ANNUAL INFORMATION FORM

For the Year ended March 31, 2024
June 25, 2024

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FORWARD-LOOKING AND OTHER STATEMENTS

This Annual Information Form (the "**AIF**") contains forward-looking statements or forward-looking information (collectively, "**forward-looking statements**") under applicable Canadian securities legislation including, without limitation, statements containing the words "believe," "may," "plan," "will," "estimate," "continue," "anticipate," "intend," "expect," "predict," "project," "potential," "continue," "ongoing" or the negative or grammatical variations of these terms or other comparable terminology, although not all forward-looking statements contain these words and similar expressions. Forward-looking statements are necessarily based on estimates and assumptions made by us in light of our experience and perception of historical trends, current conditions and expected future developments, as well as the factors we believe are appropriate. Forward-looking statements in this AIF include, but are not limited to, statements relating to:

- our ability to continue as a going concern;
- our ability to maintain the listing of the Company's Class A common shares (the "**Common Shares**") on the TSX;
- our strategy;
- the sufficiency of our financial resources to support our activities;
- potential sources of funding;
- our deployment of resources;
- our ability to obtain necessary funding on favourable terms or at all;
- our expected expenditures and accumulated deficit level;
- our outcomes from ongoing and future research and research collaborations;
- our exploration of opportunities through collaborations, strategic partnerships and other transactions with third parties;
- our plans for the research and development ("**R&D**") of certain product candidates;
- the eligibility of certain of our programs for a priority review voucher (**"PRV"**);
- our ability to obtain funding from the U.S. Department of Defense ("**USDOD**") and the U.S. Air Force Academy ("**USAFA**");
- our intention to apply or secure certain regulatory designations, such as Fast-Track status, for our development programs;
- expectations relating to the timing of future milestone payments from Saptalis (as defined herein)
- our strategy for protecting our intellectual property;
- our ability to identify licensable products or research suitable for licensing and commercialization;
- our ability to obtain licences on commercially reasonable terms;
- our plans for generating revenue;
- our plans for future clinical trials;
- our ability to hire and retain skilled staff; and
- our intention with respect to updating any forward-looking statements after the date on which such statement is made or to reflect the occurrence of unanticipated events;

Such statements reflect our current views with respect to future events, are subject to risks and uncertainties and are necessarily based upon a number of estimates and assumptions that, while considered reasonable by Appili as of the date of such statements, are inherently subject to significant medical, scientific, business, economic, competitive, political and social uncertainties and contingencies. Many factors could cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements that may be expressed or implied by such forward-looking statements. In making the forward-looking statements included in this AIF, the Company has made various material assumptions, including but not limited to (i) the Company's ability to initiate and complete its proposed clinical trials in a timely manner; (ii) the ability of the Company to secure the requisite level of patient and site enrollment; (iii) the Company's ability to enter into the requisite clinical trial agreements relating to any proposed clinical trials; (iv) obtaining positive results of clinical trials; (v) obtaining regulatory approvals; (vi) general business and economic conditions; (vii) the Company's ability to successfully out-license or sell its current products and in-license and develop new products; (viii) the availability of financing on reasonable terms; (ix) the Company's ability to attract and retain skilled staff; (x) market competition; (xi) the products and technology offered by the Company's competitors; (xii) the Company's ability to protect patents and proprietary rights; (xiii) our ability to continue to partner with the USDOD and USAFA with respect to the funding of ATI-1701; and (xiv)

In evaluating forward-looking statements, current and prospective shareholders should specifically consider various factors, including risks related to:

- limited operating history and early stage of development;
- identifying, developing and commercializing product candidates;
- regulatory risks;
- market competition;
- the Company's dependence on third parties;
- clinical trial risks;
- third-party manufacturing and supplier risks;
- the Company's potential redeployment of resources;
- the ownership and protection of intellectual property;
- litigation and product liability risks;
- employee matters and managing growth;
- ownership of the Company's securities;
- working capital and capital resources, including the Company's ability to secure the full anticipated funding from the USDOD and USAFA for its ATI–1701;
- ability to retain key personnel;
- the Company's existing credit facility with Long Zone Holdings Inc. ("**LZH**")
- implementation and development delays;
- product deficiencies;
- volatility of share price; and
- the other risks discussed under the heading "*Risk Factors*".

Should one or more of these risks or uncertainties, or a risk that is not currently known to us, materialize, or should assumptions underlying those forward-looking statements prove incorrect, actual results may vary materially from those described herein. These forward-looking statements are made as of the date of this AIF and we do not intend, and do not assume any obligation, to update these forward-looking statements, except as required by applicable securities laws. Investors are cautioned that forward-looking statements are not guarantees of future performance and are inherently uncertain. Accordingly, investors are cautioned not to put undue reliance on forward-looking statements.

MEANING OF CERTAIN REFERENCES

As used in this AIF, unless the context otherwise indicates:

- the terms "Appili", "Company", "we", "us" and "our" mean Appili Therapeutics Inc.; and
- unless otherwise indicated all dollar amounts are in Canadian dollars.

For an explanation of certain technical terms and abbreviations used in this prospectus, see the "*Glossary of Terms*" section of this AIF.

