



RAKOVINA THERAPEUTICS INC.

ANNUAL INFORMATION FORM

Dated May 1, 2023

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INTRODUCTION

In this annual information form (the “**Annual Information Form**” or “**AIF**”), unless the context requires otherwise, references to the “Company”, “Rakovina”, “we”, “us”, “our” and similar words refer to Rakovina Therapeutics Inc. or any predecessor thereto, as the context requires. The information in this Annual Information Form is presented as of December 31, 2022, unless otherwise indicated. All dollar amounts in this Annual Information Form are in Canadian dollars, except where otherwise indicated.

CAUTION REGARDING FORWARD-LOOKING STATEMENTS AND RISK FACTORS

Certain statements and information in this Annual Information Form contain forward-looking statements or forward-looking information under applicable Canadian securities legislation that may not be based on historical fact, including, without limitation, statements containing the words “believe”, “may”, “plan”, “will”, “estimate”, “continue”, “anticipate”, “intend”, “expect”, “predict”, “project”, “potential”, “ongoing”, “could”, “would”, “seek”, “target” or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words and similar expressions.

Forward-looking statements are necessarily based on estimates and assumptions made by us in light of our experience and perception of historical trends, current conditions and expected future developments, as well as factors that we believe are appropriate. Forward-looking statements in this Annual Information Form include, but are not limited to, statements relating to:

- the initiation, timing, cost, progress and success of our research and development programs;
- our ability to safely dose and re-dose, formulate and develop drug candidates;
- our ability and our partners’ and potential future partners’ ability to advance product candidates into, and successfully complete, clinical trials;
- the expected therapeutic benefits, effectiveness and safety of our product candidates, including our belief that our approach may reduce the risk, time and cost of developing therapeutics by avoiding some of the uncertainty associated with certain research and preclinical stages of drug development;
- our ability to obtain marketing approval for any of our products;
- our ability to obtain funding for our operations, including funding for research and commercial activities;
- our ability to achieve profitability;
- our 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;
- our ability to enter into agreements or partnerships with pharmaceutical or biotechnology companies that have sales and marketing capabilities, which will enable us to increase our returns from our product candidates or to further accelerate development of our product candidates;
- the manufacturing capacity of third-party manufacturers for our product candidates;
- the implementation of our business model and strategic plans;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
- our expectations regarding federal, provincial and foreign regulatory requirements;
- the timing of and the costs of obtaining and maintaining regulatory approvals in the United States, Canada and other jurisdictions for our product candidates;
- our ability and our collaborator’s ability to obtain and maintain regulatory approvals in the United States, Canada, and other jurisdictions for our product candidates;
- the rate and degree of market acceptance and clinical utility of our future products, if any;
- our expectations regarding market risk, including interest rate changes and foreign currency fluctuations;
- our ability to engage and retain the consultants or employees required to grow our business;
- the compensation that is expected to be paid to consultants or employees of the Company;
- our future financial performance and projected expenditures;
- developments relating to our competitors and our industry, including the success of competing therapies that are or become available;
- our expectations regarding the kt-2000 series, kt-3000 series and kt-4000 series candidates;

- the impact of the coronavirus pandemic (“**COVID-19**”) on the Company’s operations;
- our expectations regarding the size and growth of the cancer therapeutics and PARP-inhibitor markets; and
- estimates of our expenses, future revenue, capital requirements and our needs for additional financing.

Such forward-looking statements reflect our current views with respect to future events, are subject to risks and uncertainties and are necessarily based upon a number of estimates and assumptions that, while considered reasonable by Rakovina as of the date of such statements, are inherently subject to significant medical, scientific, business, economic, competitive, political and social uncertainties and contingencies. Many factors could cause our actual results, performance, achievements, prospects or opportunities 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 Annual Information Form, the Company has made various material assumptions, including, but not limited to:

- obtaining positive results of non-clinical research and human clinical trials;
- obtaining regulatory approvals;
- assumptions regarding general business and economic conditions;
- assumptions regarding the cost and timing of any preclinical research study or human clinical trials;
- the COVID-19 pandemic not having a material impact on our operations;
- that the Company’s current positive relationships with third parties will be maintained;
- the availability of financing on reasonable terms;
- the Company’s ability to attract and retain skilled consultants;
- assumptions regarding market competition;
- the products and technology offered by the Company’s competitors; and
- 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 herein under the heading “*Risk Factors*”. Should one or more of these risks or uncertainties, or a risk that is not currently known to us, materialize, 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 Annual Information Form and we do 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.

CORPORATE STRUCTURE

General

The Company was incorporated under the *Business Corporations Act* (British Columbia) on May 6, 2019 under the name “Vincero Capital Corp.” Prior to completing its Qualifying Transaction (as defined below), the Company listed its shares on the TSX Venture Exchange (“**TSX-V**”) as a capital pool company (“**CPC**”) (as defined in the TSX-V Policy 2.4 – *Capital Pool Companies*) on February 7, 2020. As a CPC, the Company had no assets other than cash and did not carry on any operations.

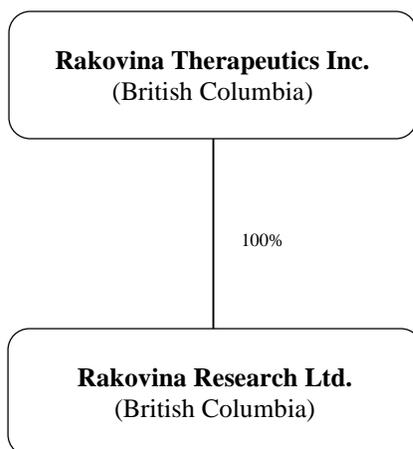
On March 25, 2021, the Company announced that, pursuant to a business combination agreement dated August 28, 2020, as amended from time to time (the “**Business Combination Agreement**”), between the Company and NewGen Therapeutics, Inc. (“**NewGen**”), the Company had completed its qualifying transaction (the “**Qualifying Transaction**”). The Qualifying Transaction was effected by way of a “three-cornered” amalgamation, in which: (a) a subsidiary of NewGen (“**Subco**”) amalgamated with a wholly-owned subsidiary of the Company (“**Vincero Subco**”) to form an amalgamated company (“**Amalco**”); (b) all issued and outstanding shares of the Subco were exchanged for shares of the Company on a 1:1 basis; (c) all issued and outstanding warrants of the Subco were replaced by warrants of the Company on the same terms; and (d) Amalco became a wholly-owned subsidiary of the Company under the name “Rakovina Research Ltd.” The Qualifying Transaction was a reverse-takeover of the Company and upon completion thereof, the Company changed its name to “Rakovina Therapeutics Inc.” On April 1, 2021 following the completion of the Qualifying Transaction, the common shares of the Company (the “**Common Shares**”) resumed

trading on the TSX-V under the symbol “RKV”. The Company’s first financial year-end subsequent to the completion of the Qualifying Transaction was December 31, 2021. A Notice of Change in Corporate Structure was filed by the Company on March 31, 2021.

Following completion of the Qualifying Transaction, the Company continued to conduct the biotechnology business previously conducted by Subco until March 23, 2021, when Subco and a subsidiary of the Company were amalgamated, with Amalco being the successor entity. The Company’s head office and registered and records office is located at Suite 105, 1008 Beach Avenue, Vancouver, British Columbia, V6E 1T7.

Incorporate Relationships

The following is a current corporate organizational chart displaying the Company and Rakovina Research Ltd., Rakovina’s wholly-owned subsidiary.



GENERAL DEVELOPMENT OF THE BUSINESS

Three Year History

2020

The Company entered into a letter of intent (the “**Letter of Intent**”) with NewGen on May 22, 2020 to acquire Tricyclic Inhibitors of Poly(ADP-Ribose) Polymerase (PCT/US2012/040304) (“**PARP Inhibitor Program Technology**” or “**kt-2000 series**”) and all patents, patent applications (and the patents resulting therefrom) filed thereafter based upon or claiming priority from any such patents or patent applications, including any re-issues, re-examinations, extensions (including any supplementary protection certificate), continuations, continuations in part (to the extent the claims thereof are supported by the specifications of patent applications otherwise included herein), divisions, provisionals, substitute applications, registration patents or patents of addition based on any such patent and all foreign counterparts of any of the foregoing, and additional technology and know-how related to this intellectual property, including unpublished data and experimental results and experimental drug substances and related analogues. On May 26, 2020, trading in Common Shares was halted on the TSX-V, pending the announcement of the Letter of Intent.

In August 2020, the Company signed the Business Combination Agreement with NewGen to acquire the kt-2000 series drug candidates in a Qualifying Transaction that would create Rakovina Therapeutics Inc., a new TSX-V listed company capitalized to continue development of the kt-2000 series drug candidates and explore other programs in the DNA damage response (“**DDR**”) inhibitor field.

In September 2020, NewGen incorporated Subco to facilitate the Qualifying Transaction pursuant to the Business Combination Agreement.

In November 2020, Subco acquired certain rights to the kt-3000 and kt-400 series of drug candidates. These rights have subsequently been acquired by us in the Qualifying Transaction.

In December 2020, Subco entered into a collaborative research agreement dated December 23, 2020 (the “**UBC Collaborative Research Agreement**”) with the University of British Columbia (“**UBC**”) to enable the conduct of lead optimization activities in a dedicated laboratory at UBC. The rights and obligations under the UBC Collaborative Research Agreement have been assumed by us in the Qualifying Transaction.

In connection with the Business Combination Agreement, the Company incorporated Vincero Subco which amalgamated with Subco to form Amalco (the “**Amalgamation**”), pursuant to which all the outstanding shares of Vincero Subco and Subco were cancelled. The Company acquired 100% of the issued and outstanding shares of Amalco and each holder of Subco shares acquired one Common Share for every share of Subco held prior to the Amalgamation. Additionally, every Subco common share purchase warrant was exchanged for a common share purchase warrant of the Company. The terms of payment and consideration in the Business Combination Agreement were determined pursuant to arm’s length negotiations between management of each of the Company and NewGen.

Prior to completion of the Qualifying Transaction, Subco completed a private placement of subscription receipts (the “**Subscription Receipts**”) for aggregate gross proceeds of \$4,565,900. Upon satisfaction of certain escrow release conditions, each Subscription Receipt was automatically exchanged, with no payment of additional consideration, for one unit of Subco (a “**Unit**”). Each Unit consisted of one Subco share and one half of a Subco warrant (each warrant, a “**Subco Unit Warrant**”). Each Subco Unit Warrant entitled the holder thereof to purchase one Subco share at an exercise price of \$0.40 per Subco share for a period of 24 months. Upon closing of the Qualifying Transaction, all Subco shares were exchanged for shares of the Company and all Subco warrants were replaced by warrants of the Company on the same terms.

2021

On March 25, 2021, the Company announced that, pursuant to the Business Combination Agreement, between the Company and NewGen, the Company had completed the Qualifying Transaction.

On April 1, 2021 following the completion of the Qualifying Transaction, the Common Shares resumed trading on the TSX-V under the symbol “**RKV**”.

On April 5, 2021, the Company announced the appointment of Julie Cherrington, PhD to the board of directors of the Company (the “**Board**”). Dr. Cherrington is an accomplished life science executive with a record of demonstrated success in advancing drug candidates into human clinical trials and through to commercialization. She has been a key contributor to the successful development of multiple U.S. Food and Drug Administration (“**FDA**”) approved products, including the anti-cancer agents SUTENT® and PALLADIA® and the anti-viral agents VISTIDE®, VIREAD®, and HEPSERA®.

On April 8, 2021, the Company announced that the European and Canadian Patent Offices had granted patents entitled “**Tricyclic Inhibitors of Poly(ADP-Ribose) Polymerase**”. The granted patent claims cover the composition of matter and uses of drug candidates from the Company’s kt-2000 series, one of three novel series of DDR inhibitors being researched by the Company as potential targeted cancer therapies under of the UBC Collaborative Research Agreement.

On April 29, 2021, the Company formed its inaugural Scientific Advisory Board made up of experts in biology, medicinal chemistry and pharmacology. The Scientific Advisory Board will contribute to Rakovina’s development of new cancer treatments informed by the latest scientific research, and practical and clinical perspectives. Under the advisement of the Scientific Advisory Board, the Company aims to develop innovative therapies for a range of cancer indications. The inaugural members of the Scientific Advisory Board include Dennis Brown, PhD, Leonard Post, PhD, Neil Sankar, MD and Wang Shen, PhD.

On June 23, 2021, the Company presented to potential interested investors at the 2021 Emerging Growth Conference.

On September 16, 2021, the Company delivered a video presentation at the inaugural JCA-AACR Precision Medicine Conference. Data presented at the conference demonstrated that select compounds from the Company's kt-3000 series exhibit strong inhibition of both poly (ADP-ribose) polymerase ("**PARP**") and histone deacetylase ("**HDAC**") in a single molecule and that activity at each target is comparable to FDA-approved single-target PARP or HDAC inhibitors.

