
# DEFENCE THERAPEUTICS INC.

# ANNUAL INFORMATION FORM

For the Financial Year Ended June 30, 2021

Dated November 22, 2021

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## ANNUAL INFORMATION FORM

In this Annual Information Form, unless otherwise noted or the context indicates otherwise, the "Company", "Defence", "we", "us" and "our" refer to Defence Therapeutics Inc. and its subsidiaries.

All financial information in this Annual Information Form is prepared in Canadian dollars, unless otherwise indicated, and using International Financial Reporting Standards as issued by the International Accounting Standards Board. The information contained herein is dated as of November 22, 2021, unless otherwise stated.

## FORWARD-LOOKING STATEMENTS

This Annual Information Form contains certain statements which may constitute "forward-looking information" and "forward-looking statements" within the meaning of Canadian securities law requirements (collectively, "**forward-looking statements**"). These forward-looking statements are made as of the date of this Annual Information Form and the Company does not intend, and does not assume any obligation, to update these forward-looking statements, except as required under applicable securities legislation. Forward-looking statements relate to future events or future performance and reflect Company management's expectations or beliefs regarding future events. In certain cases, forward-looking statements can be identified by the use of words such as "plans", "expects" or "does not expect", "is expected", "budget", "scheduled", "estimates", "forecasts", "intends", "anticipates" or "does not anticipate", or "believes", or variations of such words and phrases or statements that certain actions, events or results "may", "could", "would", "might" or "will be taken", "occur" or "be achieved" or the negative of these terms or comparable terminology. In this document, certain forward-looking statements are identified by words including "may", "future", "expected", "intends" and "estimates". By their very nature forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of the Company to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. The Company provides no assurance that forward-looking statements will prove to be accurate, as actual results and future events could differ materially from those anticipated in such statements. Accordingly, readers should not place undue reliance on forward-looking statements. Certain forward-looking statements in this Annual Information Form include, but are not limited to, statements relating to or concerning our expectations for the following:

- the pre-clinical testing of the Accum technology in connection with the enhancement of the therapeutic efficacy of cell-based vaccination and the costs associated therewith;
- the ability of the Accum technology to increase T-DM1 effectiveness with further development;
- the budget to modify ADCs with the Accum technology;
- the Company negotiating a formal agreement with Heidelberg Pharma with respect to its Accum-αA-ADCs platform;
- the development of an "intelligent" Poly-AccuTOX molecule (a chain of various AccuTOX molecules) and the costs associated therewith;
- the development of HPV-related vaccines and the costs associated therewith, including the costs of the two pre-clinical projects;
- the development of the Company's COVID- 19 vaccine using the Accum technology;
- the Company's current financial resources being sufficient to fund operations for the next 12 months; and

- the market potential for the Company's products;

The above and other aspects of the Company's anticipated future operations are forward-looking in nature and, as a result, are subject to certain risks and uncertainties. Although the Company believes that the expectations reflected in these forward-looking statements are reasonable, undue reliance should not be placed on them as actual results may differ materially from the forward-looking statements. Such forward-looking statements are estimates reflecting the Company's best judgment based upon current information and involve a number of risks and uncertainties, and there can be no assurance that other factors will not affect the accuracy of such forward-looking statements. Such factors include but are not limited to the Company being a start-up in the early stages of its product development, the Company's ability to obtain the necessary financing, the general impact of financial market conditions, competition, government regulations, the impacts of COVID-19 on the business of the Company and on the economy generally, and other risks as set out under "Risk Factors" below.

## GLOSSARY OF TERMS

The following is a glossary of certain terms used in this Annual Information Form.

"**Accum Invention**" means the invention known as "Novel Immunoconjugates with cholic acid nuclear localization sequence peptide and uses thereof".

"**Accum Therapeutics**" means Accum Therapeutics Inc., a precursor entity to the Company.

"**ADC**" means antibody drug conjugates.

"**AIF**" or "**Annual Information Form**" means this annual information form of the Company dated November 22, 2021 for the year ended June 30, 2021;

"**Amended IP Assignment and Royalty Agreement**" means the Amended and Restated Intellectual Property Assignment and Royalty Agreement between the Company and TTS which amends the Original IP Assignment and Royalty Agreement.

"**Athena**" means Athena Ventures Inc.

"**Audit Committee**" means the audit committee of the Company.

"**Audit Committee Charter**" means the Audit Committee's Charter, attached hereto as Exhibit "B".

"**BCBCA**" means the *Business Corporations Act* (British Columbia), as amended, together with all regulations promulgated thereto.

"**BLA**" means Biologics License Application.

"**Board**" means the Board of Directors of the Company.

"**Business Day**" means a day other than Saturday, Sunday or a statutory holiday in British Columbia, Canada.

"**CAGR**" means compound annual growth rates.

"**CEO**" means Chief Executive Officer.

"**CFO**" means Chief Financial Officer.

"**cGMP**" means current Good Manufacturing Practice.

"**Common Share**" means a Class A common share in the capital of the Company.

"**Company**" means Defence Therapeutics Inc., a company incorporated on July 18, 2017 under the *Business Corporations Act* (Québec) and continued under the laws of the Province of British Columbia on July 10, 2020.

"**company**" means unless specifically indicated otherwise, a corporation, incorporated association or organization, body corporate, partnership, trust, association or other entity other than an individual.

"**CSE**" or the "**Exchange**" means the Canadian Securities Exchange operated by the CNSX Markets Inc.

"**CTA**" means a Clinical Trial Application.

"**CTSO**" means Chief Technical Science Officer.

"**DCs**" means dendritic cells.

"**DRS**" means the Direct Registration System.

"**FDA**" means the Food and Drug Administration in the U.S.

"**FDCA**" means the Federal Food, Drug and Cosmetic Act in the U.S.

"**Finder's Warrants**" means (a) the 1,071,400 warrants to purchase Common Shares issued to certain eligible finders pursuant to the Private Placement, which are exercisable into Common Shares at $0.15 for a period of 36 months after becoming a Reporting Issuer, and (b) the 850,000 warrants to purchase Common Shares issued to certain eligible finders pursuant to the Unit Offering and the Special Warrant Offering, which are exercisable into Common Shares at $0.60 until May 7, 2023.

"**First Tranche**" means the first tranche of the Private Placement, pursuant to which 15,180,000 Common Shares were issued on June 18, 2020 at a price of $0.15 per Common Share.

"**GCP**" means Good Clinical Practice.

"**GLP**" means Good Laboratory Practice.

"**GMP**" means the Good Manufacturing Practices.

"**IgG**" means immunoglobulin G antibody.

"**IND**" means Investigational New Drug.

"**Insider**" means:

(a) a director or senior officer of the Company;

(b) a director or senior officer of the Company that is an Insider or subsidiary of the Company,

(c) a Person that beneficially owns or controls, directly or indirectly, Common Shares carrying more than 10% of the voting rights attached to all outstanding voting shares of the Company; or

(d) the Company itself if it holds any of its own securities.

"**IRB**" means Independent Review Boards.

"**mAb**" means monoclonal antibody.

"**MD&A**" means management's discussion and analysis of financial condition and operating results.

"**NDS**" means a New Drug Submission submitted to Health Canada.

"**NI 52-110**" means National Instrument 52-110 – *Audit Committees.*

"**NI 58-101**" means National Instrument 58-101 – *Disclosure of Corporate Governance Practices*.

"**NLS**" means nuclear localization signal.

"**NOL**" means a No Objection Letter issued from Health Canada.

"**Option**" or "**Options**" means options issued pursuant to the Stock Option Plan.

"**Original IP Assignment and Royalty Agreement**" means the Intellectual Property Assignment and Royalty Agreement amongst Accum Therapeutics, Michel Delisle, TTS, Simon Beaudoin and Jeffrey Leyton.

"**Person**" or "**Entity**" means an individual, natural person, corporation, government or political subdivision or agency of a government, and where two or more persons act as a partnership, limited partnership, syndicate or other group for the purpose of acquiring, holding or disposing of securities of the Company, such syndicate or group will be deemed to be a Person or Entity.

"**Private Placement**" means the non-brokered private placement of the Company of 21,415,000 Common Shares at a price of $0.15 per Common Share for gross proceeds of $3,212,250, the First Tranche of which completed on June 18, 2020 and pursuant to which 15,180,000 Common Shares were issued, the Second Tranche of which completed on August 31, 2020 and pursuant to which 4,200,000 Common Shares were issued, the Third Tranche of which completed on October 9, 2020 and pursuant to which 2,035,000 Common Shares were issued.

"**REB**" means Research Ethics Boards.

"**Reporting Issuer**" means, inter alia, a company that has issued securities in respect of which a prospectus was filed and a receipt was issued by a Securities Commission of a province in Canada, has any securities that have been listed and trading on an exchange in Canada or completed a takeover with a listed issuer.

"**RPII**" means the enzyme RNA Polymerase II.

"**Second Tranche**" means the second tranche of the Private Placement, pursuant to which 4,200,000 Common Shares were issued on August 31, 2020 at a price of $0.15 per Common Share.

"**Sediamek**" means Sediamek Inc.

"**Shareholders**" means holders of Common Shares.

"**Socpra**" means Socpra Sciences Sante Et Humaines, S.e.c., operating under the name of TransferTech Sherbrooke, a limited partnership constituted under the Civil Code of Quebec.

"**Special Warrant Offering**" means the non-brokered private placement of the Company of 6,137,000 Special Warrants for gross proceeds of $3,682,200 which completed on December 24, 2020 and January 25, 2021, and which resulted in the deemed exercise of Special Warrants for 6,137,000 Common Shares and 6,137,000 Warrants.

"**Special Warrants**" means the special warrants issued by the Company at a price of $0.60 per Special Warrant, pursuant to the Special Warrant Offering, each of which was deemed to be converted, for no additional consideration, into one Common Share and one Warrant.

"**Stock Option Plan**" means the 10% rolling stock option plan of the Company providing for the granting of incentive Options to the Company's directors, officers, employees and consultants in accordance with the rules and policies of the Exchange.

"**Third Tranche**" means the third tranche of the Private Placement, pursuant to which 2,035,000 Common Shares were issued on October 9, 2020 at a price of $0.15 per Common Share.

"**Transfer Agent**" means the transfer agent and registrar of the Company, Computershare Trust Company of Canada.

"**TTS**" means TransferTech Sherbooke.

"**Unit Offering**" means the non-brokered private placement of the Company of 2,588,000 Units at a price of $0.60 per Unit for gross proceeds of $1,552,800, which completed on December 24, 2020 and January 25, 2021.

"**Units**" means units of the Company sold pursuant to the Unit Offering, with each Unit comprised of one common share and one Unit Warrant.

"**Unit Warrant**" means the Common Share purchase warrants of the Company issued pursuant to the Unit Offering, with each Unit Warrant entitling the holder to acquire one Common Share at a price of $1.25 per Common Share until until May 7, 2023.

"**U.S.**" or "**United States**" means the United States of America, its territories or its possessions, any state of the United States or the District of Columbia.

"**VP**" means vice president.

"**Warrant Shares**" means the Common Shares issuable upon exercise of the Warrants.

"**Warrants**" means the Common Share purchase warrants of the Company.

## CORPORATE STRUCTURE

### Name, Address, and Incorporation

Defence Therapeutics Inc. (the "**Company**") was incorporated on July 18, 2017 under the Business Corporations Act (Québec) under the name Accum Therapeutics Inc. On March 26, 2020, the Company changed its name to Defence Therapeutics Inc. and on July 10, 2020, the Company was continued into British Columbia under the Business Corporations Act (British Columbia).

The head office of the Company is located at 1680 – 200 Burrard Street, Vancouver, British Columbia, V6C 3L6 and the registered and records office of the Company is located at 1680 – 200 Burrard Street, Vancouver, British Columbia, V6C 3L6. The Company has no subsidiaries.

The Common Shares are listed on the CSE under the trading symbol "DTC". Defence is a Reporting Issuer in Canada in the Provinces of British Columbia, Alberta, Manitoba and Ontario.

## GENERAL DEVELOPMENT OF THE BUSINESS

**Three-Year History**

On May 12, 2017, prior to the incorporation of the Company, Accum Therapeutics Inc. ("**Accum**"), a precursor entity to the Company and Michel Delisle, who would become a principal of the Company, entered into an Intellectual Property Assignment and Royalty Agreement (the "**Original IP Assignment and Royalty Agreement**") with TransferTech Sherbrooke, a limited liability partnership ("**TTS**") and Jeffrey Leyton, a Professor at the Université de Sherbrooke and the Company's Head of ADCs and Nuclear Targeted Strategies Developments. The Original IP Assignment and Royalty Agreement assigns Jeffrey Leyton's invention known as "Novel Immunoconjugates with cholic acid nuclear localization sequence peptide and uses thereof" (the "**Accum Invention**") and any related intellectual property to Accum.

On May 20, 2020, the Company and TTS entered into an Amended and Restated Intellectual Property Assignment and Royalty Agreement (the "**Amended IP Assignment and Royalty Agreement**") which amends, restates, and supersedes the Original IP Assignment and Royalty Agreement, assigning the Accum Invention and any related intellectual property to the Company in exchange for consideration consisting of a (i) a $25,000 cash payment, (ii) the issuance of 2,085,714 Common Shares, which represented 30% of the Common Shares on a fully-diluted basis upon their issuance and are subject to a 36 months voluntary escrow see "*Escrowed Securities*" below, (iii) certain milestone payments payable in connection with various clinical and regulatory milestones relating to the Accum Invention and any related or derivative inventions and (iv) a royalty payment of three percent (3%) calculated on the net revenues and all commercial activities involving the Accum Invention and four percent (4%) calculated on the net revenues and all commercial activities involving any new inventions that the Company acquires through exercise of its exclusive option to acquire new inventions pursuant to the Amended IP Assignment and Royalty Agreement. The Amended IP Assignment and Royalty Agreement may be terminated by TTS in the event of a material breach by the Company (subject to a 30-day notice and cure provision), which material breach would include the Company failing to prosecute, maintain, protect and defend the intellectual property and technology associated with the Accum Invention, including the patents associated therewith, in order to preserve their value. On termination of the Amended IP Assignment and Royalty Agreement, all intellectual property rights, patents, and technology associated with the Accum Invention, as well as any new inventions developed in connection therewith, must be transferred back to TTS at a nominal value and at the Company's expense. The intellectual property rights, patents, and technology associated with the Accum Invention, as well as any new inventions developed in connection therewith, must also be reassigned to TTS for one dollar if the Company fails to pursue significant commercial activities after five years of the Agreement and further fails to sell the intellectual property rights, patents, and technology associated with the Accum Invention within 4-months

from its failure to commercialize. The Agreement would also be terminated if a court of competent jurisdiction were to declare the Accum patent invalid. For additional information regarding the Accum Invention and related intellectual property, see "*Intellectual Property*" below.

On September 18, 2020, the Company entered into the executive consulting agreements for the services of the following consultants: Sébastien Plouffe (CEO), P. Joseph Meagher (CFO), Carrie Cesarone (Corporate Secretary), Dr. Simon Beaudoin (CTSO) and Dr. Moutih Rafei (VP Research and Development). For additional information, see "*Employment, Consulting and Management Agreements*" below.

On September 18, 2020, the Company also entered into a consultant services agreement with Axiom Services Inc ("**Axiom**"), a Company of which Dr. Moutih Rafei (VP Research and Development and a director of the Company) is a principal, in connection with the provision of services relating to the completion of a study on the Accum technology. For additional information, see "*Employment, Consulting and Management Agreements*" below.

On December 1, 2020, the Company entered into an Option and Right of First Refusal Agreement (the "**Option and Right of First Refusal Agreement**") with WASSC Technologie Inc. ("**WASSC**"), a company owned and controlled by Simon Beaudoin. Under the terms of this agreement, WASSC, which has invented certain targeted antibody-drug conjugate cancer treatment (the "**WASSC Technology**") has granted the Company a two year option to purchase the WASSC Technology and various assets and intellectual property rights associated therewith for a sum of $75,000 and an agreement to incur certain additional future expenditures in connection with the development of the WASSC Technology totaling a minimum of $300,000. The Option and Right of First Refusal Agreement also includes a 5-year right of first refusal in favor of the Company with respect to the WASSC Technology. A failure to exercise the option could arise if it was determined by management that the WASSC technology did not result in sufficient proven value, in which case the Company would have to redirect its Research & Development capital toward developing alternative technologies. This could result in a significant loss in value and it is uncertain if the Company could develop any alternative technologies with similar potential. See also "*Risk Factors*".

On December 1, 2020, the Company and the University of Montreal entered into a Collaborative Research Agreement for the development of protein- and cell-based vaccines using the Accum technology. Pursuant to the terms of the agreement, the research and development work is to be carried out at the University of Montreal by Dr. Moutih Rafei, who is also an Associate Professor at the Department of Pharmacology and Physiology at the University of Montreal, and the Company is obligated to expend $54,608, representing 40% of the overhead cost relating to the cost of the research project. This agreement expires on December 31, 2021 unless terminated sooner in accordance with the provisions thereof.

On May 31, 2021, the Company entered into a scientific project agreement with Clinical Research Institute HUCH Ltd/HUS Comprehensive Cancer Center at Helsinki, Finland, to be in effect until September 30, 2021. The parties will collaborate on the preclinical selection of an optimized Accum-T-DM1 conjugate based on *in vitro* assessments. These studies will highlight the additive effect mediated by the Company's Accum technology and guide the selection of optimal Accum-T-DM1 for further *in vivo* testing on breast and gastric cancer animal models. Under the terms of this agreement, the Company paid 6,551.75 Euros for completion of the research.

On June 16, 2021, the Company entered into a Collaboration Agreement with the Institut Curie (Paris, France) (the "**Curie Agreement**") to evaluate the therapeutic efficacy of Accum-T-DM1 ADC in patient-derived xenograft ("**PDX**") models of breast cancer. Objectives of the Curie Agreement include performing head-to-head toxicology profile comparisons of T-DM1 versus Accum-T-DM1 in mice, completing a dose escalation study in mice bearing PDX that are T-DM1 resistant, and conducting a complete breast cancer efficacy study on PDX mice undergoing the ADC therapy, including in 3 HER2+ and in 1 triple-negative PDX. Under the Curie Agreement, the research and development work will be carried out by Dr. Elisabetta Marangoni for Institut Curie and Dr. Simon Beaudoin, the Company's CTSO. The cost of the project is 148,200 Euros, of

which 89,000 Euros was paid on execution and the balance of 59, 200 Euros will be paid when the final report is completed. The Curie Agreement is for a term of a maximum of 18 months.

On July 23, 2021, the Company entered into an agreement with German renowned pharmaceutical consulting and advisory company, Pharmalex GmbH, through Biopharma Excellence. Dr. Michael Pfleiderer of Biopharma Excellence will advise and guide the Company through both strategy and regulatory affairs, related mainly to integrated drugs/product developments, manufacturing, control, clinical trials, FDA IND, and potential strategic pharma partners. Dr. Michael Pfleiderer of Biopharma Excellence is the Lead Scientist working to achieve the mandate of the agreement. Under the terms of the agreement, the Company will pay the Pharmalex GmbH consultants for work incurred based on an agreed upon rate per hour. The agreement is for a term of five years.

On September 1, 2021, the Company and the University of Montreal entered into a further Collaborative Research Agreement for exploiting the Accum platform in vaccine design. Pursuant to the terms of the agreement, the research and development work is to be carried out at the University of Montreal by Dr. Moutih Rafei, who is also an Associate Professor at the Department of Pharmacology and Physiology at the University of Montreal. The Company shall pay to the University of Montreal a total amount of $317,892.40 in four equal installments of $79,473.10 each, over a period of 18 months, with the last payment being on August 31, 2023, unless terminated sooner in accordance with the provisions thereof.

