constitute an infringement of its patents. In addition, because the drug substance of some of Kalytera's product candidates is repurposed, such substance may not be eligible for patent protection or data exclusivity.

If Kalytera is unable to maintain effective proprietary rights for its product candidates, Kalytera may not be able to compete effectively in its markets.

In addition to the protection afforded by any patents currently owned and that may be granted, historically, Kalytera has relied on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that Kalytera elects not to patent, processes that are not easily known, knowable or easily ascertainable, and for which patent infringement is difficult to monitor and enforce and any other elements of its product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. Kalytera seeks to protect its proprietary technology and processes, in part, by entering into confidentiality agreements with its employees, consultants, scientific advisors, and contractors. Kalytera also seeks to preserve the integrity and confidentiality of its data, trade secrets and intellectual property by maintaining physical security of its premises and physical and electronic security of its information technology systems. Agreements or security measures may be breached, and Kalytera may not have adequate remedies for any breach. In addition, Kalytera's trade secrets and intellectual property may otherwise become known or be independently discovered by competitors.

Kalytera cannot provide any assurances that its trade secrets and other confidential proprietary information will not be disclosed in violation of its confidentiality agreements or that competitors will not otherwise gain access to its trade secrets or independently develop substantially equivalent information and techniques. Also, misappropriation or unauthorized and unavoidable disclosure of Kalytera's trade secrets and intellectual property could impair its competitive position and may have a material adverse effect on its business. Additionally, if the steps taken to maintain Kalytera's trade secrets and intellectual property

are deemed inadequate, Kalytera may have insufficient recourse against third parties for misappropriating any trade secret.

Third-party claims of intellectual property infringement may prevent or delay Kalytera's development and commercialization efforts.

Kalytera's commercial success depends in part on it avoiding infringement of the patents and proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which Kalytera is developing new product candidates. As Kalytera's industries expand and more patents are issued, the risk increases that its product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that Kalytera is employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, designs or methods of manufacture related to the use or manufacture of Kalytera's product candidates. There may be currently pending patent applications that may later result in issued patents that its product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of Kalytera's technologies infringes upon these patents.

If any third-party patents were held by a court of competent jurisdiction to cover aspects of Kalytera's formulations, processes for designs, or methods of use, the holders of any such patents may be able to block its ability to develop and commercialize the applicable product candidate unless Kalytera obtains a license or until such patent expires or is finally determined to be invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making claims against Kalytera may obtain injunctive or other equitable relief, which could effectively block its ability to further develop and commercialize one or more of its product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from Kalytera's business. In the event of a successful claim of infringement against Kalytera, it may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign its infringing product candidates or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

Kalytera may be involved in lawsuits to protect or enforce its intellectual property, which could be expensive, time consuming, and unsuccessful.

Competitors may infringe Kalytera's intellectual property. If Kalytera were to initiate legal proceedings against a third party to enforce a patent covering one of its new product candidates, the defendant could counterclaim that the patent covering its product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Under the *Leahy-Smith Act*, the validity of U.S. patents may also be challenged in post-grant proceedings before the USPTO. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

Kalytera relies heavily on Luria for their research and development services.

Kalytera relies heavily on its relationship with Luria for its research and development services provided under the SOWs. If Luria were to terminate providing its research and development services, related to Kalytera's business and/or products and/or related technology, there is no assurance Kalytera would be able to complete these tasks themselves or through an alternate third party research and development provider.

Risks Related to the Talent Acquisition

If Kalytera is unable to successfully integrate Talent into its business following the Talent Acquisition, its business, financial condition and results of operations may be negatively impacted.

Integration risks

The integration of Talent may expose Kalytera to certain risks, including the following: difficulty in integrating Talent in a cost-effective manner, including the establishment of effective management information and financial control systems; unforeseen legal, regulatory, contractual, employment or other issues arising out of the combination; combining corporate cultures; maintaining employee morale and retaining key employees; potential disruptions to Kalytera's on-going business caused by its senior management's focus on integrating Talent; and performance of the combined assets not meeting its expectations or plans. A failure to properly integrate Talent could have a corresponding material adverse effect on Kalytera's business, results of operations, financial condition or prospects.

Integrating a new company could be expensive and time consuming and could disrupt Kalytera's ongoing business, negatively affect cash flow and distract management and other key personnel from day-to-day operations.

Kalytera may not be able to combine successfully the operations of Talent with its operations, and even if such integration is accomplished, Kalytera may never realize the potential benefits of the acquisition. The integration of acquisitions with Kalytera's operations requires significant attention from management, may impose substantial demands on its operations or other projects and may impose challenges on the combined business including, but not limited to, consistencies in business standards, procedures, policies, business cultures and internal controls and compliance. Certain acquisitions involve a capital outlay, and the return that Kalytera achieved on any capital invested may be less than the return that Kalytera would achieve on its other projects or investments.

Benefits may not materialize

When evaluating potential acquisition targets, Kalytera identifies potential development that Kalytera expects to realize upon the successful completion of the acquisition and the integration of the related operations. Kalytera may, however, be unable to achieve or may otherwise never realize the expected benefits. Kalytera's ability to realize the expected benefits from any acquisition is subject to significant business, economic and competitive uncertainties and contingencies, many of which are beyond its control, such as changes to government regulation governing or otherwise impacting the cannabinoid industry, operating difficulties, client preferences, changes in competition and general economic or industry conditions. If Kalytera is unsuccessful in implementing these improvements or if Kalytera does not achieve its expected results, it may adversely impact its business, financial condition or results of operations.

Assumptions of unknown liabilities

Talent may have unknown or contingent liabilities, including, but not limited to, liabilities for failure to comply with healthcare laws and regulations. Although Kalytera typically attempts to exclude significant liabilities from its acquisition transactions and seeks indemnification from sellers for at least a portion of these matters, there will typically be certain limitations on the indemnification rights of Kalytera against sellers (including in the case of the Talent Acquisition). Even in those acquisitions in which Kalytera has such rights, Kalytera may experience difficulty enforcing the sellers' obligations, or Kalytera may incur material liabilities for the past activities of acquired facilities. Such liabilities and related legal or other costs and/or resulting damage to a company's reputation could negatively impact Kalytera's business, financial condition or results of operations.

Managing growth

Talent has had operating losses prior to such acquisition. If Kalytera fails to operate Talent profitably or effectively integrate the operations of Talent, its results of operations could be negatively impacted.

ADDITIONAL INFORMATION

Additional information about the Company, including the Annual Financial Statements, is available on SEDAR at www.sedar.com.