On October 7, 2021, the Company received notice of allowance from the United States Patent and Trademark Office. The allowed claims cover composition of matter and uses of the Company's kt-2000 series.

On October 12, 2021, the Company announced a summary of data delivered in a video presentation at the 2021 AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics entitled "In Vitro Activity of Novel kt-3000 Series Dual PARP-HDAC Inhibitors".

On November 11, 2021, the Company announced presentation of data related to lead optimization research related to its novel kt-3000 series drug candidates at the 6th biennial Canadian Cancer Research Conference.

On November 23, 2021, the Company announced that Julie Cherrington had resigned from the Board. Dr. Cherrington will continue to serve the Company as a member of the Scientific Advisory Board.

On December 21, 2021, the Company announced the receipt of non-dilutive research funding from the Canadian National Research Council of Canada Industrial Research Assistance Program ("**NRC IRAP**") and MITACS to support the development of new research infrastructure for screening and optimization of potential drug candidates from the Company of novel DNA-damage response inhibitors and to expand staffing.

2022

On January 6, 2022, the Company announced that it would be presenting virtually at the Biotech Showcase 2022 conference.

On January 25, 2022, the Company announced that Mads Daugaard, the Company's President and Chief Scientific Officer would be participating as an expert panelist at the 5th Annual DDR, ATR and PARP Inhibitors Summit alongside senior scientists from AstraZeneca and the National Brain Tumor Society to discuss insights and future directions for DDRi in the treatment of cancer. The DDR, ATR and PARP Inhibitors Summit brought together industry and academic experts focused on advancing new and novel next-generation DNA-damage repair inhibitors.

On March 3, 2022, the Company filed a short form base shelf prospectus (the "**Shelf Prospectus**") qualifying the distribution of up to \$50,000,000 securities of the Company, including Common Shares, warrants, subscription receipts, units, debt securities and share purchase contracts of the Company during the 25-month period that the Shelf Prospectus is effective.

On April 12, 2022, the Company announced its poster presentation at the American Association for Cancer Research (the "**AACR**") Annual General Meeting, entitled "Evaluation of a Novel Class of Bifunctional DNA Alkylating PARP Inhibitors".

On May 11, 2022, the Company announced that it would be presenting preclinical data on the kt-3000 series lead candidate demonstrating novel bifunctional mechanism as a potential treatment for Ewing sarcoma and other soft-tissue tumors at the 2022 AACR Special Conference on Sarcomas.

On October 28, 2022, the Company announced that it presented new data on the kt-3000 series at the 34th EORTC-NCI-AACR on Molecular Targets and Cancer Therapeutics in Barcelona, Spain.

On November 14, 2022, the Company announced the publication of a manuscript entitled "A bi-functional PARP-HDAC inhibitor with activity in Ewing sarcoma", which indicates a benefit of dual PARP and HDAC inhibition and provide proof-of-concept for a bi-functional single-molecule therapeutic strategy in the treatment of Ewing sarcoma.

On November 23, 2022, the Company announced that it would be presenting virtually at the Emerging Growth Conference.

Recent Developments

On January 26, 2023, the Company announced that Mads Daugaard, the Company's President and Chief Scientific Officer, participated in the 6th Annual DDR, ATR and PARP Inhibitors Summit, where he presented an address entitled "Exploring a Novel Dual PARP-HDAC Inhibitor for the Treatment of Ewing Sarcoma," describing the Company's research results with its novel kt-3000 series in pre-clinical models of Ewing sarcoma.

On March 10, 2023, the Company announced it may apply to the TSX-V to extend the expiry date of 11,414,750 common share purchase warrants (the "**Warrants**") issued by the Company. On March 23, 2023, the Company announced that it had extended the expiry date of the Warrants from March 24, 2023 to March 24, 2024. No other terms of the Warrants were amended and the exercise price of each Warrant remains at \$0.40. The proposed amendment of the Warrants has received the approval of the TSX-V.

On March 22, 2023, the Company announced that it is receiving advisory services and up to \$122,865 in non-dilutive research and development funding from the NRC IRAP.

On March 30, 2023, the Company announced the engagement of Red Cloud Securities Inc. ("**Red Cloud**") and Proactive Investors North America Inc. ("**Proactive**") as part of the Company's evolving strategy to improve trading liquidity and increase general market awareness of the Company and its next-generation cancer therapy development pipeline. Red Cloud is an IIROC investment dealer focused on providing unique comprehensive capital market services to small-cap public and private companies.

On April 20, 2023, the Company announced the presentation of new data during the DNA Damage Response section at the AACR Annual Meeting. The Company presented a scientific poster entitled "A novel bi-functional agent targeting PARP and HDAC in Ewing sarcoma. Data presented at the meeting demonstrate that Rakovina Therapeutics' kt-3000 prototype lead candidate exhibits higher PARP-1 vs. PARP-2 selectivity compared to the FDA-approved PARP inhibitor, olaparib. Selectivity against PARP1 is believed to correlate with an improved safety profile vs. first-generation PARP inhibitors. The data also demonstrate that the dual functional kt-3000 prototype lead candidate is more effective against Ewing sarcoma tumor cells than either a PARP inhibitor or HDAC inhibitor alone. This is achieved despite reduced potency at HDAC compared to the FDA-approved HDAC inhibitor, vorinostat.

On May 1, 2023, the Company announced that it will issue approximately thirty (30) unsecured \$50,000 convertible debenture units (the "**Units**") to a select group of investors for gross proceeds of approximately \$1,500,000. Each Unit will be comprised of a \$50,000 convertible debenture (a "**Debenture**") and 100,000 non-transferable Common Share purchase warrants (the "**Debenture Warrants**"). The principal amount of the Debenture shall be repayable in 30 months (unless earlier converted or redeemed) and carries a 12% interest rate. Each Debenture Warrant is exercisable into one Common Share at a price of \$0.15 per share for a period of 30 months. The Debenture holders will have the right to convert the principal amount of the Debenture into Common Shares at a conversion price of \$0.20 per share.

Throughout the remainder of 2023, the Company expects to continue lead-optimization research in collaboration with UBC. The Company's efforts will primarily focus on the selection of a lead clinical candidate from the kt-3000 series dual-function DNA damage response inhibitors for advancement to human clinical trials. Additional research will focus primarily on evaluation of select kt-2000 series drug candidates to explore pharmacologic differentiation compared to FDA-approved PARP inhibitors.

The aim of our research is to demonstrate potential superiority to first-generation DDR inhibitors to address significant unmet medical needs in the treatment of cancer.

The primary goal of our lead optimization research will be realized by selecting one or more lead clinical candidates its portfolio of novel DNA-damage response inhibitors by achieving the following milestones:

1. identification of one or more lead drug candidates that meet the proprietary benchmark target product profile; and
2. demonstration of an acceptable safety, biodistribution and pharmacokinetic profile to support advancement of a lead drug candidate to pivotal toxicology studies and human clinical trials.

THE BUSINESS

We are a Canadian biotechnology company with a vision to transform and extend the lives of patients with cancer. Our approach centers on researching and developing new precision medicines targeting critical DDR mutations that are the hallmarks of many cancers.¹ We are principally focused on the research and development of the novel DNA-damage response inhibitors.

We have acquired certain rights to three classes of novel preclinical small-molecule drug candidates with established proof-of-concept data. We have acquired worldwide rights, excluding the People's Republic of China, Hong Kong and Taiwan, to develop and commercialize the kt-2000 series under the terms of the purchase and patent assignment agreement dated March 19, 2021 between Subco and NewGen (the "**Contribution Agreement**"). We have also been granted an exclusive right to conduct research and development in respect of our kt-3000 and kt-4000 series under the terms of the evaluation and option agreement (the "**Evaluation and Option Agreement**") dated October 30, 2020 between Subco and their inventor, Dr. Wang Shen, under which we will evaluate the potential commercial value of the kt-3000 and kt-4000 series drug candidates prior to negotiating terms of an exclusive worldwide license to the technology. We established this pipeline of assets with the goal of advancing one or more drug candidates into human clinical trials. Based on the results of future clinical trials, we hope to obtain regulatory marketing approval for new cancer therapeutics from Health Canada, the FDA and similar international regulatory agencies.

Cancer is a leading cause of death worldwide, responsible for 9.6 million deaths globally during 2018.² The global cancer therapeutics market is expected to surpass \$180 billion by 2023.³ Growth in the cancer field will be driven by rising worldwide prevalence of cancer and continued advancements in the understanding of tumor biology.

DDR mutations can be considered the Achilles' heel⁴ of many tumors including breast, ovarian, prostate and pancreatic cancer. These mutations allow tumor cells to evade the human immune system and grow into life-threatening cancer, but they also define potential cancer-specific vulnerabilities that can be targeted with new precision medicine approaches. We believe that DDR mutations will provide opportunities to personalize therapy to specific biological features of a patient's tumor, thereby leading to high-value treatments with fewer side effects and improved treatment outcomes.

PARP-inhibitors represent the first DDR blockbuster cancer therapies. Four FDA-approved PARP-inhibitors have achieved multi-billion dollars in annual revenues.⁵

While PARP-inhibitors have become a standard treatment for certain subsets of breast, ovarian and prostate cancer, they have been shown to only delay tumor progression but do not significantly extend overall patient survival.⁶ This is in part because PARP-inhibitors only target a small subset of DDR mutations,⁷ allowing treatment resistance to develop and the tumor to return with an aggressive metastatic phenotype allowing cancer to rapidly spread throughout the body, including to the brain.

Resistance to PARP inhibitors is known to arise from multiple mechanisms.⁸ Such mechanisms include, but are not limited to upregulation of drug efflux systems that expel drug molecules from tumor cells, loss of mutational targets leading to natural selection of resistant tumor cells, the gain of new mutations that upregulate certain cellular functions leading to treatment resistance, and metastatic "escape" of tumor cells to other areas of the body that are not exposed to treatment, especially to the brain.

¹ Das, *Front. Oncol.* (2019)

² World Health Organization (2020): <https://www.who.int/news-room/fact-sheets/detail/cancer>

³ BCC Research (2019)

⁴ Darzynkiewicz, *Eur J Pharmacol* (2009)

⁵ Coherent Market Insights (2019)

⁶ Litron, *AACR* (2020)

⁷ Lozano, *British Journal of Cancer* (2020)

⁸ Li, *Mol Cancer* (2020)

We are seeking to address the challenge of treatment resistance by focusing our drug development efforts across three key areas:

- kt-2000 Novel, next-generation PARP-inhibitor candidates with potential for pharmacologic differentiation and improved pharmacokinetics and biodistribution, especially to the brain;
- kt-3000 Novel drug candidates that synergistically target multiple DDR pathways implicated in treatment resistance; and
- kt-4000 Novel drug candidates that generate tumor-specific DNA damage and also inhibit specific DDR mechanisms.

As we advance our research efforts, we will also aim to establish new understandings of DDR mechanisms that could unlock further discoveries including potential opportunities for the licensing or acquisition of additional drug candidates, leading to potential new treatment paradigms.

DDR-mutations are the hallmarks of many cancers and are involved in tumor formation and the development of treatment resistance. Our approach will be to leverage our current knowledge of DDR to initially focus on target markets where PARP-inhibitors have been approved for treatment by the FDA including, but not limited to, breast ovarian and prostate cancer. As our research and development efforts progress, we will also aim to establish new understandings of DDR mechanisms that could unlock further discoveries leading to potential new therapeutic opportunities across a range of major and rare cancers.

Breast Cancer

Breast cancer will be diagnosed in 12% of women in the United States over the course of their lifetimes. More than 250,000 new cases of breast cancer were diagnosed in the United States in 2019.⁹ The global market for breast cancer treatment is expected to exceed US\$38.5 billion by 2026.¹⁰ Breast cancer is categorized into three major subtypes based on (1) the presence or absence of molecular biomarkers for estrogen or progesterone receptors and human epidermal growth factor-2 (ERBB2; formerly HER2); (2) hormone receptor positive/ERBB2 negative (70% of patients), ERBB2 positive (15%-20%), and (3) triple-negative breast cancer (“TNBC”) tumors that lack all three standard molecular markers (15% of patients).¹¹ Nealy half (46%) of women with advanced TNBC will have metastasis to the central nervous system (“CNS”) or brain.¹²

Analysis of patient data indicates that 20-25% of TNBC patients harbor germline DDR-mutations making this a promising patient population for PARP-inhibitor therapy.¹³ The high incidence of CNS metastases represents an important unmet medical need. We are seeking to optimize our kt-2000 series PARP inhibitors to treat DDR-mutant cancers with high risk of CNS metastasis. We are researching how our kt-3000 and kt-4000 series drug candidates target recurrent and treatment-resistant cancers, including TNBC.