Except where otherwise expressly indicated, information relating to securities of the Company (including the issuance price or exercise price thereof, as applicable) is presented on a post-Share Split basis.

MARKET AND INDUSTRY DATA

Market and industry data presented in this AIF was obtained from third party sources, industry reports, journals, studies and publications, websites, and other publicly available information, as well as industry and other data prepared by us or on our behalf on the basis of our knowledge of the health care industry, markets and economies (including our opinions, estimates and assumptions relating to such industry, markets and economies based on that knowledge). Certain statistical information and market research contained in this AIF, such as the results of studies or surveys, are based on surveys or studies conducted by independent third parties. We believe that the industry, market, and economic data presented throughout this AIF is accurate and, with respect to data prepared by us or on our behalf, that our opinions, estimates, and assumptions are currently appropriate and reasonable, but there can be no assurance as to the accuracy or completeness thereof. The accuracy and completeness of the industry, market and economic data

presented throughout this AIF are not guaranteed. Actual outcomes may vary materially from those forecasted in such reports or publications, and the likelihood for material variation can be expected to increase as the length of the forecast period increases. Although we believe it to be reliable, we have not independently verified any of the data from third party sources referred to in this AIF, analyzed or verified the underlying studies or surveys relied upon or referred to by such sources, or ascertained the underlying industry, market, economic and other assumptions relied upon by such sources. Industry, market, and economic data is subject to variations and cannot be verified due to limits on the availability and reliability of data inputs, the voluntary nature of the data gathering process and other limitations and uncertainties inherent in any statistical survey.

THE CORPORATE STRUCTURE

Name, Address, and Incorporation

The Company was incorporated under the name "Appili Therapeutics Inc." pursuant to the *Companies Act* (Nova Scotia) on May 7, 2015. The Company's articles of association were amended on July 10, 2015, to allow for the issuance of uncertificated securities. On November 15, 2018, the Company was continued as a federal corporation under the provisions of the *Canada Business Corporations Act* ("**CBCA**"). The articles of continuance of the Company (the "**Articles**") filed in connection with such continuance contained provisions amending the existing authorized capital of the Company to permit (in addition to the issuance of Common Shares) the issuance of (i) an unlimited number of Class B non-voting common shares (the "**Non-Voting Shares**") and (ii) an unlimited number of preferred shares (the "**Preferred Shares**"), issuable in series, with such rights, privileges, restrictions and conditions as the board of directors of the Company (the "**Board**") may determine from time to time. On May 3, 2019, the Company amended the Articles to subdivide its Common Shares on the basis of 3.86 post-subdivision Common Shares for each one pre-subdivision Common Share (the "**Share Split**"). The Common Shares trade on the TSX under the symbol "APLI" and on the OTCPink under the symbol "APLIF". See "*Description of Share Capital*".

Appili's head office is located at #21 - 1344 Summer Street, Halifax, Nova Scotia B3H 0A8 and its registered office is located at 77 King Street West, Suite 400, Toronto-Dominion Centre Toronto, ON M5K 0A1 Canada.

Intercorporate Relationships

The Company has one wholly-owned subsidiary, Appili Therapeutics USA Inc.

BUSINESS OF THE COMPANY

Overview of the Company

Appili is a pharmaceutical company focused on the acquisition and development of novel medicines targeting unmet needs in infectious disease. Since incorporation in 2015, the Company has been focused on building and advancing a diverse portfolio of anti-infective programs. Key activities have included the acquisition and development of novel technologies, the development of strategic partnerships, targeted hiring and building out drug development capabilities, securing intellectual property, and raising funds through equity capital raises and non-dilutive funding mechanisms.

The Company's anti-infective portfolio currently includes three programs, described below: LIKMEZ™ (ATI-1501) which was approved by the United States Food and Drug Administration ("FDA") in September 2023, ATI-1701 and ATI-1801.

Subject to the renewal of certain legislation, Appili expects that two of its programs (ATI-1801 and ATI-1701) may be eligible for a PRV if approved by the United States Food and Drug Administration ("**FDA**"). The PRV program was developed to incentivize drug development in US government priority areas including tropical disease and medical countermeasures. Once issued, a PRV can be used by its holder to accelerate the review of a subsequent drug submission. PRVs are transferrable and the secondary market for PRVs is well established with over 35 transactions reported publicly and recent transactions often exceeding US$100 million.

LIKMEZ (ATI-1501)

Metronidazole is a front-line antibiotic for the treatment of anaerobic bacterial and parasitic infections (Quintiles 2016, Solomkin 2010, Flagyl® FDA Label 2018). In many jurisdictions, including the United States and Canada, the only approved oral metronidazole products are in solid dose formats. Elderly and pediatric patients with difficulty swallowing typically crush the tablets to ingest them. Metronidazole has a strong bitter and metallic taste that is exacerbated by crushing and can reduce patient adherence to treatment. ATI-1501 is aimed at making it easier for patients with difficulties swallowing and sensitivity to taste to take metronidazole, improving patient adherence to therapy and clinical outcomes.