***Private Placements***

On June 18, 2020, the Company closed the First Tranche of the Private Placement, pursuant to which it issued 15,180,000 Common Shares at a price of $0.15 per Common Shares for gross proceeds of $2,277,000. In connection with the First Tranche, the Company paid finder's fees of $227,700 and issued 1,518,000 Finder's Warrants. Each Finder's Warrant is exercisable into Common Shares at a price of $0.15 for a period of 36 months following the Company becoming a Reporting Issuer.

On August 31, 2020, the Company closed the Second Tranche of the Private Placement, pursuant to which it issued 4,200,000 Common Shares at a price of $0.15 per Common Shares for gross proceeds of $630,000. In connection with the Second Tranche, the Company compensated finders with a cash fee of $34,650 and the issuance of 189,000 Common Shares and 420,000 Finder's Warrants. Each Finder's Warrant is exercisable into Common Shares at a price of $0.15 for a period of 36 months following the Company becoming a Reporting Issuer.

On October 9, 2020, the Company closed the Third Tranche of the Private Placement, pursuant to which it issued 2,035,000 Common Shares at a price of $0.15 per Common Shares for gross proceeds of $305,250. In connection with the Third Tranche, the Company compensated finders with a cash fee of $13,431 and the issuance of 113,960 Common Shares and 203,500 Finder's Warrants. Each Finder's Warrant is exercisable into Common Shares at a price of $0.15 for a period of 36 months following the Company becoming a Reporting Issuer.

Half of the Common Shares issued pursuant to the Private Placement are subject to a voluntary escrow for a period of six months from May 7, 2021. See "*Escrowed Securities*" below.

On December 24, 2020, the Company closed the first tranche of the Special Warrant Offering, pursuant to which it issued on a private-placement basis 6,000,000 Special Warrants at a price of $0.60 per Special Warrant for gross proceeds of $3,600,000. Each Special Warrant was converted into one Common Share and one Warrant, and each Warrant entitles the holder to acquire one Common Share at a price of $1.25 per Common Share until May 7, 2023. In connection with the Special Warrant Offering, the Company paid finder's fees of $360,000 and issued 600,000 Finder's Warrants. Each Finder's Warrant issued under the Special Warrant Offering is exercisable into Common Shares at a price of $0.60 until May 7, 2023.

On December 24, 2020, the Company closed the first tranche of the Unit Offering, pursuant to which it issued on a private-placement basis 2,584,000 Units at a price of $0.60 per Unit for gross proceeds of $1,550,400. Each Unit is comprised of one Common Share and one Unit Warrant, and each Unit Warrant entitles the holder to acquire one Common Share at a price of $1.25 per Common Share until May 7, 2023. In connection with the Unit Offering, the Company paid finder's fees of $150,000 and issued 250,000 Finder's Warrants. Each Finder's Warrant issued under the Unit Offering is exercisable into Common Shares at a price of $0.60 until May 7, 2023.

On January 25, 2021, the Company closed the second tranche of the Special Warrant Offering, pursuant to which it issued on a private-placement basis 137,000 Special Warrants at a price of $0.60 per Special Warrant for gross proceeds of $82,200. Each Special Warrant was converted into one Common Share and one Warrant, and each Warrant entitles the holder to acquire one Common Share at a price of $1.25 per Common Share until May 7, 2023.

On January 25, 2021, the Company closed the second tranche of the Unit Offering, pursuant to which it issued on a private-placement basis 4,000 Units at a price of $0.60 per Unit, for gross proceeds of $2,400. Each Unit is comprised of one Common Share and one Unit Warrant, and each Unit Warrant entitles the holder to acquire one Common Share at a price of $1.25 per Common Share until May 7, 2023.

## DESCRIPTION OF THE BUSINESS

**Overview**

The principal business carried on by the Company is the business of research and development focusing on enhancing intracellular delivery of biological/biosimilar therapeutic drugs targeting cancer and infectious diseases.

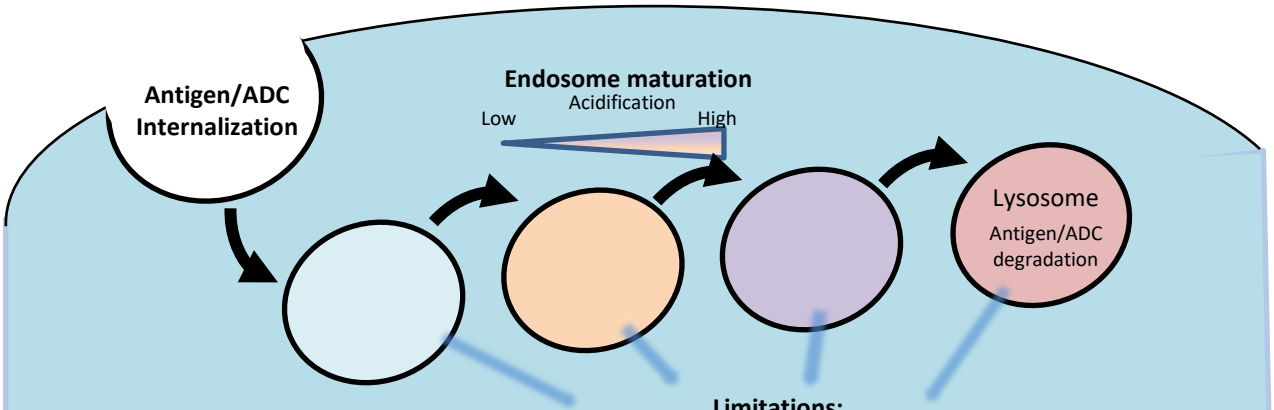
The Company's Accum technology takes multitude biological/biosimilar-based pharmaceutical to a bold new frontier by enabling efficient intracellular access to a given biological while maintaining target cell specificity. The Company's product pipeline focuses on the effective intracellular access by different type of vaccine (DNA, RNA and protein) and by protein-delivery system such as monoclonal antibody (mAb)-based therapies. The Company is actively seeking licensing, acquisition or partnership opportunities from industry and academia, in order to continue to develop this technology and bring it to market. The Accum technology platform is functional, operational and is currently in use for both ADC- and vaccine-related projects, as detailed below.

**Development of Core Technology**

***Cell Accumulator (Accum)***

The Company's core technological research is based around addressing a major and common challenge in the vaccine and antibody drug conjugates ("**ADCs**") fields limiting their efficacy: their entrapment in small intracellular vesicles named endosomes and lysosomes (Fig. 1).

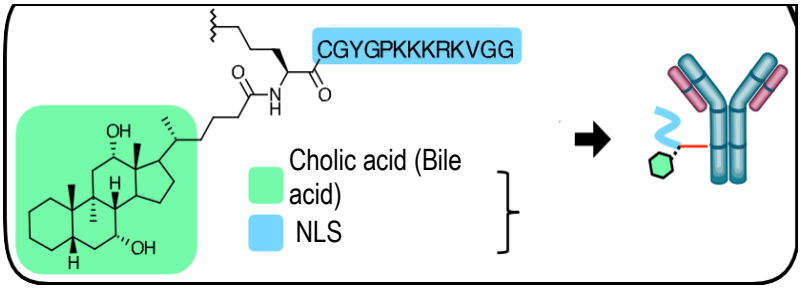
**Fig. 1 - Internalization and vesicle entrapment limitation**



Internalization Process: When the target cell binds and internalizes an antigen or an ADC, the complex is entrapped inside intracellular small vesicles named endosomes. Ultimately, these endosomes undergo maturation consequently leading to their degradation prior to eliciting their respective role/function. This endosome-lysosome entrapment is a major issue limiting the efficacy of those types of therapy.

The Company's goal is to use the Accum enhancer formulation to improve intracellular delivery of biological therapeutic agents by inducing their escape to the cytosol consequently improving their therapeutic efficacy. Accum is a compound composed of a bile acid, as cholic acid, linked to a short peptide that contains an optimized non-unspecific cell-penetrating nuclear localization signal ("**NLS**") peptide (Fig.2).

**Fig. 2**




Accum is composed by a bile acid such as cholic acid and a nuclear localization signal (NLS). Accum moiety is covalently link to an antigen or an ADC by using different protein conjugation methodology.

Only the combination of bile acid and nuclear localization activity of the NLS enables escape of the therapeutic agent from endosome-lysosome entrapment and efficiently localize inside the cytoplasm and/or nucleus.[1]

***Effective Vaccine Design***

The Accum technology is highly suitable to the vaccination field. More specifically, antigens that are normally captured by dendritic cells ("**DCs**") - the best antigen-presenting cells present in our body- are first entrapped in endosomes.[2] While maturation of these endosomal organelles occurs, the pH decreases (becomes acidic ~4-5) in order to trigger the activation of specific enzymes as a means to initiate non-specific antigen degradation.[2] As a result, the generated fragments can then pass through endosomal pores to reach the cytoplasm where specific antigen degradation takes place by the proteasomal machinery. Although this process occurs naturally, the generated antigen fragments are often damaged, which renders them unsuitable for proteasomal degradation (See Fig. 3 below).[2]

By using the Accum technology, captured antigens are preserved in their natural conformation while being delivered to the cytoplasm. As such, proteasomal degradation ends-up leading to a higher number of immunogenic and stable peptides presented at the surface of DCs and capable of eliciting potent T-cell activation (See Fig. 3 below).

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[1] S. Beaudoin *et al.*, Mol Pharm., 2016; B. Paquette *et al.*, Bioconjug Chem., 2018; V. Lacasse *et al.*, Mol Ther Methods Clin Dev. 2020.

[2] Rodriguez A. *et al.* Nature Cell Biology, 1999; I. Dingjan *et al.* Scientific Reports 2016; P. Kozik *et al.* Cell Reports, 2020.

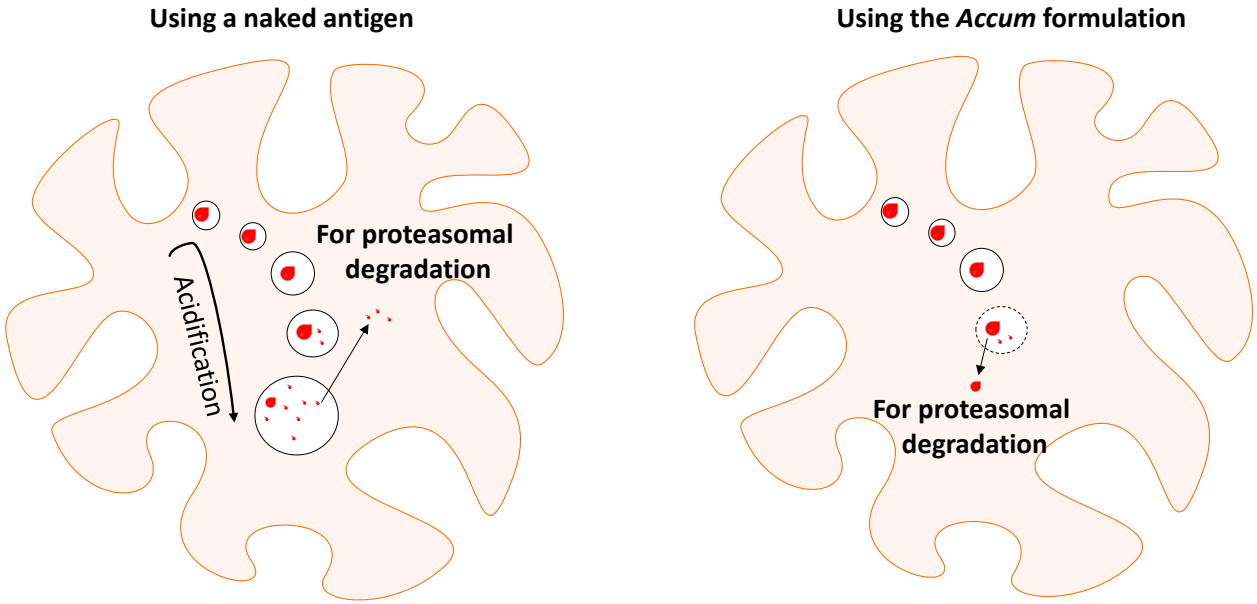



**Fig. 3. A rendered comparison of the different outcomes in antigen degradation in the absence or presence of the Accum technology.**

To date, research conducted by the Company has found that the addition of Accum enhances the therapeutic efficacy of cell-based vaccination with an increase survival rate of 50-80% (therapeutic vaccination). For instance, the use of allogeneic DCs using doses ranging from 300,000 cells to 30,000 cells per injection has been tested for its efficacy to cure established tumors. The studies show that two doses of 300,000 cells delivered a week apart can-significantly enhance the curing rate leading to enhanced survival (approximate cost of the project is estimate to be $250,000). In parallel, the Company has already began testing three different COVID-19-based vaccination protocols. In the first protocol, the protein is being directly injected with or without two different adjuvants (AddaSO3™ and AddaVax™). Generated data clearly demonstrate enhanced production of IgG titer with the use of the AddaSO3™ adjuvant. The second approach consists of delivering a DC-based cellular vaccine. In this case, DCs treated with Accum-S1 are inducing a significantly higher antibody titer than DCs treated with standard DCs. The third approach consists of preparing and testing the vaccine following its intranasal delivery in animals using the Eurocine adjuvant (designed for intranasal vaccination). Eurocine, a Swedish vaccine development company, has developed the adjuvant Endocine™, which is a safe, tolerable and effective vaccine adjuvant, based on natural lipid compounds and formulated as a liposomal dispersion. The projected cost for this pre-clinical project is $250,000.

Another infectious disease vaccine in development at Defence Therapeutics is AccuVAC-PT009 targeting HPV. This vaccine will use a mixture of 9 L1 proteins (derived from different HPV strains) linked to Accum and tested for its ability to confer protective antibodies. The potency of the vaccine will be compared to the commercially available Gardasil-9 vaccine in terms of its immunogenicity (prophylactic vaccine). In addition, Defence will be working on a second HPV-related vaccine but targeting cervical cancer. The idea behind this vaccine would be to modify both the E6 and E7 protein to covalently link Accum then test the vaccine for its ability to treat pre-established cervical cancer using the C3.43 cell line. The projected cost for these two pre-clinical projects is $250,000.

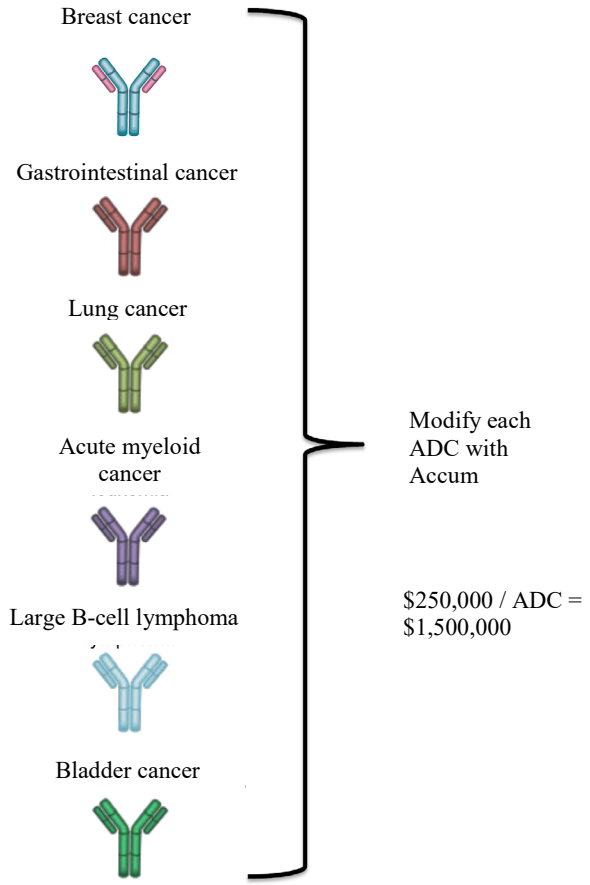
***Effective Design of ADCs***

The following section will discuss the use of ADCs as a pharmaceutical which can localize chemotherapeutic action at the site of the tumor and thereby reduces systemic toxicity associated with traditional chemotherapy. One challenge posed by ADCs is that the reliance of ADCs on lysosomal delivery results in insufficient

intracellular accumulation of the delivered chemotherapeutic necessary for potent tumor killing.[3] The Company's Accum platform induces small intracellular vesicle rupture, targeting drugs to the nucleus of the cell therefore improving their overall intracellular accumulation.

To date, we have demonstrated that the Accum technology enhances the ability of ADC Kadcyla (T-DM1) to specifically kill breast cancer cells. Accum improves the escape of ADC Kadcyla from endosomes while targeting the nucleus. In addition, Accum also enables the treatment to overcome resistance mechanisms such as reducing the number of cell surface receptors, therefore limiting the potency and delivery of T-DM1 inside the cell.[4] As a result, the Company believes that the Accum technology will be able to increase T-DM1 effectiveness with further development. The Company anticipates that the budget to modify the ADCs with Accum will initially be $250,000 and an additional $250,000 for each of the types of ADC the Company is targeting, resulting in an approximate research and development budget for ADCs of $1,500,000. (Fig. 4).

**Fig. 4.**




α-amanitin (αA) is one of the deadliest toxins known to mankind and is the principal agent of the amatoxin family of compounds produced by *Amanita phalloides*. αA specifically inhibits the enzyme RNA Polymerase II (RPII), which is responsible for synthesizing RNA from DNA. Due to its high toxicity, αA must be targeted

[3] R. Gilabert-Oriol *et al.*, Curr Pharm Dev., 2014; DM. Collins *et al.*, Cancers (Basel), 2019.
[4] V. Lacasse *et al.*, Mol Ther Methods Clin Dev. 2020.

to have a clinically acceptable therapeutic window. αA has previously been developed as an ADC and shown to effectively kill colorectal cancer (Liu et al.,*Nature,* 2015). An αA-ADC is most effective in tumor cells with a hemizygous loss of the well-known tumor suppressor gene TP53. The partial genomic deletion of TP53 frequently encompasses the neighboring RPII gene. However, αA-ADC is ineffective against tumor cells with full RPII gene expression.

Thus, the ability of Accum to increase the intracellular accumulation of ADCs is a potential strategy to increase the effectiveness of αA-ADCs independently of genomic alteration. Currently, the Company has formed a strategic partnership with Heidelberg Pharma in developing its Accum-αA-ADCs platform. Heidelberg Pharma is carrying out research with respect to applying the Accum technology to certain bladder cancer therapies, and the parties will negotiate a formal agreement should such research result in positive findings. Heidelberg Pharma is a publicly listed, biopharmaceutical company focused on oncology. Heidelberg Pharma is the first company developing the toxin αA into cancer therapies.

The Company's preliminary data shows that modification of an ADC conjugated with αA targeting aggressive breast cancer increased cell killing by factors of 2000 and 73 relative to the approved breast cancer ADC (T-DM1) and the matched αA-ADC without the Accum-modification.

***The AccuTOX Program***

The Accum technology platform is very efficient at enhancing intracellular delivery of proteins of pharmacological interests such as ADCs or vaccine antigens. However, a novel anti-cancer function was recently discovered for "free" Accum. More specifically, when directly delivered without direct linking onto protein, the Accum moiety behaves as a toxic "bullet" to cancer cells. So far, the Defence team engineered a large library of Accum variants (over 50) that are currently being testing for their therapeutic efficacy against breast, colon, melanoma and lymphoma cancers. In addition, a new strategy is currently being developed to engineer an "intelligent" Poly-AccuTOX molecule (a chain of various AccuTOX molecules) capable of selectively killing a wide range of cancer cells without collateral side effects. The projected cost for these pre-clinical projects is $350,000.