Ovarian Cancer

The American Cancer Society estimates that approximately 22,000 women a year will be newly diagnosed with ovarian cancer and approximately 14,000 women will die from the disease in the United States each year.¹⁴ The global market for ovarian cancer treatment is expected to exceed US\$6.7 billion by 2028.¹⁵

⁹ American Cancer Society (2020)

¹⁰ Fortune Business Insights (2019)

¹¹ Waks, JAMA (2019)

¹² Lin, Cancer (2008)

¹³ Papadimitriou, Cancer Treat Rev (2018)

¹⁴ American Cancer Society (2020)

¹⁵ GlobalData PC (2019)

Promising results from recent clinical trials show that PARP inhibitors benefit women with both treatment-resistant and newly diagnosed advanced ovarian cancer.¹⁶ Unfortunately, the emergence of resistance to PARP inhibitors is nearly ubiquitous in ovarian cancer, particularly following long-term treatment.¹⁷ In an effort to overcome treatment resistance, PARP inhibitors have been combined with other agents, but multi-drug combinations often have proven to be toxic, thereby limiting their clinical utility.¹⁸ We intend to screen our kt-2000 series PARP inhibitors against treatment-resistant ovarian cancer phenotypes to identify unique properties that may allow treatment of tumors that have become resistant to currently available therapies. Our kt-3000 and kt-4000 series drug candidates combine two important anti-tumor mechanisms in a single molecule potentially reducing the toxicity associated with multi-drug combinations. We plan to screen the kt-3000 and kt-4000 series drug candidates against ovarian cancer subtypes that are inherently resistant or have become resistant to treatment.

Prostate Cancer

The American Cancer Society estimates that one out of every nine men will be diagnosed with prostate cancer in their lifetime. Nearly 192,000 men will be diagnosed with prostate cancer and approximately 33,000 men will die from the disease during 2020.¹⁹ The global market for prostate cancer treatment is expected to exceed US\$9.9 billion by 2026.²⁰ Up to one-third of advanced prostate cancers harbor DDR-mutations, but only a fraction of these are mutations that correlate with response to FDA-approved PARP-inhibitor treatment.²¹

We plan to screen kt-2000 series PARP inhibitors against treatment-resistant prostate cancer phenotypes to identify unique properties that may allow treatment of tumors that have become resistant to currently available therapies. Our kt-3000 and kt-4000 series drug candidates are being researched to identify precision-medicine patient populations whose prostate cancer harbors specific mutations and are unlikely to respond to or become resistant to currently approved PARP inhibitors where kt-3000 and kt-4000 drug candidates may demonstrate the potential for improved outcomes.

Pancreatic Cancer

Pancreatic cancer is a highly fatal disease with a poor prognosis. It is the fourth leading cause of cancer death in the United States.²² Nearly 58,000 patients will be diagnosed with pancreatic cancer and more than 47,000 will die from the disease during 2020.²³ The global market for pancreatic cancer treatment is expected to exceed US\$4.2 billion by 2025.²⁴

We plan to screen the kt-2000, kt-3000 and kt-4000 series PARP inhibitors against pancreatic cancer phenotypes to identify unique biomarkers in patients whose pancreatic cancer harbors specific mutations and are unlikely to respond to or have become resistant to current treatment regimens.

¹⁶ National Cancer Institutes (2019)

¹⁷ Li, *Mol Cancer* (2020)

¹⁸ Matulonis, *Annals of Oncology* (2017)

¹⁹ American Cancer Society (2020)

²⁰ Allied Market Research (2019)

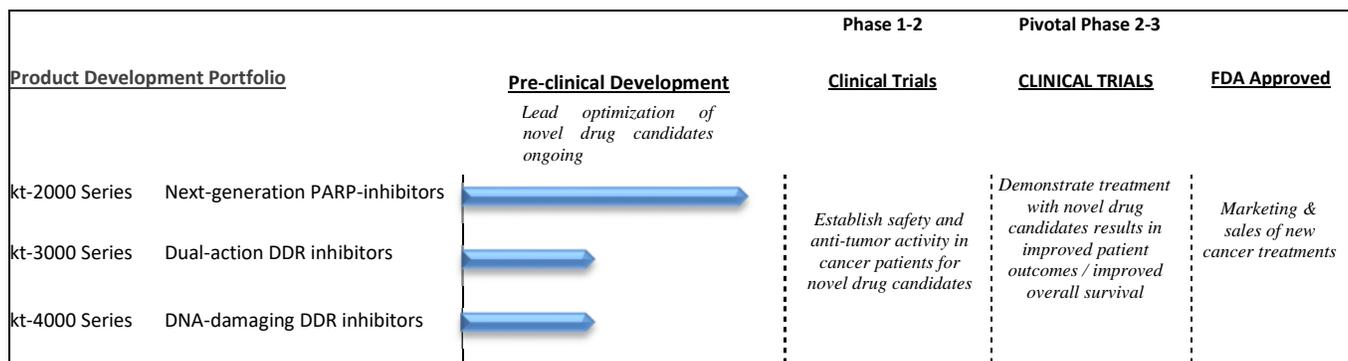
²¹ Ratta, *Prostate Cancer and Prostatic Disease* (2020); Messina, *J.Oncol* (2020)

²² Seigel, *Cancers Statistics* (2019)

²³ American Cancer Society (2020)

²⁴ Grandview Research (2019)

Product Candidate Development



Prior drug discovery and preclinical research activities undertaken prior to our acquiring rights have established initial proof of concept data. We are conducting additional preclinical “lead optimization” research activities designed to identify one or more drug candidates suitable for advancement to human clinical trials. If the outcome of our lead optimization efforts is successful, we will submit an investigational new drug (“IND”) application to regulatory authorities to allow the initiation of human clinical trials with one or more suitable product candidates. During the next 12 months our research efforts will primarily focus on the selection of a lead clinical candidate from the kt-3000 series dual-function DNA damage response inhibitors for advancement to human clinical trials. Additional research will focus primarily on evaluation of select kt-2000 series drug candidates to explore pharmacologic differentiation compared to FDA-approved PARP inhibitors. Suitable product candidates will be advanced to pivotal toxicology studies required to support submission of an IND.

Initial human clinical trials in the cancer field first involve testing in a small number of patients (Phase 1-2 clinical trials) to establish the safety, toxicity and pharmacology of a product candidate and to investigate preliminary anti-tumor activity. The goal of Phase 1-2a clinical trials is to establish a recommended dose and dosing regimen for advanced clinical studies.

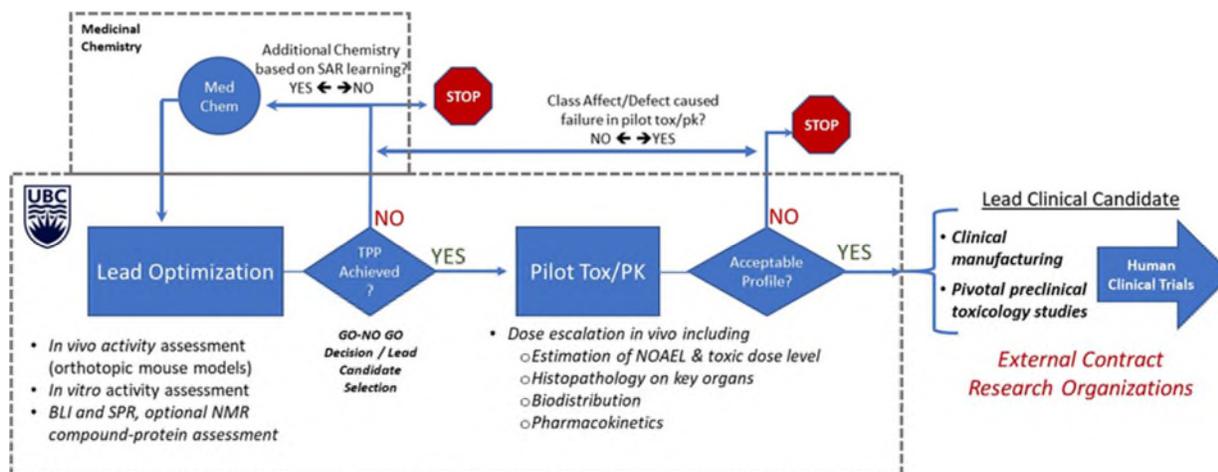
Advanced human clinical trials in the cancer field involve investigation of the safety and efficacy of a product candidate in patients suffering from a specific type of cancer. Phase 2b studies are generally conducted in up to 100 patients to evaluate outcomes and to support the design of pivotal Phase 3 clinical trials. Phase 3 clinical trials generally involve a randomized clinical trial designed to demonstrate a clinically meaningful and statistically significant improvement in patient outcomes, such as survival, for a product candidate versus the current standard of care or other control arm. Phase 3 studies may involve several hundred patients and require multiple years and tens of millions of dollars to complete.

In certain instances, the FDA and other regulatory authorities allow for accelerated approval following pivotal Phase 2 trials designed to demonstrate improvement in patient outcomes following treatment with a product candidate based on a surrogate endpoint. In the cancer field, an accepted surrogate endpoint is tumor response (tumor shrinkage). Accelerated approval allows drug developers to obtain conditional marketing approval prior to the conduct of protracted and costly randomized Phase 3 trials thereby significantly reducing the time and cost of drug development. Where possible, we plan to seek accelerated approval for our drug candidates.

kt-2000 Series drug candidates are a patented class of next-generation oral targeted small molecule inhibitors of poly (ADP-ribose) polymerase (PARP). The kt-2000 series lead candidates demonstrate potency comparable to FDA-approved PARP-inhibitors and potent anti-cancer activity in preclinical animal models. The kt-2000 series lead candidates are being optimized around potential differentiating factors and competitive advantages, including the ability to cross the blood brain barrier in order to treat tumors that have metastasized to or originate in the brain. We believe that the established data demonstrates kt-2000 series drug candidates have the potential to improve treatment outcomes and patient quality of life. We have identified multiple lead candidates from the kt-2000 series that exhibit promising pharmacokinetic profiles and demonstrated activity in *in vivo* models. During the next 12 months we plan to further investigate these candidates to identify potential competitive advantage vs. FDA-approved PARP inhibitors.

kt-3000 Series drug candidates are a patented rationally designed class of small-molecule drug candidates that we believe have the potential to overcome treatment resistance by selectively downregulating acquired mechanisms of resistance while enhancing PARP inhibitor activity. Established *in vitro* data demonstrates selective inhibition of multiple targets at similar potency to FDA-approved single-agent therapies. By targeting dual mechanisms in a single molecule, we believe that kt-3000 series drug candidates have the potential to overcome clinical resistance that arises in response to PARP inhibitor treatment. We have generated multiple novel drug candidates from the kt-3000 series and demonstrated activity in both cellular and animal-based cancer models. During the next 12 months our research efforts will primarily focus on the selection of a lead clinical candidate from the kt-3000 series dual-function DNA damage response inhibitors for advancement to human clinical trials. This research will be conducted in collaboration with UBC under the terms of the UBC Collaborative Research Agreement. We have an exclusive right to conduct research and development in respect of the kt-3000 series and an exclusive option to enter into further negotiations to license or acquire the world-wide rights to the kt-3000 series.

kt-4000 Series drug candidates are a patented rationally designed class of small-molecule drug candidates that have been engineered to cause targeted DNA-damage to a tumor cell's DNA while simultaneously inhibiting the tumor's DNA damage response. The kt-4000 series DDR inhibitors molecular structure includes a potent moiety which causes targeted DNA-damage to cause breaks in a tumor cell's DNA strands while also inhibiting DNA-damage repair mechanisms leading to cancer cell death. Established *in vitro* data demonstrates both DNA-damaging and DDR-inhibiting functionality. We believe that kt-4000 series drug candidates have the potential to expand the general utility of DDR-inhibitors to treat tumors that have become, or are inherently resistant to DDR-inhibiting therapeutics. We expect to evaluate multiple novel drug candidates from the kt-4000 series in *in vitro* to make an early assessment of their commercial potential. This research will be conducted in collaboration with UBC under the terms of the UBC Collaborative Research Agreement. We have an exclusive right to conduct research and development in respect of the kt-4000 series and an exclusive option to enter into further negotiations to license or acquire the world-wide rights to the kt-4000 series.



In general, milestones in lead-optimization and drug discovery research include establishing superiority of kt-2000, kt-3000 and kt-4000 series compounds benchmarked against FDA-approved PARP inhibitors in relevant *in vitro* and *in vivo* models and confirming preclinical safety, biodistribution and pharmacokinetic profiles within acceptable parameters for medicines in the oncology field. The superiority of kt-2000, kt-3000 and kt-4000 series drug candidates may be established based upon improved efficacy in treatment-resistant tumors and tumors of the central nervous system, improved safety or improved pharmacokinetics and biodistribution compared to FDA-approved PARP inhibitors and other FDA-approved cancer therapeutics.

The primary goal of the lead optimization research program will be realized by selecting one or more lead clinical candidates from the kt-2000, kt-3000 and/or kt-4000 series by achieving the following milestones:

1. identification of one or more lead drug candidates that meet the proprietary benchmark target product profile; and

2. demonstration of an acceptable safety, biodistribution and pharmacokinetic profile to support advancement of a lead drug candidate to pivotal toxicology studies and human clinical trials.

Lead-optimization research conducted in collaboration with UBC will evaluate kt-2000, kt-3000 and kt-4000 series drug candidates against a proprietary benchmark target product profile established to demonstrate potential superiority to FDA-approved products. Lead-optimization research conducted in collaboration with UBC is led by Dr. Mads Daugaard, the President and Chief Scientific Officer of the Company. Medicinal chemistry activities are overseen by Dr. Wang Shen at his laboratories in Shanghai, China and California, USA.

Specific activities aimed at identifying drug candidates that meet the proprietary benchmark target product profile include assessment of anti-tumor activity against cancer cell lines *in vitro* and in orthotopic tumor models *in vivo*. Advanced techniques including bioluminescence imaging and surface plasmon resonance transduction will be employed to monitor tumor growth and response to treatment and to address the affinity, kinetics and thermodynamics of drug candidate interactions at a biomolecular target. Nuclear magnetic resonance imaging will also be employed in select instances to investigate spatial interaction of a drug candidate with a biomolecular target. Successful completion of these studies and identification of drug candidates that meet the benchmark target product profile is a key development milestone for the business of the Company.

Drug candidates meeting the benchmark target product profile will be further assessed in pilot toxicology and pharmacokinetic studies conducted in collaboration with UBC. Such studies will provide an early evaluation of the safety and pharmacological features of drug candidates and provide insight into the potential for successful clinical development and commercialization. Escalating doses of potential lead clinical candidates will be studied *in vivo* to establish the no observed adverse event level and toxic dose level. Biodistribution and pharmacokinetics will be assessed to understand how a potential lead clinical candidate disperses to different organs and tumor tissue in animals following treatment over time. Results of these studies will be used to confirm lead clinical candidates will be selected for advancement to formal preclinical studies and human clinical trials. Demonstration of an acceptable drug profile based on these studies and confirmation of lead clinical candidates is a key development milestone for the business of the Company.

If no drug candidate meets the benchmark target product profile, biological data obtained will inform medicinal chemistry design of additional drug candidates. The Company's medicinal chemistry is advised by Dr. Wang Shen, the inventor of the kt-2000, kt-3000 and kt-4000 series drug candidates and a member of the Company's scientific advisory board. Data from biological studies conducted in collaboration with UBC has been used to guide desirable chemical features of new drug candidates which can be synthesized in the laboratory for further evaluation. Thus, an iterative process of rational drug design will be employed to streamline the confirmation of a potential best-in-class drug candidate for advancement to formal preclinical studies and human clinical trials thereby reducing technical risk and increasing the likelihood of success.

Specialized Skill and Knowledge

Drug development is a highly complex field involving multiple scientific and business skills including, but not limited to, biology, medicinal chemistry, pharmacology, toxicology, clinical development, regulatory affairs, manufacturing project management and finance and business development. We believe that our current staff and advisors have the requisite skills to undertake our current preclinical lead optimization research activities and to support early-stage human clinical trials. We anticipate adding additional skills through staffing expansions and consultant agreements as they become required to support our drug development and commercialization activities.

Competitive Conditions

The life sciences industry is highly competitive. We are currently developing therapeutics that will compete, if approved, with other products and therapies that currently exist or are being developed. Currently, there are four U.S. FDA-approved PARP-inhibitors, which are each expected to achieve multi-billion annual revenues over the next few years.²⁵ PARP-inhibitors have become important components in the treatment of several cancers including breast,

²⁵ Coherent Market Insights (2019)

ovarian and prostate cancer. However, clinical resistance to PARP-inhibitor treatment has emerged as an important unmet medical need. Our strategy is to build upon the clinical success of the PARP-inhibitors and new knowledge being developed related to cancer-resistance mechanisms to PARP-inhibitor treatments. Our lead optimization research efforts are aimed at advancing product candidates that have the potential to overcome treatment resistance to address this unmet medical need.

Intangible Properties

Our intangible properties currently consist of patents and patent applications, as well as proprietary know-how related to the development of our product candidates. Our product candidates are covered by issued patents and pending patent applications claiming composition of matter and method of use claims. In the future, we may rely on brand names, copy rights, trademarks and licenses to protect our product candidates.

We also own exclusive worldwide rights, excluding the People's Republic of China, Hong Kong and Taiwan, to the kt-2000 series drug candidates.

In addition, we obtained an exclusive option to license or acquire worldwide rights to the kt-3000 and kt-4000 series of drug candidates. We plan to negotiate the terms to license or acquire world-wide commercial rights with Dr. Wang Shen following the completion of the research program that will assess the potential commercial value of the kt-3000 and kt-4000 series of drug candidates, subject to the success of the research program as determined by the us.

Issued patents and pending patent applications for the kt-2000 series extend to at least 2032. Pending patent applications for the kt-3000 and kt-4000 series extend to at least 2041.

Economic Dependence

Pursuant to the Qualifying Transaction, the Company's business is substantially dependent on the below contract:

UBC Collaborative Research Agreement

On December 23, 2020, Subco entered into the UBC Collaborative Research Agreement with UBC and Vancouver Coastal Health Authority (together with UBC, the "**Institution**"). Pursuant to the UBC Collaborative Research Agreement, Subco and the Institution will collaborate to complete a characterization of novel proprietary DNA-damage response inhibitors (the "**DDRIs**") owned and supplied by Subco (the "**Project**") over a three-year period (the "**Contract Period**").

During the Contract Period, Subco will make certain payments to UBC totaling \$1,652,000 and grant UBC a non-transferable, non-exclusive license to use the DDRIs in the performance of the Project. The Institution will be granted any rights to the DDRIs resulting in a royalty or other ongoing financial obligation. The Institution will conduct research in accordance with the terms of the UBC Collaborative Research Agreement and return or destroy the DDRIs upon the expiration or termination of the UBC Collaborative Research Agreement. During the first 12-months of the Contract Period, \$913,500 is payable to UBC under the UBC Collaborative Research Agreement.

UBC will own inventions made solely by Institution employees in the research conducted under the UBC Collaborative Research Agreement ("**UBC Inventions**"). Subco and UBC will have joint right, title and interest in any inventions made by employees of the Institution and Subco ("**Joint Intellectual Property**").

Pursuant to the terms of the UBC Collaborative Research Agreement, UBC has granted Subco the option to negotiate a royalty-bearing license to use and exploit the UBC Inventions or Joint Intellectual Property. If Subco does not exercise the option, UBC may negotiate with Subco to acquire Subco's interest in the Joint Intellectual Property.

Subco may direct UBC to prepare or enforce patents in the name of UBC or in the names of UBC and Subco. UBC will be responsible for making final decisions regarding the scope and content of patent applications and prosecution. Subco will be responsible for all costs incurred in connection with the preparation, filing, prosecution and maintenance

of patent applications. Subco may discontinue financial support for the prosecution or maintenance of any patents by providing written notice to UBC.

The parties to the UBC Collaborative Research Agreement have agreed not to disclose the other party's confidential information without prior written consent, except when required to perform obligations or exercise rights under the agreement. Subco has agreed to indemnify the Institution for any claims arising out of Subco's receipt or use of the Institution's confidential information, UBC's intellectual property, Joint Intellectual Property, or other data or results arising from the Project.

Employees

We currently employ approximately 10 contract employees, including research staff management personnel and advisors under contract.

Foreign Operations

Our medicinal chemistry activities are overseen by Dr. Wang Shen at his laboratories in Shanghai, China and California, USA or at contract research organizations which may operate outside of Canada.

RISK FACTORS

Investing in our securities involves a high degree of risk. Before deciding to invest in our securities, you should carefully consider the risks described below, together with other information included in or incorporated by reference into this Annual Information Form and filed on SEDAR at www.sedar.com. If any of the following risks materialize, the business, financial condition, results of operation and future prospects of the Company will likely be materially and adversely affected. This could cause actual future events to differ materially from those described in forward-looking statements and may cause the trading price of our securities to decline. The following discussion highlights some of the risks and uncertainties facing the Company.

Risks Related to the Company's Financial Position and Need for Additional Capital

Company has never generated revenue from product sales. The Company expects to incur losses for at least the next several years and may never achieve or maintain profitability.

To date, the Company has devoted substantially all of its resources to organizing and staffing, business planning, raising capital, acquiring and discovering development programs, securing related intellectual property rights and conducting discovery, research and development activities for our research programs. As a result, the Company has not yet demonstrated its ability to successfully complete any clinical trials, including pivotal clinical trials, obtain marketing approvals, manufacture a commercial-scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. The Company expects that it will be several years, if ever, before it has a commercialized product. The Company expects to incur significant expenses and operating losses for the foreseeable future. The net losses the Company incurs may fluctuate significantly from quarter to quarter. In addition, the Company anticipates that expenses associated with the PARP Inhibitor Program Technology will increase substantially if the Company:

- identifies lead candidates for advancement into preclinical and clinical development;
- undertakes pivotal preclinical toxicology studies with lead candidates;
- undertakes current Good Manufacturing Practice ("cGMP") manufacturing of lead candidates;
- pursues the clinical development of product candidates;
- seeks regulatory approvals for any product candidates that successfully complete clinical trials;
- expands its operational, financial and management systems and increase personnel, including personnel to support its research, clinical development, manufacturing and commercialization efforts and its operations as a public company;
- maintain, expand and protect its intellectual property portfolio;

- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any products for which it may obtain marketing approval and intend to commercialize on its own or jointly; and
- acquire or in-license other product candidates and technologies.

To become and remain profitable, the Company or any potential future collaborator must develop and eventually commercialize products with significant market potential. This will require the Company to be successful in a range of challenging activities, including completing preclinical studies and clinical trials, obtaining marketing approval for product candidates, manufacturing, marketing and selling products for which the Company may obtain marketing approval and satisfying any post-marketing requirements. The Company may never succeed in any or all of these activities and, even if it does, it may never generate revenue that is significant or large enough to achieve profitability. If the Company does achieve profitability, it may not be able to sustain or increase profitability on a quarterly or annual basis. The Company's failure to become and remain profitable would decrease its value and could impair its ability to raise capital, maintain its research and development efforts, expand its business, or continue its operations. A decline in the value of the Company also could cause an investor to lose all or part of its investment in the Company.

The Company will require substantial additional financing, which may not be available on acceptable terms, or at all. A failure to obtain this necessary capital when needed could force the Company to delay, limit, reduce or terminate our research activities, product development or commercialization efforts.

The Company's operations consume substantial amounts of cash. The Company expects to spend substantial amounts to continue the preclinical and clinical development of its current and future programs. If the Company is able to gain marketing approval for product candidates that it develops, the Company will require significant additional amounts of cash in order to launch and commercialize such product candidates to the extent that such launch and commercialization are not the responsibility a collaborator that the Company may contract with in the future. In addition, other unanticipated costs may arise. Because the design and outcome of the Company's planned and anticipated clinical trials is highly uncertain, the Company cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidate the Company develops.

The Company's future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing the Company's product candidates and programs, and of conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining marketing approvals for the product candidates the Company develops, if clinical trials are successful;
- the establishment and success of collaborators that the Company may contract with in the future;
- the cost of commercialization activities for any product candidates the Company develops;
- the cost of manufacturing the Company's product candidates;
- the Company's ability to establish and maintain strategic collaboration, licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the timing, receipt and amount of sales of, or royalties on sales of, the Company's future products, if any;
- the emergence of competing products and other adverse market developments; and
- the requirement for, and cost of, developing complementary diagnostics and/or companion diagnostics.

The Company does not have any committed external source of funds or other support for its development efforts. Until the Company can generate sufficient product and royalty revenue to finance its cash requirements, which it may never do, the Company expects to finance its future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements.

If the Company raises additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, the Company may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to it. If the Company raises additional capital through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If the Company raises additional capital through debt financing, we would be subject to fixed payment obligations and may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If the Company is unable to obtain additional funding on favorable terms when needed, it may have to delay, reduce the scope of or suspend one or more of its research and development programs or clinical trials.

The Company has negative operating cash flow.

The Company has not generated cash flow from operations and therefore has negative cash flow from operating activities. The Company is devoting significant resources into researching and development, and therefore anticipates that it will have negative cash flow from operating activities in future periods. Until the Company is able to generate revenue from product sales, there can be no assurance that the Company will be able to generate a positive cash flow from its future operations.