**Protection of Intangible Assets**

Vaccines

On December 18, 2020, the Company filed with the United States Patent and Trademark Office its provisional patent application N° 63/127,731, "Covalently Modified Antigens for Improved Immune Response", invented by Dr. Simon Beaudoin, with proof-of-concept completed by Dr. Moutih Rafei. This patent application relates to covalently modified antigens to enhance or modify their immunogenicity and, more specifically, polypeptide antigens covalently conjugated to one or more steroid acid moieties for improved cellular immunity. On January 21, 2021, the company received the filing receipt from the United States Patent and Trademark Office confirming the filing date for this patent application, which is a significant step in progressing its vaccine development objectives. In order to claim the benefit of the priority filing date established by the provisional application filing, the Company will need to submit a non-provisional patent application claiming priority to the earlier filed provisional application within 12 months of the provisional patent application filing date, namely December 18, 2021. The Company anticipates submitting a non-provisional patent application in Q4 2021.

While the timeline for the US patent application process varies case-by-case and by subject matter area, USPTO statistics show that it currently takes an average of approximately 16 months from the non-provisional application filing date for a patent examiner to respond to a non-provisional patent application filing (whether in the form of a Notice of Allowance or a first non-final Office Action). If a non-final Office Action is issued, then the Company will be required to address any deficiencies identified therein. Once the USPTO is satisfied that the non-provisional patent application has met all relevant requirements and has

addressed all alleged deficiencies, the non-provisional patent application of the Company will then be allowed by the USPTO by way of a Notice of Allowance, and the Company will have 3 months therefrom to pay the required issue fee to bring the non-provisional patent application to registration.

Accum

The Company has been assigned the rights to the Accum Invention pursuant to the terms of the Amended IP Assignment and Royalty Agreement, which agreement includes the following milestone payments payable in connection with various clinical and regulatory milestones, as follows:

(a) an amount of ten thousand dollars ($10,000) payable within thirty (30) days of the completion of the first non-rodent positive toxicology study;
(b) an amount of twenty-five thousand dollars ($25,000) payable within thirty (30) days of the recruitment of the first phase l patient;
(c) an amount of fifty thousand dollars ($50,000) payable within thirty (30) days of the recruitment of the first phase 2 patient;
(d) an amount of one hundred thousand dollars ($100,000) payable within thirty (30) days of the recruitment of the first phase 3 patient; and
(e) an amount of two hundred and fifty thousand dollars ($250,000) payable within thirty (30) days of the first regulatory approval from a relevant registration authority.

A failure to make the milestones payments could arise if it was determined by management that further development of the Accum Invention did not result in sufficient proven value, in which case the Company would have to redirect its Research & Development capital toward developing alternative technologies. This could result in a significant loss in value and it is uncertain if the Company could develop any alternative technologies with similar potential. See also "*Risk Factors*".

The Accum Invention presently includes patent applications based on International Patent Application No. PCT/CA2017/050337 that entered the National Phase in Canada (patent application no CA3017950), the United States (patent application no US16/085,141), Japan (patent application no JP2018568469), Israel (patent application no IL261765), Australia (patent application no AU2017233725), and Europe (patent application no EP17765615), as set out below:

| **Patent Application Number** | **Region** | **Title** | **Inventors** | **Applicant** | **Status as of December 1, 2020** |
|---|---|---|---|---|---|
| CA3017950Al | Canada | Conjugates enhancing total cellular accumulation | Simon Beaudoin<br>Jeffrey Victor Leyton | Defence Therapeutics Inc. | Pending: Request for examination due March 15, 2022 |
| US16/085,141 | United States | Conjugates enhancing total cellular accumulation | Simon Beaudoin<br>Jeffrey Victor Leyton | Defence Therapeutics Inc. | Pending: Non-Final Action issued Nov. 18, 2020 |
| JP2018568469 | Japan | Conjugates enhancing total cellular accumulation | Simon Beaudoin<br>Jeffrey Victor Leyton | Defence Therapeutics Inc. | Pending: Awaiting next official communication |

| | | | | | |
|---|---|---|---|---|---|
| IL26 l 765D0 | Israel | Conjugates enhancing total cellular accumulation | Simon Beaudoin<br>Jeffrey Victor Leyton | Defence Therapeutics Inc. | Pending: Awaiting next official communication |
| AU2017233725 AI | Australi a | Conjugates enhancing total cellular accumulation | Simon Beaudoin<br>Jeffrey Victor Leyton | Defence Therapeutics Inc. | Pending: Request for examination due March 15, 2022 |
| EP17765615 | Europe | Conjugates enhancing total cellular accumulation | Simon Beaudoin<br>Jeffrey Victor Leyton | Defence Therapeutics Inc. | Pending: Awaiting next official communication |
| US63/256,726 | United States | Conjugates enhancing total cellular accumulation | Simon Beaudoin | Defence Therapeutics Inc. | Pending: Awaiting next official communication |

| Robic ref: | Patent application serial number | Filing date | Comments/Status |
|---|---|---|---|
| **COVALENTLY MODIFIED ANTIGENS FOR IMPROVED IMMUNE RESPONSE AND/OR STABILITY** | | | |
| 20751-2 | US 63/127,731 | 2020-12-18 | Pending US provisional application; not yet published |
| 20751-4 | US 63/202,047 | 2021-05-25 | Pending US provisional application; not yet published |
| 20751-6 | PCT/CA2021/051543 | 2021-11-01 | Pending international (PCT) application claiming priority from US 63/127,731 and US 63/202,047; not yet published |
| 20751-7 | US 17/516,161 | 2021-11-01 | Pending non-provisional US application claiming priority from US 63/127,731 and US 63/202,047; not yet published |
| **STEROID ACID-BASED IMMUNOGEN ENHANCERS** | | | |
| 20751-3 | US 63/201,620 | 2021-05-06 | Pending US provisional application; not yet published |
| **STEROID ACID-BASED HYDROGELS** | | | |
| 20751-5 | US 63/260,648 | 2021-08-27 | Pending US provisional application; not yet published |
| **STEROID ACID-PEPTIDE BASED CYTOTOXIC COMPOUNDS** | | | |
| 20751-8 | US 63/264,126 | 2021-11-16 | Pending US provisional application; not yet published |

Our success depends, in part, on our ability to obtain and maintain intellectual property protection for our platform technology, product candidates and know-how, to defend and enforce our intellectual property rights, in particular, our patent rights, to preserve the confidentiality of our know-how and trade secrets and to operate without infringing the proprietary rights of others. We seek to protect our product candidates and technologies by, among other methods, filing Canadian, U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business.

We also rely on trade secrets, know-how, continuing technological innovation and in-licensing of third-party intellectual property to develop and maintain our proprietary position. We, or our collaborators and licensors, file patent applications directed to our key product candidates in an effort to establish intellectual property positions to protect our product candidates as well as uses of our product candidates for the prevention and/or treatment of diseases.

***Trademarks***

The Company has applied to register the following trademarks:

| Trademark | Country | Application Number |
|---|---|---|
| ACCUM | Canada | 2,075,186 |
| ACCUVAC | Canada | 2,075,187 |
| ACCUM | US | 90/453,057 |
| ACCUVAC | US | 90/453,135 |
| DRUG THE UNDRUGGABLE | Canada | 2,124,758 |
| ACCUM DRUG THE UNDRUGGABLE | Canada | 2,124,756 |

***Web Domains***

The Company has use and control over the defencetherapeutics.com domain name.

**Employees**

The Company has assembled an experienced team of biotech executives and finance professionals to manage its research and development and corporate growth. The Company has five executives, Sébastien Plouffe (CEO), P. Joseph Meagher (CFO), Carrie Cesarone (Corporate Secretary), Dr. Simon Beaudoin (CTSO) and Dr. Moutih Rafei (VP Research and Development), all of whom are engaged pursuant to executive consulting agreements.

For additional information regarding the background of the Company's executives see "Directors and Executive Officers".

**Employment, Consulting and Management Agreements**

The Company has entered into the following executive consulting agreements with the following executives on the following terms:

i) **Sébastien Plouffe** – On September 18, 2020, the Company entered into an Executive Consulting Agreement (the "**Plouffe Consulting Agreement**") with Sediamek Inc. ("**Sediamek**"), a company incorporated under the *Companies Act* (Quebec) on April 18, 2006, and Sébastien Plouffe, pursuant to which Sediamek would provide the services of Sébastien Plouffe to act as the Company's CEO. Mr. Plouffe is entitled to a monthly consulting fee of $7,500 and participation in the Company's Stock Option Plan, including the issuance of 400,000 Options at an exercise price of $1.25 per Common Share, exercisable for a maximum period of 3 years from the date of issue. The Executive Consulting Agreement is for an indefinite term, subject to the termination provisions thereof, which provide that Mr. Plouffe will be paid the equivalent of 3 months in consulting fees in the event of a

termination, by either Mr. Plouffe or the Company, as a result of a change in control. Mr. Plouffe is also subject to standard confidentiality, non-competition and non-solicitation provisions.

ii) **P. Joseph Meagher** – On September 18, 2020, the Company entered into an Executive Consulting Agreement (the "**Meagher Consulting Agreement**") with Meagher Consulting Inc. ("**Meagher Consulting**") and P. Joseph Meager, pursuant to which Meagher Consulting would provide the services of Mr. Meagher to act as the Company's CFO and a Director. Mr. Meagher is entitled to a monthly consulting fee of $6,000 and participation in the Company's Stock Option Plan, including the issuance of 200,000 Options at an exercise price of $1.25 per Common Share, exercisable for a maximum period of 3 years from the date of issue. The Executive Consulting Agreement is for an indefinite term, subject to the termination provisions thereof, which provide that Mr. Meagher will be paid the equivalent of 3 months in consulting fees in the event of a termination, by either Mr. Meagher or the Company, as a result of a change in control. Mr. Meagher is also subject to standard confidentiality, non-competition and non-solicitation provisions.

iii) **Carrie Cesarone** – On September 18, 2020, the Company entered into an Executive Consulting Agreement (the "**Cesarone Consulting Agreement**") with Athena Ventures Inc. ("**Athena**"), a Company incorporated under the BCBCA on March 18, 2015, and Carrie Cesarone, pursuant to which Athena would provide the services of Ms. Cesarone to act as the Company's Corporate Secretary. Ms. Cesarone is entitled to a monthly consulting fee of $6,000 and participation in the Company's Stock Option Plan, including the issuance of 50,000 Options at an exercise price of $1.25 per Common Share, exercisable for a maximum period of 3 years from the date of issue. The Executive Consulting Agreement is for an indefinite term, subject to the termination provisions thereof, which provide that Ms. Cesarone will be paid the equivalent of three months in consulting fees in the event of a termination, by either Ms. Cesarone or the Company, as a result of a change in control. Ms. Cesarone is also subject to standard confidentiality, non-competition and non-solicitation provisions.

iv) **Dr. Simon Beaudoin** - On September 18, 2020, the Company entered into an Executive Consulting Agreement (the "**Beaudoin Consulting Agreement**")_with 9368-4272 Quebec Inc. ("**9368-4272**") and Dr. Simon Beaudoin, pursuant to which 9368-4272 would provide the services of Simon Beaudoin to act as the Company's CTSO. Dr. Beaudoin is entitled to an annual consulting fee of $75,000 and participation in the Company's Stock Option Plan, including the issuance of 50,000 Options at an exercise price of $1.25 per Common Share, exercisable for a maximum period of 3 years from the date of issue. The Executive Consulting Agreement is for an indefinite term, subject to the termination provisions thereof, which provide that Dr. Beaudoin will be paid the equivalent of 3 months in consulting fees in the event of a termination, by either Dr. Beaudoin or the Company, as a result of a change in control. Dr. Beaudoin is also subject to standard confidentiality, non-competition and non-solicitation provisions.

v) **Axiom Services Inc**. - On September 18, 2020, the Company entered into a Consultant Services Agreement (the "**Axiom Consulting Agreement**") with Axiom, a Company of which Dr. Rafei is a principal, in connection with the provision of services relating to the completion of a study on the Accum technology. Axiom is entitled to an annual consulting fee of up $110,675, with $33,203 payable on execution of the Agreement and the remainder payable in connection with meeting certain project milestones. The Axiom Consulting Agreement is for a term of up to one year with the possibility of renewal, subject to the termination provisions thereof, and was renewed for a term of one year. The Axiom Consulting Agreement contains standard confidentiality and non-solicitation provisions.

## MARKET AND REGULATORY OVERVIEW

### Principal Markets

#### *Pharmaceuticals*

If the Company is able to develop and commercialize its Accum platform to the point where it will reach the market, there is significant opportunity for growth. The global pharmaceutical market will exceed $1.5 trillion by 2023, growing at 3-6% compound annual growth rates (CAGR) over the next five years (typical growth).[5]

#### *Biopharmaceuticals*

The biopharmaceutical market currently accounts for 17% ($269.3 billion) of the pharmaceutical market.[6] However, the biopharmaceutical market is growing at a rapid CAGR of 10.8% (projected to 2025).[7] This indicates biopharmaceuticals are destined to dominate the overall pharmaceutical market in the future.
In addition, antibodies and antibody-based agents (e.g. ADCs) dominate biopharmaceutical approvals and sales. There were also 31 (15.5%) antibodies on the top 200 selling pharmaceuticals in 2018, while five of the top 10 best-selling drugs are antibodies. In total, ADCs produced $1 billion in sales in 2018.[8]

#### *Vaccines*

Cancer Vaccines

The global cancer vaccines market is valued at $4,188 million (data from 2019) with a projection to $7,303 million by 2027 (a CAGR of 12.6%).[9]

Cancer vaccines are considered as biological response modifiers designed to teach or educate the immune system to recognize and fight cancer cells. In general, cancer vaccines can be sub-divided in two branches: preventive and therapeutic cancer vaccines. Preventive cancer vaccines are used in healthy person to prevent cancer and are mostly applicable against cancers for which the etiology is caused by a virus (e.g. HPV-induced cervical cancer). Therapeutic cancer vaccines, on the other hand, are used to stimulate immunity in order to fight established tumors.

The global cancer vaccines market is segmented on the basis of technology, type, indication, end user, and region. By technology, the market is categorized into dendritic cells (DC) cancer vaccines, recombinant cancer vaccines, antigen/adjuvant cancer vaccines, and viral vector and DNA cancer vaccines. The only two indications for which a cancer vaccine have been developed are:

- cervical cancer: the preventive vaccine Gardasil developed by Merck and Cervavix by Glaxo Smithkline.
- Prostate cancer: the therapeutic vaccine Sipuleucel-T developed by Dendreon (low to null efficiency).

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[5] "The Global Use of Medicine in 2019 and Outlook to 2023: Forecasts and Areas to Watch" (29 January 2019), online: *The IQVIA Institute for Human Data Science* <www.iqvia.com/insights/the-iqvia-institute/reports/the-global-use-of-medicine-in-2019-and-outlook-to-2023>.
[6] ResearchAndMarkets.com, Press Release, "The Global Biopharmaceuticals Market is Projected to Grow by 8.7% Through to 2025 and Reach $446 Billion" (24 June 2019), online: *Business Wire* <www.businesswire.com/news/home/20190624005782/en/The-Global-Biopharmaceuticals-Market-is-Projected-to-Grow-by-8.7-Through-to-2025-and-Reach-446-Billion---ResearchAndMarkets.com>.
[7] *Ibid.*
[8] Gary Walsh, "Biopharmaceutical benchmarks 2018" (2018) 36 Nature Biotechnology 1136, online (pdf): <www.nature.com/articles/nbt.4305.pdf>.
[9] Allied Market Research, "Cancer Vaccines Market by Technology, Type, Indication, and End User: Global Opportunity Analysis and Industry Forecast, 2020-2027" (July 2020), online: *ReportLinker* <www.reportlinker.com/p05955152/Cancer-Vaccines-Market-by-Technology-Type-Indication-and-End-User-Global-Opportunity-Analysis-and-Industry-Forecast-.html?utm_source=GNW>.

Due to the absence of a shared tumor-specific antigen (TSA) against cancer, Defence Therapeutics is currently exploiting its Accum Technology to develop a semi-personalized cancer vaccine against various cancer indications. The basis of the technology used universal allogeneic DCs treated with tumor lysate derived from the target cancer for the following primary indications:

- Lymphoma
- Melanoma
- Colon cancer
- Glioblastoma

COVID-19 Vaccine

Since the Accum technology can be applied to any antigen, the Company is currently working on a novel Spike-1 formulation leading to enhanced immunity. In this case, the Accum moiety is added directly to the S1 protein (Accum-S1). Following the uptake of this antigen, DC processing and presentation will be measurably enhanced, leading to a higher number of immunogenic peptides being presented to responding CD4 and CD8 T cells. In addition, it is important to note that mRNA delivery is limited by various parameters such as the amount of mRNA that was successfully uptaken by target cells, the amount that was translated and the percentage of surviving cells in the host able to express and secrete the S1 antigen. Delivering the Accum-S1 protein can bypass all of these limitations without difficulty.

Captured antigens are usually sequestered into maturing endosomes. During this process, the pH within the endosomal lumen decreases rapidly leading to the activation of several proteases. As such, non-specific degradation of the captured antigen occurs, which will destroy immunogenic peptides normally required to mount potent T-cell response. To bypass this limitation, the Company developed a novel strategy to modify given antigens such as Spike-1 using the Accum technology. Once added chemically, the Accum moiety linked onto the antigen triggers endosomal membrane rupture prior to the acidification process leading to ‘‘intact’’ antigen import to the cytosol where it is subsequently degraded by the proteasomal machinery. Thus, all antigenic fragments are preserved and become available to be presented to responding T cells. When this technology was tested using an in vitro antigen presentation assay, dendritic cells pulsed with the Accum-antigen triggered 40-100X higher T-cell activation compared to the naked antigen. Therefore, the Accum technology is currently being used to develop a potent and strongly immunogenic Spike-1 vaccine that the Company believes will trigger superior immunity compared to currently developed COVID-19 vaccines. Although the primary target material currently tested is recombinant proteins, the Company also intends to extend the use of its technology to mRNA or DNA (commonly used in vaccine design).