Risks Related to Product Development and Regulatory Process

If the Company is unable to advance its current or future product candidates through clinical trials, obtain marketing approval and ultimately commercialize any product candidates it develops, or experiences significant delays in doing so, its business will be materially harmed.

The Company is early in its research and development efforts. The Company's ability to generate product revenues, which it does not expect will occur for several years, if ever, will depend heavily on the success of its research activities, favorable outcomes of clinical trials and eventual commercialization of the product candidates it develops, which may never occur. The Company's current product candidates, and any future product candidates it develops, will require additional preclinical and clinical development, management of clinical, preclinical and manufacturing activities, marketing approval in the United States and other markets, demonstrating effectiveness to pricing and reimbursement authorities, obtaining sufficient manufacturing supply for both clinical development and commercial production, building of a commercial organization, and substantial investment and significant marketing efforts before it generates any revenues from product sales. The success of the Company's current and future product candidates will depend on several factors, including the following:

- optimization of product candidates suitable for advancement into clinical trials;
- successful completion of preclinical studies and clinical trials;
- sufficiency of financial and other resources to complete the necessary preclinical studies and clinical trials;
- acceptance of INDs for our planned clinical trials or future clinical trials;
- successful enrollment and completion of clinical trials;
- successful data from the Company's clinical program that supports an acceptable risk-benefit profile of its product candidates in the intended populations;
- receipt of regulatory and marketing approvals from applicable regulatory authorities;
- establishing agreements with third-party manufacturers for clinical supply for the Company's clinical trials and commercial manufacturing, if the Company's product candidate is approved;
- entry into collaborations to further the development of the Company's product candidates;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for the Company's product candidates;
- successfully launching commercial sales of the Company's product candidates, if and when approved;
- acceptance of the product candidate's benefits and uses, if and when approved, by patients, the medical community and third-party payors;
- maintaining a continued acceptable safety profile of the product candidates following approval;
- effectively competing with other therapies; and
- enforcing and defending intellectual property rights and claims.

If the Company is not successful with respect to one or more of these factors in a timely manner or at all, it could experience significant delays or an inability to successfully commercialize the product candidates it develops, which would materially harm its business. If the Company does not receive marketing approvals any of the product candidates it develops, it may not be able to continue its operations.

Lead optimization and preclinical research is uncertain. The Company's preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect its ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all, which would have an adverse effect on its business.

The Company may fail to identify lead candidates suitable for advancement to clinical trials. Before the Company can commence clinical trials for a product candidate, it must complete extensive preclinical testing and studies that support its planned INDs in Canada, the United States or other jurisdictions. The Company cannot be certain of the timely completion or outcome of its preclinical testing and studies and cannot predict if Health Canada or the FDA will accept its proposed clinical programs or if the outcome of its preclinical testing and studies will ultimately support the further development of its programs. As a result, The Company cannot be sure that it will be able to submit INDs or similar applications for its preclinical programs on the timelines it expects, if at all, and it cannot be sure that submission of INDs or similar applications will result in Health Canada, the FDA or other regulatory authorities allowing clinical trials to begin.

Conducting preclinical testing is a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity, and novelty of the program, and often can be several years or more per program. Delays associated with programs for which the Company is directly conducting preclinical testing and studies may cause it to incur additional operating expenses. Moreover, the Company may be affected by delays associated with the preclinical testing and studies of certain programs that may become the responsibility of its potential future partners over which it has no control. The commencement and rate of completion of preclinical studies and clinical trials for a product candidate may be delayed by many factors, including, for example:

- an inability to generate sufficient preclinical or other *in vivo* or *in vitro* data to support the initiation of clinical studies;
- delays in reaching a consensus with regulatory agencies on study design; and
- regulatory authorities such as Health Canada or the FDA not allowing the Company to rely on previous findings of safety and efficacy for other similar but approved products and published scientific literature.

Moreover, even if clinical trials do begin for the Company's preclinical programs, the Company's development efforts may not be successful, and clinical trials that it conducts or that third-parties conduct on its behalf may not demonstrate sufficient safety, purity and potency or efficacy to obtain the requisite regulatory approvals for any of product candidates it develops. Even if the Company obtains positive results from preclinical studies or initial clinical trials, it may not achieve the same success in future trials.

The regulatory approval processes of Health Canada, the FDA, the EMA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if the Company is ultimately unable to obtain regulatory approval for its product candidates, its business will be substantially harmed.

The time required to obtain approval by Health Canada, the FDA, the EMA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. The Company has not obtained regulatory approval for any product candidate and it is possible that none of its current or future product candidates will ever obtain regulatory approval.

Clinical product development involves a lengthy and expensive process, with uncertain outcomes. The Company may experience delays in completing, or ultimately be unable to complete, the development and commercialization of our current and future product candidates.

To obtain the requisite regulatory approvals to commercialize any of the Company's product candidates, it must demonstrate through extensive preclinical studies and clinical trials that its products are safe, potent and effective in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process and the Company's future clinical trial results may not be successful.

The Company may experience delays in completing its clinical trials or preclinical studies and initiating or completing additional clinical trials. The Company may also experience numerous unforeseen events during its clinical trials that could delay or prevent its ability to receive marketing approval or commercialize the product candidates it develops, including:

- regulators or Institutional Review Boards ("IRBs"), or ethics committees may not authorize the Company or its investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- the Company may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations ("CROs");
- the number of patients required for clinical trials may be larger than the Company anticipates;
- it may be difficult to enroll a sufficient number of patients with a predictive biomarker or enrollment in these clinical trials may be slower than the Company anticipates or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than anticipated;
- third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require the Company to add new clinical trial sites or investigators; and
- the supply or quality of materials for product candidates the Company develops or other materials necessary to conduct clinical trials may be insufficient or inadequate.

The Company could encounter delays if a clinical trial is suspended or terminated by the Company, by the IRBs of the institutions in which such trials are being conducted or ethics committees, by the Data Safety Monitoring Board, for such trial or by Health Canada, the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols, inspection of the clinical trial operations or trial site by Health Canada, the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of marketing approval of the Company's product candidates.

If the Company experiences delays in the completion of, or termination of, any clinical trial of its product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing the Company's clinical trials will increase its costs, slow down its product candidate development and approval process and jeopardize its ability to commence product sales and generate revenues. Significant clinical trial delays could also allow its competitors to bring products to market before it does or shorten any periods during which it has the exclusive right to commercialize its product candidates and impair its ability to commercialize its product candidates and may harm its business and results of operations.

Any of these occurrences may harm the Company's business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of the Company's product candidates or result in the development of its product candidates being stopped early.

The results of preclinical studies and early-stage clinical trials may not be predictive of future results. Initial success in the Company's ongoing clinical trials may not be indicative of results obtained when these trials are completed or in later stage trials.

The results of preclinical studies may not be predictive of the results of clinical trials, and the results of any early-stage clinical trials commenced may not be predictive of the results of the later-stage clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. There can be no assurance that any current or future clinical trials will ultimately be successful or support further clinical development of any of the Company's product candidates. There is a high failure rate for drugs proceeding through clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies, and any such setbacks in the Company's clinical development could have a material adverse effect on its business and operating results.

The Company faces risks related to health epidemics and other outbreaks, which could significantly disrupt its operations and/or business.

In March 2020, the World Health Organization declared COVID-19 a global pandemic. This contagious disease outbreak, which has continued to spread, and any related adverse public health developments, has adversely affected workforces, economies, and financial markets globally, potentially leading to an economic downturn. It is not possible for the Company to predict the duration or magnitude of the adverse results of the outbreak and its effects on their ability to raise capital or conduct exploration activities. Operations will depend on obtaining necessary supplies, obtaining contractor services and safeguarding all personnel during the outbreak, which may be prohibitive or too costly.

The Company's business could be adversely impacted by the continued effects of the COVID-19 pandemic, or by other epidemics. A health epidemic or other outbreak, including the current COVID-19 outbreak, may materially and adversely affect the Company's business, including its ability to conduct clinical trials and develop its current and future product candidates. Such events could materially impact our financial condition, results of operations and the Company's ability to raise capital to support its research, development and commercialization activities.

The extent to which COVID-19 will continue to impact the Company's business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and actions or government mandated directives to contain COVID-19 or treat its impact, among others.

If the Company encounters difficulties enrolling patients in its clinical trials, its clinical development activities could be delayed or otherwise be adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on the Company's ability to enroll a sufficient number of patients who remain in the trial until its conclusion. The Company may experience difficulties in patient enrollment in its clinical trials for a variety of reasons. In addition, the Company's clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our current and potential future product candidates. This competition will reduce the number and types of patients available, because some patients who might have opted to enroll in the Company's trials may instead opt to enroll in a trial conducted by one of its competitors. Since the number of qualified clinical investigators is limited, the Company expects to conduct some of its clinical trials at the same clinical trial sites that some of its competitors use, which will reduce the number of patients who are available for its clinical trials at such sites. Moreover, because the Company's current and potential future product candidates may represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy, rather than enroll patients in our ongoing or any future clinical trial.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of clinical trials, which could prevent completion of these trials and adversely affect the Company's ability to advance the development of the product candidates it develops.

The Company's current or future product candidates may cause undesirable side effects or have other properties when used alone or in combination with other approved products or investigational new drugs that could halt their clinical development, prevent their marketing approval, limit their commercial potential or result in significant negative consequences.

Undesirable or clinically unmanageable side effects could occur and cause the Company or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of marketing approval by Health Canada, the FDA or comparable foreign regulatory authorities. Results of the Company's trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics.

If unacceptable toxicities or other undesirable side effects arise in the development of any of the Company's current or future product candidates, the Company, or its collaborators, could suspend or terminate the Company's trials, or Health Canada, the FDA or comparable foreign regulatory authorities could order the Company to cease clinical trials or deny approval of the product candidate for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may prevent the Company from achieving or maintaining market acceptance of the affected product candidate and may significantly harm the Company's business, financial condition and prospects.

Even if the Company completes the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent the Company or its potential future collaboration partners from obtaining approvals for the commercialization of any product candidate it develops.

Any current or future product candidate the Company may develop, and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by Health Canada, the FDA and other regulatory authorities in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent the Company from commercializing the product candidate in a given jurisdiction. The Company has not received approval to market any product candidates from regulatory authorities in any jurisdiction and it is possible that none of the product candidates it may seek to develop in the future will ever obtain regulatory approval. The Company has no experience in filing and supporting the applications necessary to gain marketing approvals and expects to rely on third-party CROs or regulatory consultants to assist it in this process.

Even if the Company receives marketing approval of a product candidate, it will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and it may be subject to penalties if it fails to comply with regulatory requirements or experience unanticipated problems with its products, if approved.

Any marketing approvals that the Company receives for any current or future product candidate may be subject to limitations on the approved indicated uses for which the product may be marketed or the conditions of approval, or contain requirements for potentially costly post-market testing and surveillance to monitor the safety, potency and efficacy of the product candidate. Regulatory authorities may also require a Risk Evaluation and Mitigation Strategy as a condition of approval of any product candidate, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if Health Canada, the FDA or a comparable foreign regulatory authority approves a product candidate, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import and export and record keeping for the product candidate will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and Good Clinical Practice ("GCP") for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with any approved product candidate, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things, the imposition of civil or criminal penalties.

Even if a current or future product candidate receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any current or future product candidate we develop receives marketing approval, whether as a single agent or in combination with other therapies, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors, and others in the medical community. For example, current approved therapies, including

immunotherapies, biologics, targeted therapy, chemotherapy and radiation therapy, are well established in the medical community, and doctors may continue to rely on these therapies. If the product candidates the Company develops do not achieve an adequate level of acceptance, it may not generate significant product revenues and it may not become profitable.

The market opportunities for any current or future product candidate the Company develops, if and when approved, may be limited to those patients who are ineligible for established therapies or for whom prior therapies have failed, and may be small.

Cancer therapies are sometimes characterized as first-line, second-line, or third-line, and approved new therapies may receive marketing approval from Health Canada, the FDA or similar international regulatory authorities initially only for third-line use. When cancer is detected early enough, first-line therapy, usually chemotherapy, hormone therapy, surgery, radiation therapy or a combination of these, is sometimes adequate to cure the cancer or prolong life without a cure. Second- and third-line therapies are administered to patients when prior therapy is not effective. The Company expects to initially seek approval of its product candidates as a therapy for patients who have received one or more prior treatments. Subsequently, for those products that prove to be sufficiently beneficial, if any, the Company would expect to seek approval potentially as a first-line therapy, but there is no guarantee that product candidates we develop, even if approved, would be approved for first-line therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

The number of patients who have the cancers the Company is targeting may turn out to be lower than expected. Additionally, the potentially addressable patient population for current programs or future product candidates may be limited, if and when approved. Even if the Company obtains significant market share for any product candidate, if and when approved, if the potential target populations are small, it may never achieve profitability without obtaining marketing approval for additional indications, including to be used as first- or second-line therapy.