**Competition**

Companies developing a DC-based cancer vaccine[10]:

[10] Blue Matter Consulting, “2021 Outlook for Cell-Based Therapies in Oncology: CAR-T Expansion and Beyond” (January 14, 2021), online: <https://bluematterconsulting.com/2021-outlook-cell-based-therapies-in-oncology/>

| 2020 Year-in-Review: DC Vaccines | | |
|---|---|---|
| *Product Name (Manufacturer)* | *Description* | *Current Status & 2020 Updates* |
| **PROVENGE** *(Dendreon)* | Autologous; prostate cancer antigen pulsed | • FDA approved 2010 in mCRPC<br>• **Data: 41% reduced risk of death as compared to androgen blockers** |
| **APCEDEN** *(APAC Biotech)* | Autologous; monocyte-derived; tumor lysate-pulsed | • Approved for use in India for various solid tumors<br>• **Data: case study published of "substantial tumor regression" in metastatic prostate cancer** |
| **DCVax-L** *(Northwest Bio)* | Autologous; monocyte-derived; tumor lysate-pulsed | • Ph3 in Glioblastoma<br>• **Datalock in October; clinical data now under review** |
| **Autologous Dendritic Cells Loaded with Autologous Tumor mRNA** *(University Hospital Erlangen – Germany)* | Autologous; monocyte-derived; tumor mRNA-loaded | • Ph3 in Uveal Melanoma |
| **Autologous Dendritic Cells Loaded with Autologous Tumor mRNA** *(Radboud University – Netherlands)* | Autologous; antigen-loaded | • Ph3 in Melanoma |
| **Cytovant (CVT-DC-01)** *(Medigene)* | WT-1/PRAME DC Vaccine | • Ph2 in AML; **planned Ph3 in 2021**<br>• Interim data showing tolerability and encouraging efficacy |

Companies with an authorized/ approved COVID-19 vaccine[11]:

| | Name | Vaccine Type | Primary Developers | Country of Origin | Authorization/Approval |
|---|---|---|---|---|---|
| 1. | Sputnik V | Non-replicating viral vector | Gamaleya Research Institute, Acellena Contract Drug Research and Development | Russia | Algeria, Argentina, Armenia, Bahrain, Belarus, Bolivia, Gabon, Guinea, Hungary, Iran, Kazakhstan, Laos, Lebanon, Mexico, Mongolia, Montenegro, Myanmar, Nicaragua, Pakistan, Palestine, Paraguay, Republika Srpska, Russia, Saint Vincent and the Grenadines, Serbia, Tunisia, Turkmenistan, United Arab Emirates, Uzbekistan, Venezuela |
| 2. | No name announced | Inactivated vaccine | Wuhan Institute of Biological Products; China National Pharmaceutical Group (Sinopharm) | China | China |
| 3. | Moderna COVID-19 Vaccine (mRNA-1273) | mRNA-based vaccine | Moderna, BARDA, NIAID | US | Canada, EU, Faroe Islands, Greenland, Iceland, Israel, Norway, Qatar, Saint Vincent and the Grenadines, Singapore, Switzerland, United Kingdom, United States |

[11] Regulatory Affairs Professional Society, "COVID-19 Vaccine Tracker" (February 18, 2021), online: <https://www.raps.org/news-and-articles/news-articles/2020/3/covid-19-vaccine-tracker>.

| | Name | Vaccine Type | Primary Developers | Country of Origin | Authorization/Approval |
|---|---|---|---|---|---|
| 4. | JNJ-78436735 (formerly Ad26.COV2.S) | Non-replicating viral vector | Janssen Vaccines (Johnson & Johnson) | The Netherlands, US | Saint Vincent and the Grenadines |
| 5. | EpiVacCorona | Peptide vaccine | Federal Budgetary Research Institution State Research Center of Virology and Biotechnology | Russia | Russia, Turkmenistan |
| 6. | COVID-19 Vaccine AstraZeneca (AZD1222); also known as Covishield | Adenovirus vaccine | BARDA, OWS | UK | Argentina, Bahrain, Bangladesh, Brazil, Chile, Dominican Republic, Ecuador, El Salvador, EU, Hungary, India, Iraq, Mexico, Morocco, Myanmar, Nepal, Pakistan, Philippines, Saint Vincent and the Grenadines, South Africa, South Korea, Sri Lanka, Thailand, UK, Vietnam |
| 7. | Covaxin | Inactivated vaccine | Bharat Biotech, ICMR | India | India |
| 8. | CoronaVac | Inactivated vaccine (formalin with alum adjuvant) | Sinovac | China | Azerbaijan, Bolivia, Brazil, Cambodia, China, Chile, Colombia, Indonesia, Laos, Turkey, Uruguay |
| 9. | Convidicea (Ad5-nCoV) | Recombinant vaccine (adenovirus type 5 vector) | CanSino Biologics | China | Mexico, China (military use), Pakistan |
| 10. | Comirnaty (BNT162b2) | mRNA-based vaccine | Pfizer, BioNTech; Fosun Pharma | Multinational | Albania, Argentina, Australia, Bahrain, Canada, Chile, Colombia, Costa Rica, Ecuador, EU, Faroe Islands, Greenland, Iceland, Iraq, Israel, Japan, Jordan, Kuwait, Malaysia, Mexico, New Zealand, Norway, Oman, Panama, Philippines, Qatar, Saint Vincent and the Grenadines, Saudi Arabia, Serbia, Singapore, Switzerland, UAE, UK, US, Vatican City, WHO |
| 11. | VLA2001 | Inactivated vaccine | Valneva; National Institute for Health Research (NIHR) | Phase 1/2 | Multiple NIHR testing sites |

Companies developing a COVID-19 vaccine[12]:

| Candidate | | Mechanism | Sponsor | Trial Phase | Institution |
|---|---|---|---|---|---|
| 1. | NVX-CoV2373 | Nanoparticle vaccine | Novavax | Phase 3 | Novavax |
| 2. | ZF2001 | Recombinant vaccine | Anhui Zhifei Longcom Biopharmaceutical, Institute of Microbiology of the Chinese Academy of Sciences | Phase 3 | Various |
| 3. | ZyCoV-D | **DNA VACCINE (PLASMID)** | Zydus Cadila | Phase 3 | Zydus Cadila |
| 4. | CVnCoV | mRNA-based vaccine | CureVac; GSK | Phase 2b/3 | CureVac |
| 5. | Bacillus Calmette-Guerin (BCG) vaccine | Live-attenuated vaccine | University of Melbourne and Murdoch Children's Research Institute; Radboud University Medical Center; Faustman Lab at Massachusetts General Hospital | Phase 2/3 | University of Melbourne and Murdoch Children's Research Institute; Radboud University Medical Center; Faustman Lab at Massachusetts General Hospital |
| 6. | INO-4800 | DNA vaccine (plasmid) | Inovio Pharmaceuticals | Phase 2/3 | Center for Pharmaceutical Research, Kansas City. Mo.; University of Pennsylvania, Philadelphia |
| 7. | VIR-7831 | Plant-based adjuvant vaccine | Medicago; GSK; Dynavax | Phase 2/3 | Medicago |
| 8. | No name announced | Adenovirus-based vaccine | ImmunityBio; NantKwest | Phase 2/3 | N/A |
| 9. | UB-612 | Multitope peptide-based vaccine | COVAXX | Phase 2/3 | United Biomedical Inc. (UBI) |

[12] Regulatory Affairs Professional Society, "COVID-19 Vaccine Tracker" (February 18, 2021), online: <https://www.raps.org/news-and-articles/news-articles/2020/3/covid-19-vaccine-tracker>.

| Candidate | | Mechanism | Sponsor | Trial Phase | Institution |
|---|---|---|---|---|---|
| 10. | Abdala (CIGB 66) | Protein subunit vaccine | Finlay Institute of Vaccines | Phase 2 | Finlay Institute of Vaccines |
| 11. | BNT162 | mRNA-based vaccine | Pfizer, BioNTech | Phase 1/2/3 | Multiple study sites in Europe, North America and China |
| 12. | AdCLD-CoV19 | Adenovirus-based vaccine | Cellid; LG Chem | Phase 1/2a | Korea University Guro Hospital |
| 13. | Nanocovax | Recombinant vaccine (Spike protein) | Nanogen Biopharmaceutical | Phase 1/2 | Military Medical Academy (Vietnam) |
| 14. | EuCorVac-19 | nanoparticle vaccine | EuBiologics | Phase 1/2 | Eunpyeong St. Mary's Hospital |
| 15. | Mambisa (CIGB 669) | Protein subunit vaccine | Finlay Institute of Vaccines | Phase 1/2 | Finlay Institute of Vaccines |
| 16. | IIBR-100 | Recombinant vesicular stomatitis virus (rVSV) vaccine | Israel Institute for Biological Research | Phase 1/2 | Hadassah Medical Center; Sheba Medical Center Hospital |
| 17. | No name announced | SF9 cell vaccine candidate | West China Hospital, Sichuan University | Phase 1/2 | West China Hospital, Sichuan University |
| 18. | Soberana 1 and 2 | Monovalent/conjugate vaccine | Finlay Institute of Vaccines | Phase 1/2 | Finlay Institute of Vaccines |
| 19. | VLA2001 | Inactivated vaccine | Valneva; National Institute for Health Research (NIHR) | Phase 1/2 | Multiple NIHR testing sites |
| 20. | No name announced | Adjuvanted protein subunit vaccine | CEPI | Phase 1/2 | N/A |
| 21. | AG0301-COVID19 | DNA vaccine | AnGes, Inc. | Phase 1/2 | AnGes, Inc.; Japan Agency for Medical Research and Development |
| 22. | GX-19N | DNA vaccine | Genexine | Phase 1/2 | N/A |
| 23. | ARCT-021 (LUNAR-COV19) | Self-replicating RNA vaccine | Arcturus Therapeutics and Duke-NUS Medical School | Phase 1/2 | Duke-NUS Medical School, Singapore |

| Candidate | | Mechanism | Sponsor | Trial Phase | Institution |
|---|---|---|---|---|---|
| 24. | No name announced | Protein subunit vaccine | Sanofi; GlaxoSmithKline | Phase 1/2 | Various |
| 25. | No name announced | Inactivated vaccine | Chinese Academy of Medical Sciences, Institute of Medical Biology | Phase 1/2 | West China Second University Hospital, Yunnan Center for Disease Control and Prevention |
| 26. | HDT-301 (HGCO19) | RNA vaccine | University of Washington; National Institutes of Health Rocky Mountain Laboratories; HDT Bio Corp; Gennova Biopharmaceuticals | Phase 1/2 | N/A |
| 27. | AV-COVID-19 | Dendritic cell vaccine | Aivita Biomedical, Inc. | Phase 1b/2 | Rumah Sakit Umum Pusat Dr Kariadi |
| 28. | PTX-COVID19-B | mRNA-based vaccine | Providence Therapeutics; Canadian government | Phase 1 | N/A |
| 29. | COVI-VAC | Intranasal vaccine | Codagenix; Serum Institute of India | Phase 1 | N/A |
| 30. | CORVax12 | DNA vaccine (plasmid) | OncoSec; Providence Cancer Institute | Phase 1 | Providence Portland Medical Center |
| 31. | MVA-SARS-2-S | Modified vaccinia virus ankara (MVA) vector vaccine candidate | Universitätsklinikum Hamburg-Eppendorf; German Center for Infection Research; Philipps University Marburg Medical Center; Ludwig-Maximilians - University of Munich | Phase 1 | University Medical Center Hamburg-Eppendorf |
| 32. | COH04S1 | Modified vaccinia virus ankara (MVA) vector vaccine candidate | City of Hope Medical Center; National Cancer Institute | Phase 1 | City of Hope Medical Center |
| 33. | pVAC | Multi-peptide vaccine candidate | University Hospital Tuebingen | Phase 1 | University Hospital Tuebingen |
| 34. | AdimrSC-2f | Protein subunit vaccine | Adimmune | Phase 1 | Adimmune |

| Candidate | | Mechanism | Sponsor | Trial Phase | Institution |
|---|---|---|---|---|---|
| 35. | bacTRL-Spike | Monovalent oral vaccine (bifidobacteria) | Symvivo | Phase 1 | Symvivo Corporation |
| 36. | COVAX-19 | Monovalent recombinant protein vaccine | Vaxine Pty Ltd. | Phase 1 | Royal Adelaide Hospital |
| 37. | DelNS1-2019-nCoV-RBD-OPT1 | Replicating viral vector | Xiamen University, Beijing Wantai Biological Pharmacy | Phase 1 | Jiangsu Provincial Centre For Disease Control and Prevention |
| 38. | GRAd-COV2 | Adenovirus-based vaccine | ReiThera; Leukocare; Univercells | Phase 1 | Lazzaro Spallanzani National Institute for Infectious Diseases |
| 39. | UQ-CSL V451 | Protein subunit vaccine | CSL; The University of Queensland | Phase 1 | N/A |
| 40. | SCB-2019 | Protein subunit vaccine | GlaxoSmithKline, Sanofi, Clover Biopharmaceuticals, Dynavax and Xiamen Innovax; CEPI | Phase 1 | Linear Clinical Research (Australia) |
| 41. | VXA-CoV2-1 | Recombinant vaccine (adenovirus type 5 vector) | Vaxart | Phase 1 | Vaxart |
| 42. | AdCOVID | Intranasal vaccine | Altimmune | Phase 1 | University of Alabama at Birmingham |
| 43. | AAVCOVID | Gene-based vaccine | Massachusetts Eye and Ear; Massachusetts General Hospital; University of Pennsylvania | Pre-clinical | N/A |
| 44. | ChAd-SARS-CoV-2-S | Adenovirus-based vaccine | Washington University School of Medicine in St. Louis | Pre-clinical | Washington University School of Medicine in St. Louis |
| 45. | HaloVax | Self-assembling vaccine | Voltron Therapeutics, Inc.; Hoth Therapeutics, Inc. | Pre-clinical | MGH Vaccine and Immunotherapy Center |
| 46. | LineaDNA | DNA vaccine | Takis Biotech | Pre-clinical | Takis Biotech |

| Candidate | | Mechanism | Sponsor | Trial Phase | Institution |
|---|---|---|---|---|---|
| 47. | MRT5500 | mRNA-based vaccine | Sanofi, Translate Bio | Pre-clinical | N/A |
| 48. | No name announced | Ii-Key peptide COVID-19 vaccine | Generex Biotechnology | Pre-clinical | Generex |
| 49. | No name announced | Protein subunit vaccine | University of Saskatchewan Vaccine and Infectious Disease Organization-International Vaccine Centre | Pre-clinical | 50.University of Saskatchewan Vaccine and Infectious Disease Organization-International Vaccine Centre |
| 51. | No name announced | mRNA-based vaccine | Chulalongkorn University's Center of Excellence in Vaccine Research and Development | Pre-clinical | 52. |
| 53. | No name announced | gp96-based vaccine | Heat Biologics | Pre-clinical | 54.University of Miami Miller School of Medicine |
| 55. | No name announced | Inactivated vaccine | Shenzhen Kangtai Biological Products | Pre-clinical | N/A |
| 56. | PittCoVacc | Recombinant protein subunit vaccine (delivered through microneedle array) | UPMC/University of Pittsburgh School of Medicine | Pre-clinical | University of Pittsburgh |
| 57. | T-COVIDTM | Intranasal vaccine | Altimmune | Pre-clinical | N/A |

The biotechnology and biopharmaceutical industries are characterized by rapid evolution of technologies, fierce competition, and strong defense of intellectual property. Any product candidates that we successfully develop and commercialize will have to compete with existing therapies and new therapies that may become available in the future.

The Company's Accum technology enhances the technology of competitors who produce the raw material ADCs, vaccines, and others. As such, the primary competitors for the Company are those who develop new vaccine enhancer or ADC enhancer technologies. At the same time, we consider that the biggest advantage the Company has over its competitors is the Accum technology, which can be applied to a variety of competitor products (Vaccines, ADCs, enhancers) and potentially transform into strategic collaborations.

While we believe that our Accum technology, rational approach to drug design, along with our scientific expertise, provide us with competitive advantages, a wide variety of institutions, including large biopharmaceutical companies, specialty biotechnology companies, academic research departments, and

public and private research institutions, are actively developing potentially competitive products and technologies.

The Company also competes with other biopharmaceutical companies whose broader aim is to discover novel chemotherapeutic drugs or drug delivery systems. As a result of this competition, the majority of which is with companies with greater financial resources, the Company may be unable to successfully discover, identify and license suitable product candidates. The Company also competes for financing with other biopharmaceutical companies, many of whom have more advanced businesses. The Company's competitors include multinational pharmaceutical companies and specialized biotechnology companies, universities, and other research institutions. The Company will face the challenge of competing with companies of varying sizes and at varying stages of licensing and levels of development of related products in the pharmaceutical industry. Other companies may develop products targeting the same conditions that the Company may be focusing on, and such competing products may be superior to the Company's potential products.

More established companies may have a competitive advantage over the Company due to their greater size, capital resources, cash flows, and institutional experience. Compared to the Company, many of its competitors may have significantly greater financial, technical, and human resources at their disposal. Due to these factors, competitors may have an advantage in marketing their approved products and may obtain regulatory approval of their product candidates before the Company can, which may limit the Company's ability to develop or commercialize its product candidates. Competitors may also develop drugs that are safer, more effective, more widely used, and less expensive, and may also be more successful in manufacturing and marketing their products. These advantages could materially impact the Company's ability to develop and commercialize its products.

We consider our most direct competitors to be Roche-Genentech, GSK, Sanofi, Innocore Pharma, Takara Bio, *Seattle* Genetics, Ascendia Pharma, and Precision NanoSystems.

The pharmaceutical industry is facing a number of significant pressures, such as decreasing research and development productivity, increasing drug development costs, increasing patent protection loss of branded drugs, high regulatory barriers, evolving payer requirements, lower return on investment, generic drug competition and post-market clinical trial result failures due to safety concerns. Pharmaceutical companies are being forced to find more efficient and cost effective ways to improve their research and development strategies.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of the Company's competitors. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties also compete with the Company in recruiting and retaining qualified personnel, establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, the Company's programs. There is no assurance that additional capital or other types of financing will be available to the Company if needed or that, if available, the terms of such financing will be favourable to the Company. See "*Risk Factors".*

**Regulatory Environment**

Drug products must be approved by the appropriate governing body before they can be sold in that country or area. Health Canada approves products for the Canadian market and the FDA approves products for the United States market. The European Medicines Agency ("**EMA**") approves products for the European Union. While the process by which products are approved by Health Canada and the FDA are very similar, each regulatory body has its own unique requirements for a product. In both cases, the development of a product through to approval can be a lengthy process and, in some cases, can take over 10 years. While early studies

conducted in one jurisdiction will usually be accepted in the other, further and somewhat modified studies may be required to have a product approved in another jurisdiction

**Canada Government Regulation**

In Canada, our product candidates and our research and development activities are primarily regulated by the Food and Drugs Act and the rules and regulations thereunder, which are enforced by Health Canada (including its Biologics and Genetic Therapies Directorate). Health Canada regulates, among other things, the research, development, testing, approval, manufacture, packaging, labeling, storage, recordkeeping, advertising, promotion, distribution, marketing, post-approval monitoring and import and export of pharmaceutical, including biologic, products. The drug approval process under Canadian laws requires licensing of manufacturing facilities, carefully controlled research and testing of products, government review and approval of experimental results prior to giving approval to sell drug products including biologic drug products. Regulators also typically require that rigorous and specific standards such as GMP, GLP and GCP are followed in the manufacture, testing and clinical development, respectively, of any drug product. The processes for obtaining regulatory approvals in Canada, along with subsequent compliance with applicable statutes and regulations, requires the expenditure of substantial time and financial resources. For further information, see "Risk Factors."

The principal steps required for drug approval in Canada are as follows:

*Preclinical Toxicology Studies*

Non-clinical studies conducted in vitro and in animals to evaluate pharmacokinetics, metabolism and possible toxic effects provide evidence of the safety of the drug candidate prior to its administration to humans in clinical studies and throughout development. Such studies are conducted in accordance with applicable laws and GLP.

*Initiation of Human Testing*

In Canada, the process of conducting clinical trials with a new drug cannot begin until we have submitted a Clinical Trial Application, or CTA, and the required number of days has lapsed without objection from Health Canada. Biological drugs carry additional risks, as compared to traditional small molecule drugs, associated with complexity and variability in manufacturing that can contribute to increased lot-to-lot variation of the final product, and with the potential for adventitious agents. Therefore, the content requirements for the quality information for biological drugs to be used in clinical trials are different from those for standard small molecule pharmaceutical drugs (for example, the inclusion of information on manufacturing facilities is required for biological drugs). In addition, it is necessary to have more stringent controls on the release of biologic drug lots used in authorized clinical trials.

Similar regulations apply in Canada to a CTA as to an IND in the United States. If the CTA is deemed by Health Canada to be acceptable, a No Objection Letter, or NOL, would be issued. A Not Satisfactory Notice will be issued by Health Canada if significant deficiencies are identified or if timely responses to information requested have not been received. Once approved by the issuance of an NOL, two key factors influencing the rate of progression of clinical trials are the rate at which patients can be enrolled to participate in the research program and whether effective treatments are currently available for the disease that the drug is intended to treat. Patient enrollment is largely dependent upon the incidence and severity of the disease, the treatments available and the potential side effects of the drug to be tested and any restrictions for enrollment that may be imposed by regulatory agencies. For further information, see "Risk Factors".