The Company may develop its product candidates in combination with other therapies, which exposes it to additional risks.

The Company may develop our product candidates, in combination with one or more currently approved cancer therapies. Even if any product candidate the Company develops were to receive marketing approval or be commercialized for use in combination with other existing therapies, it would continue to be subject to the risks that Health Canada, the FDA or similar regulatory authorities outside of the United States could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. Combination therapies are commonly used for the treatment of cancer, and the Company would be subject to similar risks if it develops any of its product candidates for use in combination with other drugs or for indications other than cancer. This could result in the Company's own products being removed from the market or being less successful commercially.

The Company may also evaluate our product candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by Health Canada, the FDA or similar regulatory authorities outside of the United States. We will not be able to market and sell any product candidate we develop in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval.

If Health Canada, the FDA or similar regulatory authorities do not approve these other drugs or revoke their approval of, or if safety, efficacy, manufacturing, or supply issues arise with, the drugs we choose to evaluate in combination with our product candidates, we may be unable to obtain approval of or market any such product candidate we develop.

We face significant competition and if our competitors develop and market products that are more effective, safer or less expensive than the product candidates we develop, our commercial opportunities will be negatively impacted.

The life sciences industry is highly competitive. We are currently developing therapeutics that will compete, if approved, with other products and therapies that currently exist or are being developed.

Products we may develop in the future are also likely to face competition from other products and therapies, some of which we may not currently be aware. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, universities and other research institutions. Many of our competitors have significantly greater financial, manufacturing, marketing, product development, technical and human resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining marketing approvals, recruiting patients and manufacturing pharmaceutical products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. As a result of these factors, our competitors may succeed in obtaining patent protection and/or marketing approval or discovering, developing and commercializing products in our field before we do.

There are a large number of companies developing or marketing treatments for cancer, including many major pharmaceutical and biotechnology companies. These treatments consist both of small molecule drug products, such as traditional chemotherapy and targeted therapies, immunotherapies, gene therapies and biologics. We are aware of academic laboratories and companies such as AstraZeneca, Bristol Meyers Squibb, Celgene, Ascentage, Repair Therapeutics and others that are conducting research and drug development activities that could directly compete with our product candidates.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe effects, are more convenient, have a broader label, are marketed more effectively, are reimbursed or are less expensive than any products that we may develop. Our competitors also may obtain Health Canada, FDA, EMA or other marketing approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Even if the product candidate we develop achieve marketing approval, they may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness.

Smaller and other early-stage companies may also prove to be significant competitors. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. In addition, the biopharmaceutical industry is characterized by rapid technological change. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our product candidates obsolete, less competitive, or not economical.

Even if we are able to commercialize any product candidates, such products may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new products vary widely from country to country. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product candidate, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product candidate in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

Our ability to commercialize any product candidates, whether as a single agent or combination therapy, successfully also will depend in part on the extent to which coverage and reimbursement for these product candidates and related treatments will be available from government authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which

medications they will pay for and establish reimbursement levels. It is difficult to predict at this time what government authorities and third-party payors will decide with respect to coverage and reimbursement for our programs.

We may not be successful in our efforts to identify or discover other product candidates and may fail to capitalize on programs or product candidates that may present a greater commercial opportunity or for which there is a greater likelihood of success.

The success of our business depends upon our ability to identify, develop and commercialize product candidates. If we do not successfully develop and eventually commercialize products, we will face difficulty in obtaining product revenue in future periods, resulting in significant harm to our financial position and adversely affecting our share price. Research programs to identify new product candidates require substantial technical, financial and human resources, and we may fail to identify potential product candidates for numerous reasons.

Additionally, because we have limited resources, we may forego or delay pursuit of opportunities with certain programs or product candidates or for indications that later prove to have greater commercial potential.

We may seek Breakthrough Therapy Designation by the FDA for a product candidate that we develop, and we may be unsuccessful. If we are successful, the designation may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek Breakthrough Therapy Designation for any product candidate that we develop. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for accelerated approval and priority review.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe a product candidate we develop meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of Breakthrough Therapy Designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if the product candidates we develop qualify as breakthrough therapies, the FDA may later decide that the drugs no longer meet the conditions for qualification and rescind the designation.

We may seek Fast Track Designation by the FDA for a product candidate that we develop, and we may be unsuccessful. If we are successful, the designation may not actually lead to a faster development or regulatory review or approval process.

We may seek Fast Track Designation for the product candidates we develop. If a product is intended for the treatment of a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, the product sponsor may apply for Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may rescind the Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program.

We may seek Orphan Drug Designation for product candidates we develop, and we may be unsuccessful or may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for market exclusivity.

As part of our business strategy, we may seek Orphan Drug Designation for any product candidates we develop, and we may be unsuccessful. Regulatory authorities in some jurisdictions, including Canada, the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, Orphan Drug Designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers.

Similarly, in Europe, the European Commission grants Orphan Drug Designation after receiving the opinion of the EMA Committee for Orphan Medicinal Products on an Orphan Drug Designation application. Orphan Drug Designation is intended to promote the development of drugs that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than 5 in 10,000 persons in Europe and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would be a significant benefit to those affected). Additionally, designation is granted for drugs intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in Europe would be sufficient to justify the necessary investment in developing the drug. In Europe, Orphan Drug Designation entitles a party to a number of incentives, such as protocol assistance and scientific advice specifically for designated orphan medicines, and potential fee reductions depending on the status of the sponsor.

Generally, if a drug with an Orphan Drug Designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same drug and indication for that time period, except in limited circumstances. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for Orphan Drug Designation or if the drug is sufficiently profitable such that market exclusivity is no longer justified.

Even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product candidate from competition because different therapies can be approved for the same condition and the same therapies can be approved for different conditions but used off-label. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan Drug Designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. While we may seek Orphan Drug Designation for applicable indications for our current and any future product candidates, we may never receive such designations. Even if we do receive such designations, there is no guarantee that we will enjoy the benefits of those designations.

We are subject to certain, Canadian, U.S. and international anti-corruption, anti-money laundering, export control, sanctions, and other Trade Laws (as defined below) and regulations. We can face serious consequences for violations.

Among other matters, Canadian, U.S. and international anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations (collectively, “**Trade Laws**”), prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals,

universities, and other organizations. We also expect our non-U.S. activities to increase in time. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations may involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations may also produce hazardous waste products. We generally plan to contract with third parties for the disposal of such materials and wastes. We cannot eliminate the risk of contamination or injury from such materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Our current and future insurance policies may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous, or radioactive materials.

Risks Related to Reliance on Third Parties

We may seek to establish additional collaborations, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

The advancement of our product candidates and development programs and the potential commercialization of our current and future product candidates will require substantial additional cash to fund expenses. For some of our programs, we may decide to collaborate with additional pharmaceutical and biotechnology companies with respect to development and potential commercialization. Any of these relationships may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Our future collaborators may control aspects of our clinical trials, which could result in delays or other obstacles in the commercialization of the product candidates we develop. If our collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

Kanion USA Inc. (“**Kanion**”) owns rights to the kt-2000 series in the People’s Republic of China, Hong Kong and Taiwan. We will have certain obligations to share information with Kanion and they with us. In the future, we may seek to collaborate with Kanion or seek to form other strategic alliances, joint ventures, or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our research, development and commercialization efforts with respect to product candidates we develop.

Our current and potential future collaborations involving our product candidates may pose, the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- collaborators may not properly enforce, maintain or defend our intellectual property rights or may use our proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation, or other intellectual property proceedings;
- disputes may arise between a collaborator and us that cause the delay or termination of the research, development or commercialization of the product candidate, or that result in costly litigation or arbitration that diverts management attention and resources;
- if a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated; and
- collaboration agreements may restrict our right to independently pursue new product candidates.

As a result, if we enter into collaboration agreements and strategic partnerships or license our intellectual property, products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to any product candidate we develop could delay the development and commercialization of our product candidates, which would harm our business prospects, financial condition, and results of operations.

If conflicts arise between us and our collaborators or strategic partners, these parties may act in a manner adverse to us and could limit our ability to implement our strategies.

If conflicts arise between our corporate or academic collaborators or strategic partners and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Future collaborators or strategic partners, may develop, either alone or with others, products in related fields that are competitive with the products or potential products that are the subject of these collaborations. Competing products, either developed by the collaborators or strategic partners or to which the collaborators or strategic partners have rights, may result in the withdrawal of partner support for our product candidates. Our current or future collaborators or strategic partners may preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely, or fail to devote sufficient resources to the development and commercialization of products. Any of these developments could harm our product development efforts.

We will rely on third parties to conduct our planned clinical trials for our product candidates we develop. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain marketing approval for or commercialize any product candidates we develop and our business could be substantially harmed.

We do not expect to have the ability to independently conduct clinical trials. We will rely on medical institutions, clinical investigators, contract laboratories, and other third parties, such as CROs, to conduct or otherwise support clinical trials for our product candidates. We will rely heavily on these parties for execution of clinical trials for our product candidates and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on CROs will not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of our clinical trials, we could be subject to untitled and warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

We and our CROs are required to comply with regulations and requirements, including GCP, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical

trials and their rights are protected. These regulations are enforced by Health Canada, the FDA, the Competent Authorities of the Member States of the EEA and comparable foreign regulatory authorities for any drugs in clinical development. Regulatory authorities may enforce GCP requirements through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and Health Canada, the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, Health Canada, the FDA will determine that any of our future clinical trials will comply with GCP. In addition, our clinical trials must be conducted with product candidates produced under cGMP regulations. Our failure or the failure of our CROs to comply with these regulations may require us to repeat clinical trials, which would delay the marketing approval process and could also subject us to enforcement action. We also are required to register certain ongoing clinical trials and provide certain information, including information relating to the trial's protocol, on a government-sponsored database, ClinicalTrials.gov, within specific timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs on commercially reasonable terms, or at all. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain are compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials such CROs are associated with may be extended, delayed or terminated, and we may not be able to obtain marketing approval for or successfully commercialize our product candidates. As a result, we believe that our financial results and the commercial prospects for our product candidates in the subject indication would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Risks Related to Intellectual Property

Intellectual property is critical to our business and our success, in part, depends on our ability to maintain, protect, and expand our portfolio of intellectual property rights.

Biotechnology and pharmaceutical companies generally, and we in particular, compete in a crowded competitive space characterized by rapidly evolving technologies and aggressive defense of intellectual property. Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our proprietary technology and products. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and drug candidates.

Our patents and patent applications are directed to our product candidates and accompanying technologies. We seek patent protection for our development programs, product candidates and related alternatives by filing and prosecuting patent applications in the U.S. and other countries as appropriate.

If we are unable to obtain and maintain patent protection for any products we develop and for our technology, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to commercialize any product candidates we may develop, and our technology may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates and the accompanying technologies we develop that are important to our business. If we are unable to secure or maintain patent protection with respect to our technology and any proprietary products and technology we develop, our business, financial condition, results of operations, and prospects could be materially harmed.

Patent positions of life sciences companies can be uncertain and involve complex factual and legal questions. No consistent policy governing the scope of claims allowable in the field of drug development has emerged in the United States. The scope of patent protection in jurisdictions outside of the United States is also uncertain. Changes in either the patent laws or their interpretation in any jurisdiction that we seek patent protection may diminish our ability to protect our inventions, maintain and enforce our intellectual property rights; and, more generally, may affect the value of our intellectual property, including the narrowing of the scope of our patents and any that we may license.

The intellectual property landscape in the field of oncology therapeutics is crowded, and third parties may initiate legal proceedings alleging that we are infringing, misappropriating, or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Due to the intense research and development undertaken by academic institutions and multiple companies, including us and our competitors, in this field, the intellectual property landscape is in flux, and it may remain uncertain for the coming years. There may be significant intellectual property-related litigation and proceedings relating to our own and other third-party intellectual property and proprietary rights in the future.

Our development and commercialization rights to our current and future product candidates and technology may be subject, in part, to the terms and conditions of licenses granted to us by others.

We expect to be reliant upon licenses to certain patent rights and proprietary technology from third parties that are important or necessary to the engineering and development of our current and future product candidates. These and other licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we choose to develop or commercialize our technology and products in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses.

We engage in collaborations with scientists at academic and non-profit institutions to access technologies and materials that are not otherwise available to us. The agreements that govern these collaborations may include an option to negotiate an exclusive license to the institution's rights in any inventions that are created in the course of these collaborations, but we may not be able to come to a final agreement with an institution holding rights in an invention that is relevant to the development and commercialization of our technology.