*Clinical Trials*

Similar regulations apply in Canada regarding clinical trials as in the United States. In Canada, Research Ethics Boards, or REBs, instead of IRBs, are used to review and approve clinical trial plans. Clinical trials involve the administration of an investigational new drug to human subjects under the supervision of qualified investigators, in most cases a physician, in accordance with current Good Clinical Practices, or cGCP, requirements, which include review and approval by REBs. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the trial procedures, the parameters to be used in monitoring safety and the efficacy criteria to be evaluated and a statistical analysis plan. Human clinical trials for new drugs are typically conducted in three sequential phases, Phase 1, Phase 2 and Phase 3, as discussed above in the context of government regulation in the United States.

The manufacture of investigational drugs for the conduct of human clinical trials is subject to current Good Manufacturing Practice, or cGMP, requirements. Investigational drugs and active pharmaceutical ingredients imported into Canada are also subject to regulation by Health Canada relating to their labeling and distribution. Progress reports detailing the results of the clinical trials must be submitted at least annually to Health Canada and the applicable REBs, and more frequently if serious adverse events occur. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, in Canada, Health Canada or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an REB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the REB's requirements or if the drug has been associated with unexpected serious harm to subjects. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group regularly reviews accumulated data and advises the study sponsor regarding the continuing safety of trial subjects, potential trial subjects and the continuing validity and scientific merit of the clinical trial. A sponsor may also suspend or terminate a clinical trial based on evolving business objectives or competitive climate.

*New Drug Submission*

Upon successful completion of Phase 3 clinical trials, in Canada the company sponsoring a new drug then assembles all the preclinical and clinical data and other testing relating to the product's pharmacology, chemistry, manufacture, and controls, and submits it to Health Canada as part of a New Drug Submission ("**NDS**"). The NDS is then reviewed by Health Canada for approval to market the drug.

As part of the approval process, Health Canada will inspect the facility or the facilities at which the drug is manufactured. Health Canada will not approve the product unless compliance with cGMP—a quality system regulating manufacturing—is satisfactory and the NDS contains data that provide substantial evidence that the drug is safe and effective in the indication studied. In addition, before approving an NDS, Health Canada will typically inspect one or more clinical sites to assure compliance with GCP.

The testing and approval process for an NDS requires substantial time, effort, and financial resources, and may take several years to complete. Biologic drugs, such as our candidates, differ from standard small molecule drugs in that applicants must include more detailed chemistry and manufacturing information. This is necessary to help ensure the purity and quality of the product, for example to help ensure that it is not contaminated by an undesired microorganism. Data obtained from preclinical and clinical testing are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. Health Canada may not grant approval of an NDS on a timely basis, or at all. In Canada, NDSs are subject to user fees and these fees are typically increased annually to reflect inflation.

Even if Health Canada approves a product candidate, it may limit the approved indications for use of the product candidate, require that contraindications, warnings or precautions be included in the product labeling,

require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms.

Biologic products in particular are monitored post-approval by being placed on a lot release schedule tailored to their potential risk, manufacturing, testing and inspection history to date. With higher risk biologics, each lot is tested before being released for sale in Canada. Moderate risk biologics are periodically tested at the discretion of Health Canada while manufacturers of low risk biologics usually only need to contact Health Canada regarding lots being sold or for providing certification of complete and satisfactory testing. Products are carefully scrutinized before they are placed in any level of the lot release process, and at any time the testing regime for a biologic may be altered.

Health Canada may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements, notification, and regulatory authority review and approval. Further, should new safety information arise, additional testing, product labeling or regulatory notification may be required.

*Canadian Biosimilars*

The terms "biosimilar biologic drug" and "biosimilar" are used by Health Canada to describe a biologic drug that enters the market subsequent to a version previously authorized in Canada and with demonstrated similarity to a reference biologic drug. Accordingly, a biosimilar, previously known in Canada as a subsequent entry biologic, or SEB, will in all instances be a subsequent entrant onto the Canadian market.

Based on Health Canada guidance documents, a biosimilar can rely in part on prior information regarding safety and efficacy that is deemed relevant due to the demonstration of similarity to the reference biologic drug and which influences the amount and type of original data required. Generic drugs are chemically derived products that are pharmaceutically equivalent to innovative drugs, whereas biosimilars are products of a biologic nature that are similar to innovative biologics. According to Health Canada, it is not currently possible to demonstrate that two biologic drugs are pharmaceutically equivalent, and therefore the regulatory approval process for generics and biosimilars is different: biosimilars are approved using the standard NDS pathway with some allowances made for reduced safety and efficacy information set out in guidance documents, while generic drugs are approved using an abbreviated new drug submission pathway set in guidance and law under the Food and Drug Regulations. In part because it continues to be set out only in guidance and not law, the specific requirements in order to receive biosimilar approval are subject to some uncertainty.

As discussed above, all biosimilars enter the market subsequent to a biologic drug product previously approved in Canada and to which the biosimilar is considered similar. As such, biosimilars are subject to existing laws and regulations outlined in the Patented Medicines (Notice of Compliance) Regulations and the Food and Drug Regulations, and related guidance documents.

Similar to the Hatch-Waxman Act in the United States, Canada has the Patented Medicines (NOC) Regulations under the Patent Act which require a company that files a drug submission that references a patented product (for example, a biosimilar) to address any relevant patents listed on the Patent Register against the reference product, prior to being able to receive approval from Health Canada. The Canadian regime is similar to the United States regime, but a number of distinctions do exist.

Like the United States, Canada also has data protection, but again differences exist between the two jurisdictions. For example, Canada's data protection applies to an "innovative drug," which is defined as a drug that contains a medicinal ingredient not previously approved in a drug and that is not a variation of a

previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph. If a product is deemed to be an innovate drug, it is eligible for an eight-year period of data protection (with an additional six-month pediatric extension in some circumstances). In general, biologics can be considered innovative drugs but typically biosimilars are not.

**United States Government Regulation**

In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act (the "**FDCA**"), and its implementing regulations, and biologics under the FDCA and the Public Health Service Act, and its implementing regulations. FDA approval is required before any new unapproved drug or biologic or dosage form, including a new use of a previously approved drug, can be marketed in the United States. In some cases, changes to aspects of an approved drug product also require pre-approval prior to implementation of these changes. Drugs and biologics are also subject to other federal, state, and local statutes and regulations. If the Company fails to comply with applicable FDA or other requirements at any time during the product development process, clinical testing, the approval process or after approval, the Company may become subject to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, civil monetary penalties or criminal prosecution. Any FDA enforcement action could have a material adverse effect on the Company.

The process required by the FDA before drug products may be marketed in the United States generally involves the following:

- completion of extensive preclinical laboratory tests and preclinical animal studies, some performed in accordance with the GLP regulations;
- submission to the FDA of an IND, which must be reviewed by the FDA and become active before human clinical trials may begin and must be updated annually;
- approval by an independent review board ("**IRB**") or ethics committee representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials conducted under Good Clinical Practices ("**GCP**") to establish the safety and efficacy of the product candidate for each proposed indication;
- preparation of and submission to the FDA of a New Drug Application ("**NDA**") or Biologics License Application ("**BLA**") after completion of all pivotal clinical trials;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA to file the application for review;
- potential review of the product application by an FDA advisory committee, where appropriate and if applicable;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities where the proposed product is produced to assess compliance with current GMP ("**cGMP**");
- a potential FDA audit of the preclinical research and clinical trial sites that generated the data in support of the NDA or BLA; and
- FDA review and approval of an NDA or BLA prior to any commercial marketing or sale of the product in the United States.

The preclinical research, clinical testing and approval process require substantial time, effort, and financial resources, and the Company cannot be certain that any approvals for the Company's product candidates will be granted on a timely basis, if at all. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans in clinical trials. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human clinical trials. The IND also includes results of animal studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic

characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational new drug.

An IND must become effective before human clinical trials may begin in the US. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to the proposed clinical trials. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before clinical trials can begin. Accordingly, submission of an IND may or may not result in the FDA allowing clinical trials to commence. As drug product programs continue in development, clinical trial protocols, additional preclinical testing results, and manufacturing information is submitted with the IND to facilitate discussions with the FDA and approval of additional clinical trials.

*Clinical Trials*

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with GCP, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. Additionally, approval must also be obtained from each clinical trial site's IRB or ethics committee, before the trials may be initiated, and the IRB or ethics committee must monitor the trial until completed. All subjects must provide informed consent prior to participating in the trial. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

The clinical investigation of a drug is generally divided into three or four phases. Although the phases are usually conducted sequentially, they may overlap or be combined.

- Phase I. The drug is initially introduced into healthy human subjects or, in some cases, patients with the target disease or condition. These studies are designed to evaluate the safety, tolerance, metabolism, pharmacokinetic and pharmacologic actions of the investigational new drug in humans, and the side effects associated with increasing doses.
- Phase II. The drug is administered to a limited patient population to evaluate safety and optimal dose levels for safety and efficacy, identify possible adverse side effects and safety risks, and preliminarily evaluate efficacy.
- Phase III. The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites to generate sufficient data to statistically evaluate dose levels, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the investigational new drug product, and to provide an adequate basis for physician labeling.
- Phase IV. In some cases, the FDA may conditionally approve an NDA or BLA for a drug product with the sponsor's agreement to conduct additional clinical trials after approval. In other cases, a sponsor may voluntarily conduct additional clinical trials after approval to gain more information about the drug. Such post-approval studies are typically referred to as Phase IV clinical trials.

Clinical trial sponsors must also report to the FDA, within certain timeframes: (i) serious and unexpected adverse reactions, (ii) any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator's brochure, or (iii) any findings from other studies or animal testing that suggest a significant risk in humans exposed to the product candidate. The FDA, the IRB, the ethics committee or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides

authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial.

The clinical trial process can take years to complete, and there can be no assurance that the data collected will support FDA approval or licensing of the product. Results from one trial are not necessarily predictive of results from later trials. The Company may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

*Submission of an NDA or BLA to the FDA*

Assuming successful completion of all required preclinical studies and clinical testing in accordance with all applicable regulatory requirements, detailed investigational new drug product information is submitted to the FDA in the form of an NDA or BLA requesting approval to market the product for one or more indications. Under federal law, the submission of most NDAs and BLAs is subject to an application user fee. An NDA or BLA must include all relevant data available from pertinent preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data comes from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product and may also come from several alternative sources, including clinical trials initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational new drug product to the satisfaction of the FDA.

Once an NDA or BLA has been submitted, the FDA's goal is to review the application within ten months after it accepts the application for filing, or, if the application relates to an unmet medical need in a serious or life-threatening indication, six months after the FDA accepts the application for filing. The review process is often significantly extended by the FDA's requests for additional information or clarification. Before approving an NDA or BLA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP and related regulations.

The FDA is required to refer an NDA or BLA for a novel drug (in which no active ingredient has been approved in any other application) to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and the conditions thereof. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

*The FDA's Decision on an NDA or BLA*

After the FDA evaluates the NDA or BLA and conducts inspections of manufacturing facilities where the product will be produced, the FDA will issue either an approval letter or a complete response letter ("**Complete Response Letter**"). An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application is not ready for approval. To satisfy deficiencies identified in a Complete Response Letter, additional clinical data and/or an additional Phase III clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing may be required for the drug product.

Even if such additional information is submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval. The FDA could also approve the NDA or BLA with a risk evaluation and mitigation strategy, which could include medication guides, physician communication plans, or elements to

assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA may also conditionally approve a drug product subject to, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical trials. Such post-market testing may include Phase IV clinical trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. New government requirements, including those resulting from new legislation, may be established during the review process, or the FDA's policies may change, which could delay or prevent regulatory approval of the Company's products under development.

**European Union Government Regulation**

*European Union Drug Development*

Similar to the United States, the various phases of preclinical and clinical research in the European Union (the "**EU**") are subject to significant regulatory controls. Although the EU Clinical Trials Directive 2001/20/EC has sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the EU, the EU Member States have transposed and applied the provisions of the Directive differently. This has led to significant variations in the member state regimes. Under the current regime, before a clinical trial can be initiated, it must be approved in each of the EU countries where the trial is to be conducted by two distinct bodies: the National Competent Authority ("**NCA**"), and one or more Ethics Committees ("**ECs**"). Under the current regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the Member State where they occurred.

The EU clinical trials legislation currently is undergoing a transition process mainly aimed at harmonizing and streamlining clinical-trial authorization, simplifying adverse-event reporting procedures, improving the supervision of clinical trials and increasing their transparency. Recently enacted Clinical Trials Regulation EU No 536/2014 ensures that the rules for conducting clinical trials in the EU will be identical. In the meantime, Clinical Trials Directive 2001/20/EC continues to govern all clinical trials performed in the EU.

*European Union Drug Review and Approval*

In the European Economic Area, or EEA, comprising the 28 Member States of the EU plus Norway, Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. There are two types of marketing authorizations:

The Community MA is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, and is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products and medicinal products containing a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.

National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member States through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized

Procedure. Under the Decentralized Procedure an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State, or RMS. The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics, or SPC, and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Member States Concerned) for their approval. If the Member States Concerned raise no objections, based on a potential serious risk to public health, to the assessment, SPC, labeling, or packaging proposed by the RMS, the product is subsequently granted a national MA in all the Member States (i.e., in the RMS and the Member States Concerned).

Under the above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

*European Union New Chemical Entity Exclusivity*

In the EU, new chemical entities, sometimes referred to as new active substances, qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. The data exclusivity, if granted, prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic application for eight years, after which generic marketing authorization can be submitted, and the innovator's data may be referenced, but not approved for two years. The overall ten year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are determined to bring a significant clinical benefit in comparison with currently approved therapies.

**Risk Factors**

This section discusses factors relating to the business of Company that should be considered by both existing and potential investors. The information in this section is intended to serve as an overview and should not be considered comprehensive and the Company may face risks and uncertainties not discussed in this section, or not currently known to us, or that we deem to be immaterial. All risks to the Company's business have the potential to influence its operations in a materially adverse manner.

**Risks Relating to the Company's Business**

***Limited Operating History***

The Company has a very limited history of operations and is considered a start-up company. As such, the Company is subject to many risks common to such enterprises, including under-capitalization, cash shortages, limitations with respect to personnel, financial and other resources and lack of revenues. There is no assurance that the Company will be successful in achieving a return on shareholders' investment and the likelihood of the Company's success must be considered in light of its early stage of operations.

***The Company's actual financial position and results of operations may differ materially from the expectations of the Company's management.***

The Company's actual financial position and results of operations may differ materially from management's expectations. The Company has experienced some changes in its operating plans and certain delays in its plans. As a result, the Company's net loss and cash flow may differ materially from the Company's projected net loss and cash flow. The process for estimating the Company's net loss and cash flow requires the use of judgment in determining the appropriate assumptions and estimates. These estimates and assumptions may be revised as additional information becomes available and as additional analyses are performed. In addition,

the assumptions used in planning may not prove to be accurate, and other factors may affect the Company's financial condition or results of operations.

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

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

- the Company's research or business development methodology or search criteria and process may be unsuccessful in identifying potential product candidates;
- the Company may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates;
- the Company's product candidates may not succeed in pre-clinical or clinical testing;
- the Company's product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval;
- competitors may develop alternatives that render the Company's product candidates obsolete or less attractive;
- product candidates the Company develops may be covered by third parties' patents or other exclusive rights;
- the market for a product candidate may change during the Company's program so that such a product may become unreasonable to continue to develop;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

If any of these events occurs, the Company may be forced to abandon its development efforts to identify, license or discover additional product candidates, which would have a material adverse effect on its business and could potentially cause the Company to cease operations. Research programs to identify new product candidates require substantial technical, financial and human resources. The Company may focus its efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

***There is no assurance that the Company will turn a profit or generate immediate revenues.***

There is no assurance as to whether the Company will be profitable, earn revenues, or pay dividends. The Company has incurred and anticipates that it will continue to incur substantial expenses relating to the development and initial operations of its business. The payment and amount of any future dividends will depend upon, among other things, the Company's results of operations, cash flow, financial condition, and operating and capital requirements. There is no assurance that future dividends will be paid, and, if dividends are paid, there is no assurance with respect to the amount of any such dividends.

***The Company as a going concern***

The continued operation of the Company as a going concern is dependent upon the Company's ability to generate positive cash flows and/or obtain additional financing sufficient to fund continuing activities and

acquisitions. While the Company continues to review its operations in order to identify strategies and tactics to increase revenue streams and financing opportunities, there is no assurance that the Company will be successful in such efforts; if the Company is not successful, it may be required to significantly reduce or limit operations, or no longer operate as a going concern. It is also possible that operating expenses could increase in order to grow the business. If the Company does not significantly increase its revenue to meet these increased operating expenses and/or obtain financing until its revenue meets these operating expenses, its business, financial condition and operating results could be materially adversely affected. The Company cannot be sure when or if it will ever achieve profitability and, if it does, it may not be able to sustain or increase that profitability.

***The Company's intellectual property and licences thereto***

The Company's success will depend in part on its ability to protect and maintain its intellectual property rights and its licenses. No assurance can be given that the license or rights used by the Company will not be challenged, invalidated, infringed or circumvented, nor that the rights granted thereunder will provide competitive advantages to the Company. It is not clear whether the pending patent applications will result in the issuance of patents. There is no assurance that the Company will be able to enter into licensing arrangements, develop or obtain alternative technology in respect of patents issued to third parties that incidentally cover its production processes. Moreover, the Company could potentially incur substantial legal costs in defending legal actions which allege patent infringement or by instituting patent infringement suits against others. The Company's commercial success also depends on the Company not infringing patents or proprietary rights of others and not breaching the exclusive license granted to the Company. There can be no assurance that the Company will be able to maintain such licenses that it may require to conduct its business or that such licences have been obtained at a reasonable cost. Furthermore, there can be no assurance that the Company will be able to remain in compliance with its licenses. Consequently, there may be a risk that such licenses may be withdrawn with no compensation or penalties to the Company.

***The Company faces product liability exposure, which, if not covered by insurance, could result in significant financial liability.***

The risk of product liability is inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. Product candidates and products that we may commercially market in the future may cause, or may appear to have caused, injury or dangerous drug reactions, and expose the Company to product liability claims. These claims might be made by patients who use the product, healthcare providers, pharmaceutical companies, corporate collaborators or others selling such products. If the Company's product candidates during clinical trials were to cause adverse side effects, the Company may be exposed to substantial liabilities. Regardless of the merits or eventual outcome, product liability claims or other claims related to the Company's product candidates may result in:

- decreased demand for our products due to negative public perception;
- injury to our reputation;
- withdrawal of clinical trial participants or difficulties in recruiting new trial participants;
- initiation of investigations by regulators;
- costs to defend or settle related litigation;
- a diversion of management's time and resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenues from product sales; and
- the inability to commercialize any of product candidates, if approved.

The Company intends to obtain clinical trial insurance once a clinical trial is initiated. However, the insurance coverage may not be sufficient to reimburse the Company for any expenses or losses it may suffer. Insurance coverage is becoming increasingly expensive, and, in the future, the Company, or any of its collaborators, may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts or at all to protect against losses due to liability. Even if the Company's agreements with any future collaborators entitle it to indemnification against product liability losses, such indemnification may not be available or adequate should any claim arise. The Company's inability to obtain sufficient product liability insurance at an acceptable cost to protect against product liability claims could prevent or inhibit the commercialization of its product candidates. If a successful product liability claim or series of claims is brought against the Company for uninsured liabilities or in excess of insured liabilities, its assets may not be sufficient to cover such claims and its business operations could be impaired.

Should any of the events described above occur, this could have a material adverse effect on the Company's business, financial condition and results of operations.

***Defence may be subject to risks related to its information technology systems, including cyber-attacks***

The Company has entered into agreements with third parties for hardware, software, telecommunications and other information technology ("**IT**") services in connection with its operations. The Company's operations depend, in part, on how well it and its suppliers protect networks, equipment, IT systems and software against damage from a number of threats, including, but not limited to, cable cuts, damage to physical plants, natural disasters, intentional damage and destruction, fire, power loss, hacking, computer viruses, vandalism and theft. The Company's operations also depend on the timely maintenance, upgrade and replacement of networks, equipment, IT systems and software, as well as pre-emptive expenses to mitigate the risks of failures. Any of these and other events could result in information system failures, delays and/or increase in capital expenses. The failure of information systems or a component of information systems could, depending on the nature of any such failure, adversely impact the Company's reputation and results of operations.

The Company has not experienced any material losses to date relating to cyber-attacks or other information security breaches, but there can be no assurance that the Company will not incur such losses in the future. The Company's risk and exposure to these matters cannot be fully mitigated because of, among other things, the evolving nature of these threats. As a result, cyber security and the continued development and enhancement of controls, processes and practices designed to protect systems, computers, software, data and networks from attack, damage or unauthorized access is a priority. As cyber threats continue to evolve, the Company may be required to expend additional resources to continue to modify or enhance protective measures or to investigate and remediate any security vulnerabilities.

***We are early in our development efforts. If we are unable to advance our product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or if we experience significant delays in doing so, our business will be materially harmed.***

We are early in our development efforts. Our most advanced product, Accum, is still in the early stages of preclinical development. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of one or more of our product candidates. The success of our product candidates will depend on several factors, including the following:

- successful completion of preclinical studies;
- successful initiation of clinical trials;
- successful patient enrollment in, and completion, of clinical trials;
- receipt and related terms of marketing approvals from applicable regulatory authorities;

- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- making and maintaining arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our product candidates;
- establishing sales, marketing and distribution capabilities and successfully launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other cancer therapies;
- obtaining and maintaining third-party coverage and adequate reimbursement; and
- maintaining a continued acceptable safety profile of our products following regulatory approval.

***Our business is highly dependent on our lead product candidate, Accum, and we must complete preclinical studies and clinical testing before we can seek regulatory approval and begin commercialization of any of our other product candidates. If we are unable to obtain regulatory approval for, and successfully commercialize Accum, our business may be materially harmed and such failure may affect the viability of our other product candidates.***

There is no guarantee that any of our product candidates will proceed in preclinical or clinical development or achieve regulatory approval. The process for obtaining marketing approval for any product candidate is very long and risky and there will be significant challenges for us to address in order to obtain marketing approval as planned or at all.

There is no guarantee that the results obtained in planned preclinical studies or our Phase 1 clinical trial of Accum or other future clinical trials will be sufficient to obtain regulatory approval. In addition, if our lead product candidate encounters safety or efficacy problems, developmental delays, regulatory issues, or other problems, our development plans and business related to our other current or future product candidates could be significantly harmed. A failure of our lead product candidate may affect the ability to obtain regulatory approval to continue or conduct clinical programs for our other or future product candidates. Further, competitors who are developing products with similar technology may experience problems with their products that could identify problems that would potentially harm our business.

***Clinical development involves a lengthy and expensive process with uncertain outcomes, and results of earlier studies and trials may not be predictive of future clinical trial results. If our preclinical studies and clinical trials are not sufficient to support regulatory approval of any of our product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product candidate.***

We cannot be certain that our preclinical study and clinical trial results will be sufficient to support regulatory approval of our product candidates. Clinical testing is expensive and can take many years to complete, and its outcomes are inherently uncertain. Human clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Our clinical trials may not be conducted as planned or completed on schedule, if at all, and failure can occur at any time during the preclinical study or clinical trial process. Despite promising preclinical or clinical results, any product candidate can unexpectedly fail at any stage of preclinical or clinical development. The historical failure rate for product candidates in our industry is high.

We may experience delays in obtaining Health Canada's authorization to initiate clinical trials. Additionally, we cannot be certain that preclinical studies or clinical trials for our product candidates will begin on time, not require redesign, enroll an adequate number of subjects on time, or be completed on schedule, if at all. Clinical trials can be delayed or terminated for a variety of reasons.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are not as positive as we expect or if there are safety concerns, our business and results of operations may be adversely affected and we may incur significant additional costs. Accordingly, our clinical trial costs are likely to be significantly higher than those for more conventional therapeutic technologies or drug product candidates. We could also experience delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety, efficacy, potency and purity profiles. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such clinical trials are being conducted, by Health Canada or by another regulatory authority.

If we experience delays in the completion, or termination, of any preclinical study or clinical trial of our product candidates, the commercial prospects of our product candidates may be harmed, and our ability to generate revenues from any of these product candidates will be delayed or not realized at all. In addition, any delays in completing our preclinical studies or clinical trials may increase our costs, slow down the development of our product candidates and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business, financial condition and prospects. 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 our product candidates. If one or more of our product candidates generally prove to be ineffective, unsafe or commercially unviable, our entire product pipeline and technology would have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

***We expect to develop Accum, and potentially future product candidates, in combination with other therapies, which exposes us to additional risks.***

We intend to develop Accum, and may develop future product candidates, for use in combination with one or more currently approved cancer therapies. Even if any product candidate we develop was to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that Health Canada, the FDA or similar foreign regulatory authorities 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 we would be subject to similar risks if we develop any of our product candidates for use in combination with other drugs or for indications other than cancer. This could result in our own products being removed from the market or being less successful commercially.

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

If Health Canada or similar foreign 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 Accum or any product candidate we develop, we may be unable to obtain approval of or market Accum or any product candidate we develop.

***Our preclinical studies and clinical trial may fail to adequately demonstrate the safety, potency and purity of any of our product candidates, which would prevent or delay development, regulatory approval and commercialization.***

Before obtaining regulatory approvals for the commercial sale of our product candidates, including our lead product candidate, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for use in each target indication. Preclinical studies and clinical trials are expensive and can take many years to complete, and their outcomes are inherently uncertain. Failure can occur at any time during the preclinical study and clinical trial processes, and, because our product candidates are in an early stage of development, there is a high risk of failure and we may never succeed in developing marketable products.

Any preclinical studies or clinical trials that we may conduct may not demonstrate the safety, potency and purity necessary to obtain regulatory approval to market our product candidates. If the results of our ongoing or future preclinical studies and clinical trials are inconclusive, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be prevented or delayed in obtaining marketing approval for such product candidates. In some instances, there can be significant variability in results between different preclinical studies and clinical of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants.

In addition, any future clinical trials that may be completed for Accum or other product candidates, we cannot guarantee that Health Canada will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the trials are not satisfactory to Health Canada to support a marketing application, approval of our product candidates may be significantly delayed or prevented entirely, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

***The results of preclinical studies and early-stage clinical trials may not be predictive of future results. Initial success in our 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 we commence 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 of our current or future clinical trials will ultimately be successful or support further clinical development of any of our product candidates. There is a high failure rate for drugs and biologics 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 our clinical development could have a material adverse effect on our business and operating results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies or clinical trials nonetheless failed to obtain Health Canada approval or approval from foreign regulatory authorities.

***Interim, "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.***

From time to time, we may publish interim, "top-line" or preliminary data from our clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions

are subject to change following a full analysis of all data related to the particular trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. Data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Interim, "top-line" or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim, "top-line," and preliminary data should be viewed with caution until the final data are available. Adverse differences between interim, "top-line" or preliminary data and final data could significantly harm our reputation and business prospects.

In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is distilled from a large body of raw data and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosures, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, product candidate or our business. If the interim, "top-line," or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our product candidates, our business, prospects, financial condition and results of operations may be harmed.

***COVID-19 may materially and adversely affect our business and financial results.***

In December 2019, a novel strain of coronavirus, which causes the disease known as COVID-19, was reported to have surfaced in Wuhan, China. Since then, COVID-19 coronavirus has spread globally. In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic.

The effects of COVID-19 could disrupt our business and delay any future clinical trials, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, financial condition and results of operations, including our ability to obtain financing. Quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases could impact personnel at third-party manufacturing facilities or the availability or cost of materials, which would disrupt our supply chain.

- In addition, any future clinical trials have been and may be further affected by the COVID-19 pandemic, including:
- delays or difficulties in enrolling patients in the clinical trial, including patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion or prioritization of healthcare resources away from the conduct of clinical trials and towards the COVID-19 pandemic, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials, who, as healthcare providers, may have heightened exposure to COVID-19 and adversely impact our clinical trial operations;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal, state or provincial governments, employers and others; and
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people.

***Disruptions at Health Canada and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products and services from being developed, approved or commercialized in a timely manner, which could negatively impact our business.***

The ability of the Health Canada to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, statutory, regulatory, and policy changes and other events that may otherwise affect Health Canada's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at Health Canada and other agencies may also slow the time necessary for new biologics to be reviewed and/or approved or cleared by necessary government agencies, which would adversely affect our business.

If a prolonged government shutdown occurs, or if global health concerns Health Canada or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of Health Canada or other regulatory authorities to timely review and process regulatory submissions, which could have a material adverse effect on our business. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

***Exchange rate fluctuations between the U.S. dollar and the Canadian dollar may negatively affect the Company's earnings cash flows.***

The Company's functional currency is the Canadian dollar. The Company may incur expenses in Canadian dollars and U.S. dollars. As a result, we are exposed to the risks that the Canadian dollar may devalue relative to the U.S. dollar, or, if the Canadian dollar appreciates relative to the U.S. dollar, that the inflation rate in Canada may exceed such rate of devaluation of the Canadian dollar, or that the timing of such devaluation may lag behind inflation in Canada. The Company cannot predict any future trends in the rate of inflation in Canada or the rate of devaluation, if any, of the Canadian dollar against the U.S. dollar.

***If patent laws or the interpretation of patent laws change, the Company's competitors may be able to develop and commercialize our discoveries.***

Important legal issues remain to be resolved as to the extent and scope of available patent protection for biopharmaceutical products and processes in Canada, and other important markets outside Canada, such as Europe or the United States. As such, litigation or administrative proceedings may be necessary to determine the validity, scope and ownership of certain of our and others' proprietary rights. Any such litigation or proceeding may result in a significant commitment of resources in the future and could force the Company to do one or more of the following: cease selling or using any of its future products that incorporate a challenged intellectual property, which would adversely affect its revenue; obtain a license or other rights from the holder of the intellectual property right alleged to have been infringed or otherwise violated, which license may not be available on reasonable terms, if at all; and redesign its future products to avoid infringing or violating the intellectual property rights of third parties, which may be time-consuming or impossible to do. In addition, changes in patent laws in Canada and other countries may result in allowing others to use its discoveries or develop and commercialize our products. The Company cannot provide assurance that the patents it obtains will afford it significant commercial protection.

***The Company may not be able to enforce its intellectual property rights throughout the world. This risk is exacerbated because it expects that one or more of its product candidates will be manufactured and used in a number of foreign countries.***

The laws of foreign countries may not protect intellectual property rights to the same extent as the laws of Canada. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. This risk is exacerbated for the Company because it expects that future product candidates could be manufactured and used in a number of foreign countries.

The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to life sciences. This could make it difficult to stop the infringement or other misappropriation of the Company's intellectual property rights. For example, several foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents and trade secrets may provide limited or no benefit.

Most jurisdictions in which the Company intends to apply for patents have patent protection laws similar to those of Canada, but some of them do not. For example, the Company may do business in the future in countries that may not provide the same or similar protection as that provided in Canada. Additionally, due to uncertainty in patent protection law, the Company has not filed applications in many countries where significant markets exist.

Proceedings to enforce patent rights in foreign jurisdictions could result in substantial costs and divert the Company's efforts and attention from other aspects of its business. Accordingly, efforts to protect intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in Canada, the U.S., and foreign countries may affect our ability to obtain adequate protection for the Company's technology and the enforcement of its intellectual property.

***The Company continues to sell shares for cash to fund operations, capital expansion, mergers and acquisitions that will dilute the current shareholders.***

There is no guarantee that the Company will be able to achieve its business objectives. The continued development of the Company will require additional financing. The failure to raise such capital could result in the delay or indefinite postponement of current business objectives or the Company going out of business. There can be no assurance that additional capital or other types of financing will be available if needed or that, if available, the terms of such financing will be favourable to the Company.

If additional funds are raised through issuances of equity or convertible debt securities, existing shareholders could suffer significant dilution, and any new equity securities issued could have rights, preferences and privileges superior to those of holders of Common Shares. The Company's articles permit the issuance of an unlimited number of Common Shares, and shareholders will have no pre-emptive rights in connection with such further issuance. The directors of the Company have discretion to determine the price and the terms of issue of further issuances. In addition, from time to time, the Company may enter into transactions to acquire assets or the shares of other companies. These transactions may be financed wholly or partially with debt, which may temporarily increase the Company's debt levels above industry standards. Any debt financing secured in the future could involve restrictive covenants relating to capital raising activities and other financial and operational matters, which may make it more difficult for the Company to obtain additional capital and to pursue business opportunities, including potential acquisitions. The Company may require additional financing to fund its operations to the point where it is generating positive cash flows. Negative cash flow may restrict the Company's ability to pursue its business objectives.

***Negative Cash Flow From Operations***

The Company has negative operating cash flow. The Company cannot guarantee if it will have positive cash flow from operating activities in future periods. The Company cannot provide any assurance that it will achieve sufficient revenues to achieve or maintain profitability or positive cash flow from operating activities.

If the Company does not achieve or maintain profitability or positive cash flow from operating activities, then there could be a material adverse effect on the Company's business, financial condition and results of operation and the Company may need to deploy a portion of its working capital to fund such negative operating cash flows or seek additional sources of funding, of which there is no assurance that any required funding will be obtained.

In the event that cash flow from operations do not adequately support the fixed costs of the Company, the Company will then be required to re-evaluate its planned expenditures, reallocate its total resources and may require future financings in such a manner as the Board of Directors and management deem to be in the Company's best interest. This may result in a substantial reduction of the scope of the Company's existing and planned operations. The presence of these conditions may indicate the existence of a material uncertainty that may cast significant doubt regarding the Company's ability to continue as a going concern.

***The Company's officers and directors may be engaged in a range of business activities resulting in conflicts of interest.***

***The Company may be subject to various potential conflicts of interest because some of its officers and directors may be engaged in a range of business activities. In addition, the Company's executive officers and directors may devote time to their outside business interests, so long as such activities do not materially or adversely interfere with their duties to the Company. In some cases, the Company's executive officers and directors may have fiduciary obligations associated with these business interests that interfere with their ability to devote time to the Company's business and affairs and that could adversely affect the Company's operations. These business interests could require significant time and attention of the Company's executive officers and directors.***

In addition, the Company may become involved in other transactions which conflict with the interests of its directors and officers who may from time to time deal with persons, firms, institutions or Companies with which the Company may be dealing, or which may be seeking investments similar to those desired by it. The interests of these persons could conflict with those of the Company. In addition, from time to time, these persons may be competing with the Company for available investment opportunities. Conflicts of interest, if any, will be subject to the procedures and remedies provided under applicable laws. In particular, if such a conflict of interest arises at a meeting of the Company's directors, a director who has such a conflict will abstain from voting for or against the approval of such participation or such terms. In accordance with applicable laws, the directors of the Company are required to act honestly, in good faith and in the best interests of the Company.

***In certain circumstances, the Company's reputation could be damaged.***

Damage to the Company's reputation can be the result of the actual or perceived occurrence of any number of events, and could include any negative publicity, whether true or not. The increased usage of social media and other web-based tools used to generate, publish and discuss user-generated content and to connect with other users has made it increasingly easier for individuals and groups to communicate and share opinions and views regarding the Company and its activities, whether true or not. Although the Company believes that it operates in a manner that is respectful to all stakeholders and that it takes care in protecting its image and reputation, the Company does not ultimately have direct control over how it is perceived by others. Reputation loss may result in decreased investor confidence, increased challenges in developing and maintaining community relations and an impediment to the Company's overall ability to advance its projects, thereby having a material adverse impact on financial performance, financial condition, cash flows and growth prospects.

***Competition in the Life Sciences Industry***

The pharmaceutical industry is intensely competitive in all of its phases and we compete with many companies possessing greater financial and technical resources. Competition in our industry is primarily for the following: securing intellectual property rights; technical expertise to find, develop, and manage such intellectual properties; labour to develop and produce products; and capital for the purpose of funding such projects. Many competitors not only conduct research and development, but also conduct product development and production operations on a world-wide basis. Such competition may result in us being unable to: acquire desired intellectual properties; recruit or retain qualified employees; or obtain the capital necessary to fund our operations and develop our intellectual properties. Existing or future discoveries in the life sciences and pharmaceutical industry could make our product technically obsolete, or may otherwise materially adversely affect our prospects for success in the future. Furthermore, increased competition could result in increased costs and lower prices for our products which, in turn, could reduce profitability. Consequently, our revenues, operations and financial condition could be materially adversely affected.

***Negative Operating Cash Flow***

The Company's business has incurred losses since its inception. Although the Company expects to become profitable, there is no guarantee that will happen, and the Company may never become profitable. The Company currently has a negative operating cash flow and may continue to have a negative operating cash flow for the foreseeable future. To date, the Company has not generated any revenues and a large portion of the Company's expenses are fixed, including expenses related to facilities, equipment, contractual commitments and personnel. As a result, the Company expects for its net losses from operations to improve. The Company's ability to generate additional revenues and potential to become profitable will depend largely on its ability to manufacture and market its products and services. There can be no assurance that any such events will occur or that the Company will ever become profitable. Even if the Company does achieve profitability, the Company cannot predict the level of such profitability. If the Company sustains losses over an extended period of time, the Company may be unable to continue its business.

***Need for additional financing***

The Company believes that it will have sufficient capital to operate its business for at least 12 months following the date of this AIF. However, it is possible that costs associated with the operation of the Company's business will exceed its projections depending on the timing of future operating and capital expenses. Assuming the Company's existing funds sustain its operations for this period, the Company believes that it may thereafter require additional capital for additional product development, sales and marketing operations, other operating expenses and for general corporate purposes to fund growth in the Company's markets. The Company does not know how much additional funding it may require. The Company may therefore be required to seek other sources of financing in the future, which sources (assuming it is able to locate such alternative sources of financing) may be on terms less favorable to the Company than those in the Special Warrant Offering. Any additional equity financing may be dilutive to shareholders, and debt financing, if available, may involve restrictive covenants. If additional funds are raised through the issuance of equity securities, the percentage ownership of the shareholders of the Company will be reduced, shareholders may experience additional dilution in net book value per share, or such equity securities may have rights, preferences or privileges senior to those of the holders of the Common Shares. If adequate funds are not available on acceptable terms, the Company may be unable to develop or enhance its products and services, take advantage of future opportunities or respond to competitive pressures, any of which could have a material adverse effect on its business, financial condition and operating results, or the Company may be forced to cease operations.

***Uncertainty of Use of Proceeds***

Although the Company has set out its intended use of proceeds available to it, these intended uses are estimates only and may be subject to change. While management does not contemplate any material variation, management does retain broad discretion in the application of such proceeds. The failure by the Company to apply these funds effectively could have a material adverse effect on the Company's business, including the Company's ability to achieve its stated business objectives.

***If the Company has a material weakness in its internal controls over financial reporting, investors could lose confidence in the reliability of its financial statements, which could result in a decrease in the value of its securities.***

One or more material weaknesses in the Company's internal controls over financial reporting could occur or be identified in the future. In addition, because of inherent limitations, the Company's internal controls over financial reporting may not prevent or detect misstatements, and any projections of any evaluation of effectiveness of internal controls to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the Company's policies or procedures may deteriorate. If the Company fails to maintain the adequacy of its internal controls, including any failure or difficulty in implementing required new or improved controls, its business and results of operations could be harmed, the Company may not be able to provide reasonable assurance as to its financial results or meet its reporting obligations and there could be a material adverse effect on the price of its securities.