In addition, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering the technology that we license from third parties. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our licensors fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our products that are the subject of such licensed rights could be adversely affected. Additionally, we may be required to reimburse our licensors for all of their expenses related to the prosecution, maintenance, enforcement and defense of patents and patent applications that we in-license from them.

Our licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Risks Related to Employee Matters, Managing Our Growth and Other Risks Related to Our Business

We are highly dependent on our key personnel, and if we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

We are highly dependent on members of our executive team. The loss of the services of any of them may adversely impact the achievement of our objectives. Any of our executive officers could leave our employment at any time, as all of our employees are “at-will” employees or consultants. We currently do not have “key person” insurance on any of our employees. The loss of the services of one or more of our current employees might impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining qualified employees, consultants and advisors for our business, including scientific and technical personnel, also will be critical to our success. Competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies and academic institutions for skilled individuals. In addition, failure to succeed in preclinical studies, clinical trials or applications for marketing approval may make it more challenging to recruit and retain qualified personnel. The inability to recruit, or the loss of services of certain executives, key employees, consultants or advisors, may impede the progress of our research, development and commercialization objectives and have a material adverse effect on our business, financial condition, results of operations and prospects.

Our employees, independent contractors, vendors, principal investigators, CROs and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk that our employees, independent contractors, vendors, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of Health Canada, the FDA and comparable foreign regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the United States and abroad; or laws that require the reporting of financial information or data accurately. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We intend to adopt, prior to the completion of this offering, a code of conduct applicable to all of our employees, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Global financial conditions may negatively impact the ability of the Company to in the future obtain equity or debt financing on terms favourable to the Company.

Global financial conditions have in recent years been, and continue to be, subject to heightened instability and increased volatility. Numerous financial institutions have experienced losses and either gone into bankruptcy or had to be rescued by governmental authorities. Access to public capital markets for junior companies has at times been restricted and/or cut off entirely, as credit markets froze following financial sector losses from sub-prime mortgages

and the collapse of the asset-backed commercial paper market. These factors may negatively impact the ability of the Company to in the future obtain equity or debt financing on terms favourable to the Company, if at all. If these increased levels of volatility and market turmoil continue, the Company’s operations and planned growth could be adversely impacted and the trading price of the Company’s securities could be adversely affected.

DIVIDENDS

The Company has not, since its inception, declared or paid any dividends on its Common Shares. The declaration of dividends on our Common Shares is within the discretion of the Board and will depend on the assessment of, among other factors, capital requirements, earnings, and the operating and financial condition of the Company. At the present time, Rakovina’s anticipated capital requirements are such that Rakovina follows a policy of retaining all available funds and any future earnings in order to finance Rakovina’s technology advancement, business development and corporate growth. Rakovina does not intend to declare or pay cash dividends on its Common Shares within the foreseeable future.

CAPITAL STRUCTURE

The authorized share capital of the Company is an unlimited number of Common Shares without par value. As at the date of this AIF, we have 69,829,500 Common Shares issued and outstanding as fully paid and non-assessable. As of the date of this AIF, there are 5,780,000 stock options and 12,733,690 Warrants to purchase Common Shares issued and outstanding.

Common Shares

All of the Common Shares of the Company are of the same class and, once issued, rank equally. The holders of Common Shares are entitled to dividends, if, as and when declared by the Board, to one vote per Common Share at meetings of the shareholders of the Company and, upon liquidation, to share equally in such assets of the Company as are distributable to the holders of Common Shares. There are no pre-emptive or conversion rights.

MARKET FOR SECURITIES

Trading Price and Volume

The Common Shares are listed on the TSX-V under the trading symbol “RKV”. The following table sets forth the reported high and low prices and the aggregate monthly volume of trading on the TSX-V during the most recently completed financial year:

	High	Low	Volume
January 2022	\$0.235	\$0.14	1,835,375
February 2022	\$0.20	\$0.185	229,285
March 2022	\$0.20	\$0.16	217,040
April 2022	\$0.18	\$0.15	174,000
May 2022	\$0.175	\$0.12	326,408
June 2022	\$0.175	\$0.13	315,107
July 2022	\$0.165	\$0.12	35,138
August 2022	\$0.16	\$0.115	141,100

September 2022	\$0.25	\$0.13	712,251
October 2022	\$0.20	\$0.17	669,000
November 2022	\$0.20	\$0.15	273,000
December 2022	\$0.195	\$0.135	321,150

PRIOR SALES

The following table summarizes details of each class of securities of the Company that is outstanding but not listed or quoted on a marketplace issued by the Company during the most recently completed financial year.

Date of Issuance/Grant	Type of Security	Number of Securities Issued	Issue/Exercise Price
May 25, 2022	Options	150,000	\$0.15

ESCROWED SECURITIES

The following table sets forth the securities of the Company subject to escrow or to a contractual restriction on transfer and the percentage that number represents of the outstanding securities of that class as of the date of this AIF.

Designation of Class	Number of securities held in escrow or are subject to a contractual restriction on transfer	Percentage of Class
Common Shares	9,225,000 ⁽¹⁾	13.2%

Notes:

- (1) The Common Shares are held pursuant to an escrow agreement dated March 25, 2021 among the Company, NewGen and Computershare Investor Services Inc. (the “**Escrow Agreement**”) in connection with the Qualifying Transaction.

DIRECTORS AND OFFICERS

The names of the directors and executive officers of the Company as of the date hereof, their province or state and country of residence, their respective positions with our Company and the date upon which the directors were first elected to the Board are set out in the table below. The term of each director expires on the date of our next annual meeting.

Name and Residence	Position with the Company	Principal Occupation for Past Five Years	Director Since
Jeffrey Bacha ⁽¹⁾⁽²⁾ British Columbia, Canada	Executive Chairman and Director	CEO and Director, Edison Oncology Holding Corp.; Director, NewGen Therapeutics; President, CEO and Director, DelMar Pharmaceuticals	Since March 25, 2021

Name and Residence	Position with the Company	Principal Occupation for Past Five Years	Director Since
Dr. Dennis Brown ⁽²⁾ California, United States	Director	Director of NewGen prior to 2018	Since March 25, 2021
Alfredo De Lucrezia ⁽¹⁾⁽²⁾ British Columbia, Canada	Vice Chairman and Director	President, CEO and Director, Califfi Capital Corp. and Vincero Capital Corp.	Since May 6, 2019
Michael Liggett, CPA ⁽¹⁾ British Columbia, Canada	Director	President, OGEE Finance Solutions Corp.	Since March 25, 2021
Mads Daugaard, PhD British Columbia, Canada	President and Chief Scientific Officer	Senior Researcher, Vancouver Prostate Center; Associate Professor, University of British Columbia; Chairman of the Board of Directors, VAR2 Pharmaceuticals, OncoMal, and Diagnostics	N/A
John Langlands, PhD British Columbia, Canada	Chief Operating Officer	Principal and Owner, Langlands & Associates Consulting Inc.	N/A
David Hyman, CPA Alberta, Canada	Chief Financial Officer and Corporate Secretary	Contract CFO, Tandem Innovation Group; CFO, Theracann International; CFO, Merrco Payments	N/A

Notes:

- (1) Current member of the Audit Committee of the Board (the “**Audit Committee**”).
- (2) Current member of the Governance and Nomination Committee.

As of the date of this AIF, the directors and executive officers of the Company owned, directly or indirectly, or exercised control or direction over 31,865,635 (45.6%) of the issued and outstanding Common Shares of the Company.

Cease Trade Orders

To the best of our knowledge, no director or executive officer of the Company, is, or within the ten years prior to the date hereof, has been, a director, chief executive officer or chief financial officer that: (i) while that person was acting in that capacity was the subject of a cease trade order or similar order or an order that denied the other issuer access to any exemptions under Canadian securities legislation, that was in effect for a period of more than thirty consecutive days or, (ii) after that person ceased to act in that capacity, was the subject of a cease trade order or similar order, or an order that denied the other issuer access to any exemptions under Canadian securities legislation, that was in effect

for a period of more than thirty consecutive days and which resulted from an event that occurred while that person was acting in that capacity.

Penalties or Sanctions

To the best of our knowledge, no director or executive officer of the Company, or a shareholder holding a sufficient number of shares of the Company to affect materially the control of the Company, has been subject to any penalties or sanctions imposed by a court relating to Canadian securities legislation or by a Canadian securities regulatory authority or has entered into a settlement agreement with a Canadian securities authority, or any other penalties or sanctions imposed by a court or regulatory body that would likely be considered important to a reasonable investor in making an investment decision.

Personal Bankruptcies

To the best of our knowledge, no director or executive officer of the Company, or a shareholder holding a sufficient number of shares of the Company to affect materially the control of the Company, (i) has, during the ten years prior to the date hereof, been a director or executive officer of any company that, while that person was acting in that capacity, become bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency, or been subject to or instituted any proceedings, arrangement or compromise with creditors, or had a receiver, receiver manager or trustee appointed to hold his, her or its assets or (ii) has, during the ten years prior to the date hereof, become bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency, or been subject to or instituted any proceedings, arrangement or compromise with creditors, or had a receiver, receiver manager or trustee appointed to hold his, her or its assets.

Conflicts of Interest

Concurrent with their roles with the Company, the directors and officers of the Company are engaged in, and will continue to be engaged in, either individually or with other directors and officers of the Company, other business activities on their own behalf and on behalf of other companies.

In the event that a director or senior officer of the Company believes the potential for a conflict exists, in accordance with the BCBCA, the director or senior officer will disclose his or her interest in such property, contract, agreement or engagement and shall refrain from voting on any matter in respect of such property, contract, agreement or engagement.

To the knowledge of the management of the Company, as at the date hereof, there are no existing or potential material conflicts of interests between the Company and a director or officer of the Company except as otherwise disclosed in this Annual Information Form.

AUDIT COMMITTEE INFORMATION

Audit Committee Charter

The primary function of the Audit Committee is to assist the Board in fulfilling its oversight responsibilities with respect to the quality and integrity of the consolidated financial statements of the Company; appointing and overseeing the external auditors and reviewing the qualifications and independence of the external auditors; reviewing the performance of the external auditors; ensuring compliance by the Company with all legal and regulatory requirements for audit and related financial functions of the Company; reviewing financial information contained in public filings of the Company; reviewing earnings announcements of the Company prior to release to the public; monitoring the Company's systems of and compliance with internal financial controls; reviewing the Company's auditing, accounting and financial reporting processes; and dealing with all complaints regarding accounting, internal accounting controls and auditing matters. The Audit Committee Charter is attached as Appendix "A".

Composition of Audit Committee

The Audit Committee consists of Michael Liggett, Jeffrey Bacha and Alfredo De Lucrezia. The Board has determined that Mr. Liggett is “independent” as such term is defined in National Instrument 52-110 – *Audit Committees* (“**NI 52-110**”), and Mr. Bacha and Mr. De Lucrezia are not “independent”. Mr. Liggett and Mr. De Lucrezia are the non-executive officers, employees or control person members of the Audit Committee. In addition, our Board has determined that each member of the Audit Committee is “financially literate” under NI 52-110.

Relevant Education and Experience

The education and experience of each member of the Audit Committee that is relevant to the performance of his responsibilities as a member of the Audit Committee is described below:

Michael Liggett

Michael Liggett has over 19 years of financial experience in public companies, completing over \$300 million in equity and debt financing and approximately \$200 million in merger and acquisition transactions. Previously, Mr. Liggett acted as Chief Financial Officer of Eacom Timber Corporation (“**Eacom**”), a start-up softwood lumber company listed on the TSX-V. Prior to Eacom, Mr. Liggett acted as the Chief Financial Officer of Inflazyme Pharmaceuticals Ltd. (“**Inflazyme**”), an early-stage company focused on research and development for new drugs in inflammation. At Inflazyme, Mr. Liggett structured the largest life sciences strategic partnership in Canada at that time and completed over \$100 million in private placements and secondary offerings and listed the company on the Toronto Stock Exchange. Mr. Liggett is a Chartered Professional Accountant and worked for PwC prior to joining Inflazyme.