**Risks Relating to the Common Shares**

***Market Price of Common Shares and Volatility***

The Common Shares are listed for trading on the Exchange. As such, external factors outside of our control such as announcements of quarterly variations in operating results, revenues and costs, and sentiments toward the cannabis sector stocks may have a significant impact on the market price of our Common Shares. Global stock markets, including the Exchange, have from time to time experienced extreme price and volume fluctuations that have often been unrelated to the operations of particular companies. There can be no assurance that an active or liquid market will develop or be sustained for the Common Shares.

***Dividends***

The Company intends to retain earnings, if any, to finance the growth and development of the Company's business and does not intend to pay cash dividends on the Common Shares in the foreseeable future. The payment of future cash dividends, if any, will be reviewed periodically by the Board and will depend upon, among other things, conditions then existing including earnings, financial condition and capital requirements, restrictions in financing agreements, business opportunities and conditions and other factors.

***Financial Reporting and Other Disclosure Requirements***

We are subject to reporting and other obligations under applicable Canadian securities laws and rules the CSE. These reporting and other obligations place significant demands on our management, administrative, operational and accounting resources. If we are unable to accomplish any such necessary objectives in a timely and effective manner, our ability to comply with our financial reporting obligations and other rules applicable to Reporting Issuers could be impaired. Moreover, any failure to maintain effective internal controls could cause us to fail to satisfy our reporting obligations or result in material misstatements in our financial statements. If we cannot provide reliable financial reports or prevent fraud, our reputation and operating results could be materially adversely affected which could also cause investors to lose confidence in our reported financial information, which could result in a reduction in the trading price of the Common Shares.

***Dilution***

Future sales or issuances of equity securities could decrease the value of the Common Shares, dilute shareholders' voting power and reduce future potential earnings per Common Share. The Company intends to sell additional equity securities in subsequent offerings (including through the sale of securities convertible into Common Shares) and may issue additional equity securities to finance its operations, development, exploration, acquisitions or other projects. The Company cannot predict the size of future sales and issuances of equity securities or the effect, if any, that future sales and issuances of equity securities will have on the market price of the Common Shares. Sales or issuances of a substantial number of equity securities, or the perception that such sales could occur, may adversely affect prevailing market prices for the Common Shares. With any additional sale or issuance of equity securities, investors will suffer dilution of their voting power and may experience dilution in the Company's earnings per Common Share.

## DIVIDENDS AND DISTRIBUTIONS

Defence has not declared nor paid any cash dividends on any of its issued shares since its inception. Other than requirements imposed under applicable corporate law, there are no other restrictions on the Company's ability to pay dividends under the Company's constating documents. The Company has not paid any dividends on the Common Shares since its incorporation. The Company has no present intention of paying dividends on the Common Shares, as it anticipates that all available funds will be invested to finance the growth of its business and, when appropriate, retire debt.

## DESCRIPTION OF CAPITAL STRUCTURE

The authorized capital of the Company consists of an unlimited number of Class A Common Shares without par value (the "**Common Shares**"), an unlimited number of Class A Special shares without par value ("**Class A Special Shares**"), an unlimited number of Class B Common shares without par value ("**Class B Common Shares**"), an unlimited number of Class B Special shares without par value ("**Class B Special Shares**"), an unlimited number of Class C Common shares without par value ("**Class C Common Shares**"), an unlimited number of Class C Special shares without par value ("**Class C Special Shares**") and an unlimited number of Class D Special shares without par value ("**Class D Special Shares**").

As at June 30, 2021, the issued share capital consisted of 35,220,774 Common Shares, and no other classes of shares are issued and outstanding.

**Common Shares**

Each Common Share carries the right to attend and vote at all general meetings of shareholders. Holders of Common Shares are entitled to receive on a pro rata basis such dividends, if any, as and when declared by the Board at its discretion from funds legally available for the payment of dividends and upon the liquidation, dissolution or winding up of the Company are entitled to receive on a pro rata basis the net assets of the Company after payment of debts and other liabilities, in each case subject to the rights, privileges, restrictions and conditions attaching to any other series or class of shares ranking senior in priority to or on a pro rata basis with the holders of Common Shares with respect to dividends or liquidation. The Common Shares do not carry any pre-emptive, subscription, redemption or conversion rights, nor do they contain any sinking or purchase fund provisions.

As of the date of this AIF, there are 36,042,774 Common Shares issued and outstanding (47,005,174 fully-diluted).

*Class A Special Shares*

The holders of the Class A Special Shares will be entitled to receive notice of, attend and vote at all meetings of shareholders, except meetings at which only holders of a specified class of shares (other than the Class A Special Shares) are entitled to vote. Each Class A Special Share will entitle its holder to one (1) vote.

Save and except for such dividends or distributions as are expressly permitted in the Articles, the holders of the Class A Special shares will not be entitled to further participation in any earnings or profits of the Company or in the value of its assets. Annual, non-cumulative dividends may be declared by the directors on the Class A Special Shares provided that the aggregate amount thereof will not be greater than 8% of the aggregate redemption value of all issued and outstanding Class A Special Shares, and further provided that such dividends will only be payable if, as and when declared and at such times and in such manner as the directors may determine in their discretion. The holders of the Class A Special Shares will not be entitled to any dividends other than or in excess of the above dividends.

The Company may redeem any Class A Special Share issued by it at a price equal to the redemption value thereof. At the time of payment of such redemption price, the Company will pay to the holder of said share the amount of any dividend declared thereon and unpaid.

*Class B Common Shares*

The Class B Common Shares rank pari passu in all respects with the Common Shares, save and except that subject to the provisions of the BCBCA, the holders of the Class B Common Shares will not, as such, have any right to receive notice of, attend or vote at meetings of shareholders.

*Class B Special Shares*

Subject to the provisions of the BCBCA, the holders of the Class B Special Shares will not, as such, have any right to receive notice of, attend or vote at meetings of shareholders.

Save and except for such dividends or distributions as are expressly contemplated in the Articles, the holders of the Class B Special Shares will not be entitled to further participation in any earnings or profits of the Company or in the value of its assets.

The Company may redeem any Class B Special Share issued by it at a price equal to the redemption value thereof. At the time of payment of such redemption price, the Company will pay to the holder of said share the amount of any dividend declared thereon and unpaid.

Upon dissolution of the Company, the holders of the Class B Special Shares will be entitled to receive an amount per share equal to the redemption value thereof, together with any dividends declared thereon and unpaid, and no more, the whole in priority to the distribution of any property to the holders of the Common Shares, Class B Common Shares, Class C Common Shares and Class A Special Shares.

*Class C Common Shares*

The Class C Common Shares rank pari passu in all respects with the Common Shares and Class B Common shares, save and except that (a) subject to the provisions of the Act, the holders of the Class C Common Shares will not, as such, have any right to receive notice of, attend or vote at meetings of shareholders; and (b) the directors will not be obliged to declare dividends on the Class C Common Shares when declaring dividends on the Common Shares and Class B Common Shares.

*Class C Special Shares*

Subject to the provisions of the BCBCA, the holders of the Class C Special Shares will not, as such, have any right to receive notice of, attend or vote at meetings of shareholders.

Save and except for such dividends or distributions as are expressly contemplated in the Articles, the holders of the Class C Special Shares will not be entitled to further participation in any earnings or profits of the Company or in the value of its assets.

Annual, non-cumulative dividends may be declared by the directors on the Class C Special Shares provided that the aggregate amount thereof will not be greater than 9% of the aggregate redemption value of all issued and outstanding Class C Special Shares, and further provided that such dividends will only be payable if, as and when declared and at such times and in such manner as the directors may determine in their discretion. The holders of the Class C Special Shares will not be entitled to any dividends other than or in excess of the above dividends.

The Company may, and upon the demand of any holder thereof will, redeem any Class C Special Share issued by it at a price equal to the amount of the redemption value thereof. At the time of payment of such redemption price, the Company will pay to the holder amount of any dividend declared thereon and unpaid.

Upon dissolution of the Company the holders of the Class C Special Shares will be entitled to receive an amount per share equal to the redemption value thereof, together with any dividends declared thereon and unpaid, and no more, the whole in priority to the distribution of any property to the holders of the Common Shares, Class B Common Shares, Class C Common Shares, Class A Special Shares and Class B Special Shares.

*Class D Special Shares*

Subject to the provisions of the BCBCA, the holders of Class D Special Shares will not, as such, have any right to receive notice of, attend or vote at meetings of shareholders.

Monthly, non-cumulative dividends may be declared by the directors on the Class D Special Shares provided that the aggregate amount thereof will not be greater than 1% of the aggregate redemption value of all issued and outstanding Class D Special Shares, and further provided that such dividends will only be payable if, as and when declared and at such times and in such manner as the directors may determine in their discretion. The holders of the Class D Special Shares will not be entitled to any dividends other than or in excess of the above dividends.

The Company may, and upon the demand of any holder thereof will, redeem any Class D Special Share issued by it at a price per share equal to the redemption value thereof. At the time of payment of such redemption price, the Company will pay to the holder of said share the amount of any dividend declared thereon and unpaid.

Upon dissolution of the Company, the holders of the Class D Special Shares will be entitled to receive an amount per share equal to the redemption value thereof, together with any dividends declared thereon and unpaid, and no more, the whole in priority to the distribution of any of the property to the holders of any other class of shares.

**Dilutive Securities**

As of the date of this AIF, the dilutive securities are summarized as follows:

| Security Type | Common Shares Issuable (#) | Exercise price (average) ($) | Cash proceeds or debt reduction if exercised ($) |
|---|---|---|---|
| Warrants [(1)] | 9,402,400 | 1.15 | 10,854,165 |
| Stock Options [(2)] | 1,560,000 | 1.53 | 2,694,500 |

Notes:

(1) Details of Warrants outstanding:705,900 Warrants have an exercise price of $0.60 and expire on April 30, 2023, 8,296,500 Warrants have an exercise price of $1.25 and expire on May 7, 2023, 400,000 Warrants have an exercise price of $0.15 and expire on April 30, 2024.

(2) Details of stock options outstanding:100,000 Options have an exercise price of $2.56 and expire on May 10, 2022, 50,000 Options have an exercise price of $7.05 and expire on June 17, 2022, 10,000 Options have an exercise price of $7.35 and expire on August 22, 2022, 700,000 Options have an exercise price of $1.25 and expire on October 9, 2023, 250,000 Options have an exercise price of $1.25 and expire on October 23, 2023, 400,000 Options have an exercise price of $1.25 and expire on January 5, 2024, and 50,000 Options have an exercise price of $6.50 and expire on November 9, 2024.

## MARKET FOR SECURITIES

### Trading Price and Volume

The Common Shares have been listed on the CSE under the trading symbol "DTC" since May 7, 2021. The following tables set forth information relating to the trading of the Common Shares on the CSE for the months indicated.

| Month | Price Range ($) | | Total Volume (#) |
|---|---|---|---|
| | High | Low | |
| November 1-22, 2021 | 6.60 | 5.21 | 247,136 |
| October 2021 | 6.85 | 6.28 | 187,732 |
| September 2021 | 8.15 | 6.70 | 119,356 |
| August 2021 | 7.43 | 6.15 | 279,217 |
| July 2021 | 7.30 | 6.00 | 424,954 |
| June 2021 | 7.85 | 4.93 | 235,881 |
| May 2021 | 4.98 | 2.60 | 733,646 |

### Prior Sales

During the year ended June 30, 2021, the Company issued the following securities, which are convertible into Common Shares but are not listed or quoted on a marketplace:

| Date of Issuance | Security Type | Number of Securities | Issue/Exercise Price |
|---|---|---|---|
| August 13, 2020 | Finder's Warrants | 420,000[(1)] | $0.15 |
| October 9, 2020 | Options | 700,000[(2)] | $1.25 |
| October 9, 2020 | Finder's Warrants | 203,500[(3)] | $0.15 |
| October 23, 2020 | Options | 250,000[(2)] | $1.25 |
| December 24, 2020 | Special Warrants | 6,000,000[(4)] | $0.60 |
| December 24, 2020 | Warrants | 2,584,000[(5)] | $1.25 |

| | | | |
|---|---|---|---|
| December 24, 2020 | Finder's Warrants | 850,000[6] | $0.60 |
| January 5, 2021 | Options | 400,000[2] | $1.25 |
| January 25, 2021 | Special Warrants | 137,000[7] | $0.60 |
| January 25, 2021 | Warrants | 4,000[5] | $1.25 |
| May 10, 2021 | Options | 100,000[8] | $2.56 |
| June 17, 2021 | Options | 50,000[9] | $7.05 |

**Notes:**

(1) Issued in connection with the Second Tranche of the Private Placement. The Finder's Warrants issued in connection with the Private Placement are exercisable into Common Shares at $0.15 for a period of 36 months following the Company becoming a Reporting Issuer. Of these Warrants, none remain outstanding as at the date hereof

(2) Issued to certain directors and officers of the Company pursuant to consulting agreements. See "*General Development of the Business and the Company - Employment, Consulting and Management Agreements"* and "*Options and Other Rights to Purchase Securities*". All of these Options, being 1,350,000,remain outstanding as at the date hereof

(3) Issued in connection with the Third Tranche of the Private Placement. The Finder's Warrants issued in connection with the Private Placement are exercisable into Common Shares at $0.15 until April 30, 2024. Of these Finder's Warrants, none remain outstanding as of the date hereof.

(4) Issued in connection with the Special Warrant Offering. Each Special Warrant was deemed exercised in exchange for one Common Share and one Warrant on April 25, 2021.

(5) Issued pursuant to the Unit Offering. Each Unit Warrant entitles the holder to acquire one Common Share at a price of $1.25 per Common Share until May 7, 2023. Of these Unit Warrants, 2,464,000 remain outstanding as of the date hereof.

(6) Issued pursuant to the Special Warrant Offering and the Unit Offering. The Finder's Warrants issued in connection with the Special Warrant Offering and the Unit Offering are exercisable into Common Shares at $0.60 until May 7, 2023. Of these Unit Warrants, 705,900 remain outstanding as of the date hereof.

(7) Issued in connection with the Special Warrant Offering. Each Special Warrant was deemed exercised in exchange for one Common Share and one Warrant on May 5, 2021.

(8) Of these Options, 100,000 remain outstanding.

(9) Of these Options, 50,000 remain outstanding.

Subsequent to the financial year ended June 30, 2021, the Company issued the following securities convertible into Common Shares but are not listed or quoted on a marketplace:

| Date of Issuance | Security | Number of Securities | Issue/Exercise Price Per Security ($) |
|---|---|---|---|
| August 30, 2021 | Options | 10,000[1] | $7.35 |
| November 9, 2021 | Options | 50,000[2] | $6.50 |

Notes:

(1) Of these options, 10,000 remain outstanding as at the date hereof.

(2) Of these options, 50,000 remain outstanding as at the date hereof.

## ESCROWED SECURITIES

The following table includes the balance of escrowed securities as at June 30, 2021:

| Designation of Class | Number of Securities held in Escrow [1] | Percentage of Class [2] |
|---|---|---|
| Common Shares | 3,844,542 | 10.9% |
| Options | Nil | Nil |
| Warrants | Nil | Nil |

Notes:

(1) Pursuant to an escrow agreement dated April 29, 2021, 2,186,000 Common Shares were deposited into escrow with the Company's transfer agent with respect to the listing of the Common Shares on the CSE. The release of the escrowed Common Shares under the escrow agreement is as follows: 10% on date of listing on the CSE and thereafter 15% released every six months over a 36-month period. As at June 30, 2021, 1,639,500 Common Shares are still under escrow pursuant to the escrow agreement. In addition, 1,877,142 Common Shares issued in connection with an assignment of certain IP rights were subject to voluntary escrow as at June 30, 2021, with 312,857 such Common Shares being released from escrow every six months after listing of the Common Shares on the CSE.

(2) Based on 35,220,774 Common Shares issued and outstanding as at June 30, 2021.

As of the date of this AIF, there were 3,203,785 Common Shares held in escrow.

## DIRECTORS AND OFFICERS

### Name, Occupation and Security Holding

The following table sets forth information regarding our directors and executive officers. Each of the directors is elected to hold office until the next annual meeting of the Company or until a successor is duly elected or appointed.

| Name, Province or State and Country of Residence | Positions with the Company | Date of Appointment | Principal Occupation Within the Past Five Years(1) |
|---|---|---|---|
| **Sébastien Plouffe**<br>Quebec, Canada | President, Chief Executive Officer and Director | June 2, 2020 | Co-founder, Director, President and Chief Executive Officer ("CEO") of the Company since June 2020; Founder, President and CEO of Sediamek Inc. since 2006; Vice-President Investment advisor of Canaccord Genuity Wealth Management from 1998-2004. |
| **P. Joseph Meagher**<br>British Columbia, Canada | Chief Financial Officer and Director | January 5, 2021 | Chief Financial Officer ("CFO") of the Company since September, 2020; CFO and Corporate Secretary of Gatling Exploration Inc. since 2018; CFO of Huntsman Exploration Inc. since 2016; CFO of Pacton Gold Inc. since 2013; CFO of Bonterra Resources Inc. from 2014 to 2019 |
| **Dr. Moutih Rafei** PhD<br>Quebec, Canada | Vice President, Research and Development, and Director | January 5, 2021 | Associate Professor and Principal Investigator in Immuno-oncology at Université de Montréal since 2013; Director and VP Research and Development at Defence Therapeutics since 2020; CEO and Founder of Axiom Services Inc. Since 2019; CSO and Co-Founder of Intellistem Technologies since 2018; Head of Discovery at Medicenna Therapeutics 2018-2020; CSO at Medlink360 2014-2017 |
| **Dr. Raimar Löbenberg**(2)<br>Alberta, Canada | Director | January 5, 2021 | Professor at the Faculty of Pharmacy and Pharmaceutical Sciences at the University of Alberta since 2000; director of the Company; director of Xphyto Therapeutics Corp. since 2019; Chief Scientific Officer of RS Therapeutics since 2018 |
| **Dr. Sarkis Meterissian**<br>MD, FRCS, FACS (2) | Director | January 5, 2021 | Professor of Surgery and Oncology McGill University since 2020; Director of the Breast Clinic of the MUHC since 2006; Head of the |

| Name, Province or State and Country of Residence | Positions with the Company | Date of Appointment | Principal Occupation Within the Past Five Years[(1)] |
|---|---|---|---|
| Quebec, Canada | | | Breast Cancer Clinical Program McGill University Health Center since 2012 |
| **Dr. Riam Shammaa**[(2)] Ontario, Canada | Director | November 9, 2021 | Principal of Farmia Agritech since 2020; Founder and CEO of IntelliStem Technologies since 2019; Managing Director of Regen Capital since 2018; Founder and CEO of Pallianera Pharma since 2017; Medical Director at The Canadian Centres for Regenerative Therapy since 2016 |

Notes:

(1) The information as to the principal occupation, business or employment is not within the knowledge of the Company and has been furnished by the respective director.

(2) Member of the Audit Committee

As of the date of the AIF, our directors and executive officers, as a group, beneficially owned, directly or indirectly, or exercised control or direction over 2,120,000 Common Shares, representing approximately 5.9% of the issued and outstanding Common Shares. The statement as to the number of Common Shares beneficially owned directly or indirectly, or over which control or direction is exercised by the directors and executive officers of the Company as a group is based upon information furnished by the directors and executive officers.

**Cease Trade Orders, Bankruptcies, Penalties or Sanctions**

Except as disclosed below, no director or executive officer of the Company is, as at the date of this AIF, or has been within 10 years before the date of this AIF, a director, chief executive officer or chief financial officer of any company (including the Company), that:

(a) was subject to a cease trade order, an order similar to a cease trade order, or an order that denied the relevant company access to any exemption under securities legislation, that was in effect for a period of more than 30 consecutive days, that was issued while the director or executive officer was acting in the capacity as director, chief executive officer or chief financial officer, or

(b) was subject to a cease trade order, an order similar to a cease trade order, or an order that denied the relevant company access to any exemption under securities legislation, that was in effect for a period of more than 30 consecutive days, that was issued after the director or executive officer ceased to be a director, chief executive officer or chief financial officer and which resulted from an event that occurred while that person was acting in the capacity as director, chief executive officer or chief financial officer.

Carrie Cesarone was the CFO, Secretary and a director of Argentum Silver Corp. when it failed to file its annual audited financial statements and the related management's discussion and analysis for the year ended June 30, 2015. On November 2, 2015, the British Columbia Securities Commission issued an order ceasing all trading by Ms. Cesarone of the securities of Argentum Silver Corp. The order was revoked on December 16, 2015.

No director or executive officer of the Company, nor a shareholder holding a sufficient number of securities of the Company to affect materially the control of the Company:

(a) is, as at the date of this AIF, or has been within 10 years before the date of this AIF, a director or executive officer of any company (including the Company) that, while that person was acting in that capacity, or within a year of that person ceasing to act in that capacity, became bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency or was subject to or instituted any proceedings, arrangement or compromise with creditors or had a receiver, receiver manager or trustee appointed to hold its assets; or

(b) has, within 10 years before the date of this AIF, become bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency, or become subject to or instituted any proceedings, arrangement or compromise with creditors, or had a receiver, receiver manager or trustee appointed to hold the assets of the proposed director.

No director or executive officer of the Company has been subject to:

(a) any penalties or sanctions imposed by a court relating to securities legislation or by a securities regulatory authority or has entered into a settlement agreement with a securities regulatory authority; or

(b) any other penalties or sanctions imposed by a court or regulatory body that would likely be considered important to a reasonable security holder in deciding whether to vote for a proposed director.

**Conflicts of Interest**

The Company's directors and officers may serve as directors or officers, or may be associated with, other reporting companies, or have significant shareholdings in other public companies. To the extent that such other companies may participate in business or asset acquisitions, dispositions, or ventures in which the Company may participate, the directors and officers of the Company may have a conflict of interest in negotiating and concluding terms respecting the transaction. If a conflict of interest arises, the Company will follow the provisions of the BCBCA dealing with conflict of interest. These provisions state that where a director has such a conflict, that director must, at a meeting of the Company's directors, disclose his or her interest and refrain from voting on the matter unless otherwise permitted by the BCBCA. In accordance with the laws of the Province of British Columbia, the directors and officers of the Company are required to act honestly, in good faith, and the best interest of the Company.

## PROMOTERS

Sébastien Plouffe is a Promoter of the Company. Mr. Plouffe currently holds 1,600,000 Common Shares of the Company, being 4.4% of the issued and outstanding Common Shares. For further information on the security holdings and consideration received by the Promoter, see "Employment, Consulting and Management Agreements."

## LEGAL PROCEEDINGS

During the financial year ended June 30, 2021, there are no legal proceedings to which the Company is a party to or to which any of its property is subject outside of the ordinary course of the Company's business, and no such proceedings are known to the Company to be contemplated.

## REGULATORY ACTIONS

The Company does not know of any:

(a) penalties or sanctions imposed against the Company by a court relating to provincial and territorial securities legislation or by a securities regulatory authority within the three years preceding the date of this AIF;

(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 making an investment decision; and

(c) settlement agreements the Company entered into before a court relating to provincial and territorial securities legislation or with a securities regulatory authority within the three years preceding the date of this AIF.

## INTERESTS OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS

Other than as disclosed elsewhere in this AIF and in the consolidated financial statements of the Company for the year ended June 30, 2021, to the best of the Company's knowledge, none of the directors or executive officers of the Company, or any shareholders who beneficially own, control or direct, directly or indirectly, more than 10% of the Company's outstanding Common Shares, or any known associates or affiliates of such persons, had any material interests, direct or indirect, in any transaction within the three most recently completed financial years or during the current year that has materially affected or is reasonably expected to materially affect the Company.

## TRANSFER AGENT AND REGISTRARS

The Company's Registrar and Transfer Agent is Computershare Investor Services Inc., located at 510 Burrard Street, 2nd Floor, Vancouver, British Columbia V6C 3B9.

## MATERIAL CONTRACTS

Except for contracts entered into in the ordinary course of business, the only contracts entered into by the Company during the 12-month period ended June 30, 2021 which are material or entered into before the 12-month period ended June 30, 2021, but are still in effect and which are required to be filed with Canadian securities regulatory authorities in accordance with Section 12.2 of National Instrument 51-102 – Continuous Disclosure Obligations are the following:

(a) the Amended IP Assignment and Royalty Agreement, as described under "Three Year History";

(b) the Option and Right of First Refusal Agreement, as described under "Three Year History";

(c) the Plouffe Consulting Agreement, as described under "Employment, Consulting and Management Agreements";

(d) the Meagher Consulting Agreement, as described under "Employment, Consulting and Management Agreements";

(e) the Cesarone Consulting Agreement, as described under "Employment, Consulting and Management Agreements";

(f) the Beaudoin Consulting Agreement, as described under "Employment, Consulting and Management Agreements";

(g) the Axiom Consulting Agreement, as described under "Employment, Consulting and Management Agreements";

(h) the Non-Offering Prospectus Agreement, as described in the Company's Prospectus dated April 29, 2021 and filed under the Company's profile on SEDAR at www.SEDAR.com; and

(i) the Stock Option Plan, as described in the Company's Prospectus dated April 29, 2021 and filed under the Company's profile on SEDAR at www.SEDAR.com.

## INTEREST OF EXPERTS

### Name of Experts

The following are the persons or companies who were named as having prepared or certified a statement, report or valuation in this AIF either directly or in a document incorporated by reference and whose profession or business gives authority to the statement, report or valuation made by the person or company:

Crowe Mackay LLP, the Company's independent auditors, has prepared an independent audit report dated October 27, 2021 in respect of the Company's audited consolidated financial statements for the years ended June 30, 2021 and 2020.

### Interests of Experts

Crowe Mackay LLP, auditors of the Company, have confirmed that they are independent of the Company within the meaning of the 'Rules of Professional Conduct' of the Chartered Professional Accountants of British Columbia.

## AUDIT COMMITTEE

The Company's audit committee has various responsibilities as set forth in NI 52-110 made under securities legislation, concerning constitution of its audit committee and its relationship with its independent auditor and among such responsibilities being a requirement that the audit committee establish a written charter that sets out its responsibilities.

### Composition of the Audit Committee

The Audit Committee of the Company consists of Raimar Löbenberg (Chair), Riam Shammaa and Sarkis Meterissian. All of the members of the Audit Committee are independent.

All members of the Audit Committee are considered to be financially literate as required by section 1.6 of NI 52-110. For a summary of the experience and education of the Audit Committee members see "*Directors and Officers*".

**Audit Committee Charter**

A copy of the charter of the audit committee is available as Schedule "A" to this AIF.

**Audit Committee Oversight**

The Audit Committee has not made any recommendations to the Board to nominate or compensate any auditor other than Crowe Mackay LLP for the fiscal year ended June 30, 2021.

**Reliance on Certain Exemptions**

At no time has theCompany relied on an exemption from NI 52-110, in whole or in part, granted under Part 8 of NI 52-110.

**Pre-Approval Policies and Procedures**

The Audit Committee has not adopted specific policies and procedures for the engagement of non-audit services, other thn as set out in the audit committee charter.

**External Auditor Service Fees (By Category)**

The Audit Committee has reviewed the nature and amount of the audit services provided by MNP to the Company to ensue auditor independence. The aggregate fees billed by the Company's external auditor during the financial years ended June 30, 2021 and June 30, 2020 were as follows:

| Financial Period Ending | Audit Fees ($) [1] | Audit Related Fees ($) [2] | Tax Fees ($) [3] | All Other Fees ($) [4] |
|---|---|---|---|---|
| 2021 | $24,500 | Nil | $2,500 | $21,500 |
| 2020 | $11,000 | Nil | $2,000 | Nil |

(1) "Audit Fees" includes fees for the performance of the annual audit and for accounting consultations on matters reflected in the financial statements.

(2) "Audit-Related Fees" includes fees for assurance and related services that are related to the performance of the review of the financial statements including fees for Annual Information Form and "earn-in" audit work and are not reported under (1).

(3) "Tax Fees" includes fees for tax compliance, tax planning and tax advice.

(4) "All Other Fees" includes audit fees for work done by the auditors in connection with the Company's long form non-offering prospectus dated April 29, 2021.

## ADDITIONAL INFORMATION

Additional information rlating to the Company is available under the Company's profile on SEDAR at www.sedar.com.

Additional information, including directors' and officers' remuneration and indebtedness, principal holders of the Company's securities, and securities authorized for issuance under the Company's equity compensation plas, as applicable, is contained in the Company's Management Information Circular for its most recent Annual General Meeting.

Additional financial information is provided in the Company's Audited Consolidated Financial Statements and Management's Discussion and Analysis for the year ended June 30, 2021 which may be obtained upon reques from the Company's head office, or may be viewed on the Company's website (https://defencetherapeutics.com) or on the SEDAR website (www.sedar.com).

**SCHEDULE "A"**
**AUDIT COMMITTEE CHARTER**

[see attached.]

# DEFENCE THERAPEUTICS INC.
# CHARTER OF THE AUDIT COMMITTEE

## PURPOSE AND PRIMARY RESPONSIBILITY

1. This charter sets out the Audit Committee's purpose, composition, member qualification, member appointment and removal, responsibilities, operations, manner of reporting to the Board of Directors (the "**Board**") of Defence Therapeutics Inc. (the "**Company**"), annual evaluation and compliance with this charter.

2. The primary responsibility of the Audit Committee is that of oversight of the financial reporting process on behalf of the Board. This includes oversight responsibility for financial reporting and continuous disclosure, oversight of external audit activities, oversight of financial risk and financial management control, and oversight responsibility for compliance with tax and securities laws and regulations as well as whistle blowing procedures. The Audit Committee is also responsible for the other matters as set out in this charter and/or such other matters as may be directed by the Board from time to time. The Audit Committee should exercise continuous oversight of developments in these areas.

## MEMBERSHIP

3. At least a majority of the Audit Committee must be comprised of independent directors of the Company as defined in sections 1.4 and 1.5 of National Instrument 52-110 – *Audit Committees* ("**NI 52-110**"), provided that should the Company become listed on a more senior exchange, each member of the Audit Committee will also satisfy the independence requirements of such exchange.

4. The Audit Committee will consist of at least two members, all of whom shall be financially literate, provided that an Audit Committee member who is not financially literate may be appointed to the Audit Committee if such member becomes financially literate within a reasonable period of time following his or her appointment. Upon graduating to a more senior stock exchange, if required under the rules or policies of such exchange, the Audit Committee will consist of at least three members, all of whom shall meet the experience and financial literacy requirements of such exchange and of NI 52-110.

5. The members of the Audit Committee will be appointed annually (and from time to time thereafter to fill vacancies on the Audit Committee) by the Board. An Audit Committee member may be removed or replaced at any time at the discretion of the Board and will cease to be a member of the Audit Committee on ceasing to be an independent director.

6. The Chair of the Audit Committee will be appointed by the Board.

## AUTHORITY

7. In addition to all authority required to carry out the duties and responsibilities included in this charter, the Audit Committee has specific authority to:

(i) engage, set and pay the compensation for independent counsel and other advisors as it determines necessary to carry out its duties and responsibilities, and any such consultants or professional advisors so retained by the Audit Committee will report directly to the Audit Committee;

(ii) communicate directly with management and any internal auditor, and with the external auditor without management involvement; and

(iii) incur ordinary administrative expenses that are necessary or appropriate in carrying out its duties, which expenses will be paid for by the Company.

**DUTIES AND RESPONSIBILITIES**

8. The duties and responsibilities of the Audit Committee include:

(i) recommending to the Board the external auditor to be nominated by the Board;

(ii) recommending to the Board the compensation of the external auditor to be paid by the Company in connection with (i) preparing and issuing the audit report on the Company's financial statements, and (ii) performing other audit, review or attestation services;

(iii) reviewing the external auditor's annual audit plan, fee schedule and any related services proposals (including meeting with the external auditor to discuss any deviations from or changes to the original audit plan, as well as to ensure that no management restrictions have been placed on the scope and extent of the audit examinations by the external auditor or the reporting of their findings to the Audit Committee);

(iv) overseeing the work of the external auditor;

(v) ensuring that the external auditor is independent by receiving a report annually from the external auditors with respect to their independence, such report to include disclosure of all engagements (and fees related thereto) for non-audit services provided to the Company;

(vi) ensuring that the external auditor is in good standing with the Canadian Public Accountability Board by receiving, at least annually, a report by the external auditor on the audit firm's internal quality control processes and procedures, such report to include any material issues raised by the most recent internal quality control review, or peer review, of the firm, or any governmental or professional authorities of the firm within the preceding five years, and any steps taken to deal with such issues;

(vii) ensuring that the external auditor meets the rotation requirements for partners and staff assigned to the Company's annual audit by receiving a report annually from the external auditors setting out the status of each professional with respect to the appropriate regulatory rotation requirements and plans to transition new partners and staff onto the audit engagement as various audit team members' rotation periods expire;

(viii) reviewing and discussing with management and the external auditor the annual audited and quarterly unaudited financial statements and related Management Discussion and Analysis ("**MD&A**"), including the appropriateness of the Company's accounting policies, disclosures (including material transactions with related parties), reserves, key estimates and judgements (including changes or variations thereto) and obtaining reasonable assurance that the financial statements are presented fairly in accordance with IFRS and the MD&A is in compliance with appropriate regulatory requirements;

(ix) reviewing and discussing with management and the external auditor major issues regarding accounting principles and financial statement presentation including any significant changes in the selection or application of accounting principles to be observed in the preparation of the financial statements of the Company and its subsidiaries;

(x) reviewing and discussing with management and the external auditor the external auditor's written communications to the Audit Committee in accordance with generally accepted auditing standards and other applicable regulatory requirements arising from the annual audit and quarterly review engagements;

(xi) reviewing and discussing with management and the external auditor all earnings press releases, as well as financial information and earnings guidance provided to analysts and rating agencies prior to such information being disclosed;

(xii) reviewing the external auditor's report to the shareholders on the Company's annual financial statements;

(xiii) reporting on and recommending to the Board the approval of the annual financial statements and the external auditor's report on those financial statements, the quarterly unaudited financial statements, and the related MD&A and press releases for such financial statements, prior to the dissemination of these documents to shareholders, regulators, analysts and the public;

(xiv) satisfying itself on a regular basis through reports from management and related reports, if any, from the external auditors, that adequate procedures are in place for the review of the Company's disclosure of financial information extracted or derived from the Company's financial statements that such information is fairly presented;

(xv) overseeing the adequacy of the Company's system of internal accounting controls and obtaining from management and the external auditor summaries and recommendations for improvement of such internal controls and processes, together with reviewing management's remediation of identified weaknesses;

(xvi) reviewing with management and the external auditors the integrity of disclosure controls and internal controls over financial reporting;

(xvii) reviewing and monitoring the processes in place to identify and manage the principal risks that could impact the financial reporting of the Company and assessing, as part of its internal controls responsibility, the effectiveness of the over-all process for identifying principal business risks and report thereon to the Board;

(xviii) satisfying itself that management has developed and implemented a system to ensure that the Company meets its continuous disclosure obligations through the receipt of regular reports from management and the Company's legal advisors on the functioning of the disclosure compliance system, (including any significant instances of non-compliance with such system) in order to satisfy itself that such system may be reasonably relied upon;

(xix) resolving disputes between management and the external auditor regarding financial reporting;

(xx) establishing procedures for:

1. the receipt, retention and treatment of complaints received by the Company from employees and others regarding accounting, internal accounting controls or auditing matters and questionable practises relating thereto; and

2. the confidential, anonymous submission by employees of the Company of concerns regarding questionable accounting or auditing matters.

(xxi) reviewing and approving the Company's hiring policies with respect to partners or employees (or former partners or employees) of either a former or the present external auditor;

(xxii) pre-approving all non-audit services to be provided to the Company or any subsidiaries by the Company's external auditor;

(xxiii) overseeing compliance with regulatory authority requirements for disclosure of external auditor services and Audit Committee activities;

(xxiv) establishing procedures for:

3. reviewing the adequacy of the Company's insurance coverage, including the Directors' and Officers' insurance coverage;

4. reviewing activities, organizational structure, and qualifications of the Chief Financial Officer ("**CFO**") and the staff in the financial reporting area and ensuring that matters related to succession planning within the Company are raised for consideration at the Board;

5. obtaining reasonable assurance as to the integrity of the Chief Executive Officer ("**CEO**") and other senior management and that the CEO and other senior management strive to create a culture of integrity throughout the Company;

6. reviewing fraud prevention policies and programs, and monitoring their implementation;

7. reviewing regular reports from management and others (e.g., external auditors, legal counsel) with respect to the Company's compliance with laws and regulations having a material impact on the financial statements including:

(I) Tax and financial reporting laws and regulations;

(II) Legal withholding requirements;

(III) Environmental protection laws and regulations; and

(IV) Other laws and regulations which expose directors to liability;

9. A regular part of Audit Committee meetings involves the appropriate orientation of new members as well as the continuous education of all members. Items to be discussed include specific business issues as well as new accounting and securities legislation that may impact the organization. The Chair of the Audit Committee will regularly canvass the Audit Committee members for continuous education needs and in conjunction with the Board education program, arrange for such education to be provided to the Audit Committee on a timely basis.

10. On an annual basis the Audit Committee shall review and assess the adequacy of this charter taking into account all applicable legislative and regulatory requirements as well as any best practice guidelines recommended by regulators or stock exchanges with whom the Company has a reporting relationship and, if appropriate, recommend changes to the Audit Committee charter to the Board for its approval.

**MEETINGS**

11. The quorum for a meeting of the Audit Committee is a majority of the members of the Audit Committee.

12. The Chair of the Audit Committee shall be responsible for leadership of the Audit Committee, including scheduling and presiding over meetings, preparing agendas, overseeing the preparation of briefing documents to circulate during the meetings as well as pre-meeting materials, and making regular reports to the Board. The Chair of the Audit Committee will also maintain regular liaison with the CEO, CFO, and the lead external audit partner.

13. The Audit Committee will meet in camera separately with each of the CEO and the CFO of the Company at least annually to review the financial affairs of the Company.

14. The Audit Committee will meet with the external auditor of the Company in camera at least once each year, at such time(s) as it deems appropriate, to review the external auditor's examination and report.

15. The external auditor must be given reasonable notice of, and has the right to appear before and to be heard at, each meeting of the Audit Committee.

16. Each of the Chair of the Audit Committee, members of the Audit Committee, Chair of the Board, external auditor, CEO, CFO or secretary shall be entitled to request that the Chair of the Audit Committee call a

meeting which shall be held within 48 hours of receipt of such request to consider any matter that such individual believes should be brought to the attention of the Board or the shareholders.

**REPORTS**

17. The Audit Committee will report, at least annually, to the Board regarding the Audit Committee's examinations and recommendations.

18. The Audit Committee will report its activities to the Board to be incorporated as a part of the minutes of the Board meeting at which those activities are reported.

**MINUTES**

19. The Audit Committee will maintain written minutes of its meetings, which minutes will be filed with the minutes of the meetings of the Board.

**ANNUAL PERFORMANCE EVALUATION**

20. The Board will conduct an annual performance evaluation of the Audit Committee, taking into account the Charter, to determine the effectiveness of the Committee.