Jeffrey Bacha

Jeffrey Bacha currently serves as Chief Executive Officer of Edison Oncology Holding Corp., a company he co-founded in 2018 to develop and commercialize new cancer treatments. From 2010 to 2017, Mr. Bacha served as Chief Executive Officer and Chairman of DelMar Pharmaceuticals (now Kintara Therapeutics, Inc., NASDAQ: KTRA) a company he co-founded in 2010. Mr. Bacha led the company’s growth from founding through initiation of pivotal registration-directed clinical trials and its listing on NASDAQ. Since 2005 until founding DelMar Pharmaceuticals, Mr. Bacha has consulted with a number of life sciences companies and served as Executive Vice President, Corporate Affairs and Chief Operating Officer of Clera Inc. From 2008 to 2022, Mr. Bacha served on the Board of Sernova Corp., where he served as a member of the audit committee and as chair of the compensation committee. From 2002 through 2005 Mr. Bacha served as Founding Chief Executive Officer of Inimex Pharmaceuticals, where he was responsible for establishing the company’s research & development team and leading venture capital financing and grant funding efforts which raised more than \$35 million to support the company’s research programs. From 1999 to 2002, Mr. Bacha served as Vice President, Corporate Development of Inflazyme Pharmaceuticals Ltd. Prior to his operating roles, Mr. Bacha served as Senior Manager and Director of KPMG Health Ventures. He holds an MBA from the Goizueta Business School at Emory University and a degree in biophysics from the University of California, San Diego School at Emory University and a degree in biophysics from the University of California, San Diego.

Alfredo De Lucrezia

Alfredo De Lucrezia is an experienced businessman who has founded a number of publicly listed companies. From 2013 to 2016, Mr. De Lucrezia was Chief Executive Officer, Chief Financial Officer, President and Director of Manera Capital Corp. (now GT Gold - 24 - Corp.). He also founded Califfi Capital Corp., and has been its Chief Executive Officer since 2017, as well as Vincero Capital Corp. Mr. De Lucrezia has been a director and/or officer for reporting issuers over the past 25 years, culminating in a wealth of experience in board management, company growth, and strategy. Currently, Mr. De Lucrezia manages a multi-million dollar real estate and business portfolio of private companies. He obtained a Business Administration Diploma from Capilano College in 1988.

Audit Committee Oversight

Since the commencement of the Company's most recently completed financial year, there has not been a recommendation of the Audit Committee to nominate or compensate an external auditor which was not adopted by the Board.

Pre-Approval of Audit Services and Permitted Non-Audit Services

The Audit Committee has not adopted specific policies and procedures for the engagement of non-audit services.

External Auditor Service Fees

The following table sets forth, by category, the fees billed by Davidson & Company LLP to the Company for each of the last two fiscal years for audit services. During these years, Davidson & Company LLP was the Company's only external auditor.

Financial Year Ending	Audit Fees	Audit Related Fees ⁽¹⁾	Tax Fees ⁽²⁾	All Other Fees ⁽³⁾	Total
December 31, 2021	\$26,500.00	\$12,000.00	\$3,000.00	Nil	\$41,500.00
December 31, 2022	\$28,000.00	Nil	\$14,300.00	Nil	\$42,300.00

Notes:

- (1) Audit related fees are for review and prospectus work and filing statement work not included under "Audit Fees".
- (2) Tax fees are for tax advisory services provided to management, including tax compliance, tax advice, and tax planning.
- (3) All other fees include fees provided to the Company's auditor, other than fees under "Audit Related Fees" and "Tax Fees".

LEGAL PROCEEDINGS AND REGULATORY ACTIONS

There are no pending or contemplated legal proceedings to which the Company is a party or of which any of our properties is the subject.

As of December 31, 2022 and the date of this AIF, the Company is not subject to:

- (a) any penalties or sanctions imposed against the Company by a court relating to securities legislation or by a securities regulatory authority during the financial year ended December 31, 2022; or
- (b) any other penalties or sanctions imposed by a court or regulatory body against the Company that would likely be considered important to a reasonable investor in making an investment decision; or
- (c) settlement agreements the Company entered into before a court relating to securities legislation or with a securities regulatory authority during the financial year ended December 31, 2022.

The Company is unaware of any condition of default under any debt, regulatory, exchange related or other contractual obligation.

INTEREST OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS

Except as described below, no director, officer or principal shareholder of the Company, or any associate or affiliate of any of the foregoing persons or entities, has any direct or indirect material interest in any transaction within three years of the date of this Annual Information Form or in any proposed transaction of the Company that has materially affected or will materially affect the Company or any of our subsidiaries.

On May 15, 2019, the Company entered into a transaction with Alfredo De Lucrezia, the Company's then President and Chief Executive Officer, pursuant to which the Company agreed to pay \$2,500 per month for rent and the provision of office and administrative services at the Company's head office. Mr. De Lucrezia was also additionally reimbursed

for the cost of all supplies required by the Company in carrying on its business at the office, all utility bills related thereto, and for any additional expenses in respect of other administrative and general expenses incurred by him on behalf of the Company.

Alfredo De Lucrezia is currently and was at the time of the Qualifying Transaction, a director of the Company and of Vincero Capital Corp. At the time of the Qualifying Transaction, Mr. De Lucrezia owned, directly and indirectly 4,000,000 common shares in the capital of Vincero Capital Corp., which represented approximately 26.67% of the total Vincero Capital Corp. common shares issued and outstanding immediately before closing of the Qualifying Transaction. Additionally, NewGen, a party to the Business Combination Agreement, currently owns 24,265,625 Common Shares, which represents approximately 35% of the issued and outstanding Common Shares of the Company. NewGen is a wholly owned subsidiary of Edison Oncology Holding Corp., a company controlled by Jeffrey Bacha, a director and Executive Chairman of the Company, and Dennis Brown, a director of the Company.

REGISTRAR AND TRANSFER AGENT

The registrar and transfer agent for the Common Shares is Odyssey Trust Company, 323 – 409 Granville Street, Vancouver, British Columbia, Canada, V6C 1T2.

MATERIAL CONTRACTS

The following are the material contracts of the Company as defined in National Instrument 51-102 - *Continuous Disclosure Obligations* that are outstanding as of the date of this AIF:

- (a) Escrow Agreement. See “*Escrowed Securities*” for additional information;
- (b) Evaluation and Option Agreement. See “*General Development of the Business – Three Year History*” for additional information;
- (c) Collaborative Research Agreement. See “*General Development of the Business – Three Year History*” for additional information; and
- (d) Contribution Agreement. See “*The Business*” for additional information.

INTERESTS OF EXPERTS

Our auditor is Davidson & Company LLP, Chartered Accountants, of Vancouver, British Columbia. Davidson & Company LLP has advised the Company that it is independent in accordance with the rules of professional conduct of the Institute of Chartered Accountants of British Columbia.

ADDITIONAL INFORMATION

Additional information relating to the Company, including information relating to the Qualifying Transaction, directors’ and officers’ remuneration and indebtedness, principal holders of our securities and securities authorized for issue under equity compensation plans is contained in our filing statement dated March 17, 2021 and filed at www.sedar.com and our Notice of Annual General Meeting and Management Information Circular dated May 25, 2021 and filed at www.sedar.com. Additional financial information is provided in our audited consolidated financial statements and management’s discussion and analysis for our most recently completed financial year, each of which and is available under the Company’s profile at www.sedar.com.

**APPENDIX “A”
Audit Committee Charter**

Purpose

The audit committee (the “Committee”) of Rakovina Therapeutics Inc. (the “Company”) is responsible for ensuring accounting integrity and solvency. The Committee is also responsible for ensuring the appropriateness of insurance, investment of liquid funds, information security policies, material contracts and events that could lead to material liabilities. The Committee will assist the board of directors of the Corporation (the “Board”) in fulfilling its oversight responsibilities by:

- reviewing the integrity of the consolidated financial statements of the Company;
- appointing and removing (subject to shareholder ratification if required), determine funding for, and oversee the external auditors and reviewing the external auditors’ qualifications and independence;
- reviewing the performance of the Company’s external auditors;
- in conjunction with the Chief Financial Officer, reviewing the timely compliance by the Company with all legal and regulatory requirements for audit and related financial functions of the Company;
- in conjunction with the Chief Financial Officer, reviewing financial information contained in public filings of the Company prior to filing;
- in conjunction with the Chief Financial Officer, reviewing earnings announcements of the Company prior to release to the public;
- in conjunction with the Chief Financial Officer, reviewing the Company’s systems of and compliance with internal financial controls;
- in conjunction with the Chief Financial Officer, reviewing the Company’s auditing, accounting and financial reporting processes;
- dealing with all complaints brought to the attention of the audit committee regarding accounting, internal accounting controls and auditing matters; and
- dealing with any issues that result from the reviews set forth above.

Membership and Reporting

The Committee will be comprised of directors and will have a minimum of three members. All members of the Committee must have a working familiarity with basic finance and accounting practices and be able to read and understand financial statements.

Appointments and replacements to the Committee will be made by the Board and will be reviewed on an annual basis. The Board will provide for continuity of membership, while at the same time allowing fresh perspectives to be added.

The chairman of the Committee (the “Chairman”) will be appointed by a majority vote of the Board on an annual basis.

The Committee will report to the Board, at the next scheduled meeting of the Board, the proceedings of the Committee and any recommendations made by the Committee.

Each member of the Committee will be “financially literate”, as such term is defined in National Instrument 52-110”.

The external auditors will report directly to the Committee.

Terms of Reference

1. The Committee is responsible for overseeing the work of the external auditors and will communicate directly with the external auditors as required.
2. The Committee will meet as required, but at least once quarterly (to review the quarterly financial statements, management accounting, management discussion and analysis (“MD&A”) and any related press release before such documents are presented to the Board or filed with regulatory authorities, as the case may be). Special meetings of the Committee will be authorized at the request of any member of the Committee or at the request of the Company’s external auditors. The external auditors will be informed about, and can attend, meetings of the Committee as deemed appropriate by the Chairman of the Committee. Provision will be made to meet privately with external auditors on a quarterly basis and to meet privately with management at least once per annum.
3. The Committee will review, with the external auditors, the results of the external audit and any changes in accounting practices or policies and the financial statements impact thereof. In addition, the Committee will review any accruals, provisions, or estimates that have a significant effect upon the financial statements as well as other sensitive matters such as disclosure of related party transactions.
4. The Committee will review and approve interim financial statements, MD&A and any related press release on behalf of the Board and sign a resolution to that effect.
5. In addition, the Committee will review other financial statements, information and documents that require the approval of the Board. These will include year-end audited statements, year-end MD&A, statements in prospectuses and other offering memoranda and statements required by regulatory authorities. The Committee will sign a resolution to the effect that such financial statements, information or documents that are being presented to the Board are satisfactory, and recommend their approval.
6. The Committee will review and discuss with management and the external auditors any major issue as to the adequacy and effectiveness of internal controls over the accounting and financial reporting systems of the Company, either directly, or through the external auditors or other advisors and obtain and review a report from the external auditors, at least annually, regarding same; and the Committee will review and discuss with management and the external auditors any special steps adopted in light of material internal control deficiencies and the adequacy of disclosures about changes in internal controls over financial reporting.
7. The Committee will review any policies and practices developed by the Company regarding the regular examination of officers’ expenses and perquisites, including the use of the assets of the Company.
8. The Committee will review the basis and amount of the external auditors’ fees and pre-approve all auditing services and permitted non-audit services.
9. The Committee will consider whether the external auditors should be re-appointed and make recommendations to the Board. At least on an annual basis, the Committee will evaluate the qualifications, performance and independence of the external auditors and the senior audit partners having primary responsibility for the audit, including considering whether the auditors’ quality controls are adequate.
10. The Committee will pre-approve the appointment of the external auditors for all accounting services, internal control related services and permitted non-audit services to be provided to the Company. The Committee may establish policies and procedures, from time to time, pre-approving the appointment of the external auditors for certain non-audit services. In addition, the Committee may delegate to one or more members the authority to pre-approve the appointment of the external auditors for any non-audit service to the extent permitted by applicable law, provided that any pre-approvals granted pursuant to such delegation will be reported to the full Committee at its next scheduled meeting.

11. The Committee will review and approve the Company's hiring of partners and employees of the external auditors of the Company.
12. The Committee will establish procedures for the receipt, retention and treatment of complaints received by the Company regarding accounting, internal accounting controls or auditing matters and for the confidential, anonymous submission by employees of the Company of concerns regarding questionable accounting or auditing matters.
13. The Committee will review and reassess the adequacy of this mandate annually.
14. The Committee has the authority, to the extent it deems necessary or appropriate, to retain independent legal, accounting or other advisors ("Advisors"). The Company will provide appropriate funding, as determined by the Committee, for payment of compensation to the external auditors for the purpose of rendering or issuing an audit report and to any Advisors employed by the Committee.
15. The Committee will issue any necessary reports required of the Committee to be included in the Company's annual proxy statement. The Committee will review and recommend to the Board the approval of all documents filed with securities regulatory authorities.
16. The Committee will approve all related party transactions brought to the attention of the Committee.
17. The Committee will discuss with management and the external auditors any correspondence with regulators or governmental agencies and any published reports that raise material issues regarding the Company's financial statements or accounting policies.
18. The Committee will receive from the external auditors a formal written statement delineating all relationships between the external auditors and the Company and will actively engaging in a dialogue with the external auditors with respect to any disclosed relationships or services that may impact the objectivity and independence of the external auditors.