LIKMEZ (ATI-1501) is a liquid oral reformulation of the antibiotic metronidazole, which has been licensed to Saptalis Pharmaceuticals LLC ("Saptalis") for commercialization in the U.S., and other selected territories.

ATI-1701

ATI-1701 is a novel, live-attenuated vaccine for *Francisella tularensis* ("*F. tularensis*"). *F. tularensis*, the bacterium which causes tularemia, is a Category A pathogen which can be aerosolized and is over 1,000 times more infectious than anthrax when inhaled (PHAC PSDS Anthrax 2011, PHAC PSDS Tularemia 2011). Category A pathogens are organisms or biological agents that, according to the U.S. National Institutes of Health ("NIH"), pose the highest risk to National Security and public health (NIH website). The signs, symptoms, and prognosis of tularemia depend on the route of infection. Pneumonic tularemia, caused by inhalation of *F. tularensis*, is among the most severe forms of tularemia, causing respiratory issues and difficulty breathing in patients and can be fatal if untreated, (CDC 2018, WHO 2007). Since it is a highly infectious pathogen capable of causing severe illness, medical counter measures for *F. tularensis* are a top biodefense priority for the United States and allied governments around the world. There is currently no approved vaccine for the prevention of tularemia in the United States or other major global markets.

ATI-1801

ATI-1801 is a novel topical formulation of paromomycin (15% w/w) under advanced clinical development for the treatment of cutaneous leishmaniasis, a disfiguring infection of the skin that affects hundreds of thousands of people around the world annually and is characterized by the formation of lesions and ulcers that often lead to scarring, disfigurement, disability, and stigmatization of the infected individual (CDC 2020. WHO 2022, Okwor 2016). ATI-1801 has demonstrated safety and efficacy for the treatment of cutaneous leishmaniasis in a Phase 3 study completed in Tunisia. Appili is currently engaging with the FDA and submitted a type-B meeting request with the FDA in 2024 to discuss the previously generated Phase 3 data and agree on the necessary registration package to support an NDA submission, which the Company expects will include available nonclinical, manufacturing, and clinical data generated to date, along with additional non-clinical data necessary to bring the Investigational New Drug ("**IND**") up to current standards and, pending alignment with the FDA, an additional clinical bridging study to demonstrate the comparability of the product produced by the new manufacturer to the prior manufacturer. Appili expects to pursue funding and partnership opportunities with NGOs and government agencies which share the Company's focus on tropical diseases to help complete remaining development work. The Company's current plans, assuming the availability of non-dilutive funding, would be to complete the additional work indicated above and submit an NDA in the future.

Recent Developments

On April 26, 2024, the Company announced it had secured additional bridge financing in the amount of C$300,000 from Bloom Burton & Co Inc. ("**Bloom Burton**").

On April 2, 2024, the Company announced it had entered into a definitive arrangement agreement (the "**Arrangement Agreement**") pursuant to which Aditxt Inc. (NASDAQ: ADTX), a Richmond, Virginia- based company dedicated to discovering, developing, and deploying promising health innovation, through its wholly-owned subsidiary, Adivir, Inc., agreed to acquire all of the issued and outstanding Common Shares by way of a court-approved plan of arrangement under the CBCA (the "**Aditxt Arrangement**").

Three-Year History

Fiscal 2024 (April 2023 to March 2024)

On March 12, 2024, the Company announced a publication in the journal *Frontiers in Bacteriology* on the prevention of tularemia. Appili's Director of Non-Clinical Research, Dr. Carl Gelhaus, Ph.D., together with medical doctors from the United States Uniformed Services University of the Health Sciences and Ukrainian researchers published a perspective manuscript "*Considerations for prevention of and emergency response to tularemia outbreaks in Ukraine: vaccine involvement*".

On December 15, 2023, the Company announced the issuance of patent for ATI-1701 biodefense vaccine candidate to protect against tularemia. This patent covers the composition and preparation methods for ATI-1701 through 2039.

On November 13, 2023, the Company announced that it had appointed Prakash Gowd, MBA, BSc. Pharm, C.Dir., to its Board of Directors. The Company also appointed Mr. Gowd as Chair of its Audit Committee.

On October 25, 2023, the Company announced that it had secured a commitment for the second stage of funding for ATI-1701 from USAFA.

On October 25, 2023, the Company announced with great sadness that one of its Directors, Rochelle Stenzler passed away.

On October 13, 2023, the Company's recently issued U.S. patent related to LIKMEZ (ATI-1501), U.S. Application No. 18/072,154 was listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations", commonly known as the "Orange Book".

On September 27, 2023, the Company presented an update on non-clinical data for ATI-1701 during the International Tularemia Conference.

On September 25, 2023, the Company announced that its partner, Saptalis received approval from the FDA for Metronidazole Oral Suspension 500mg/5mL (ATI-1501). The FDA also approved LIKMEZ as the brand name for ATI-1501.

On June 29, 2023, the Company announced that it had entered into an unsecured $300,000 bridge loan from Bloom Burton. Pursuant to the terms of the agreement, this bridge loan matures on the earlier of September 28, 2024, or the date on which Appili receives aggregate reimbursements from USAFA of not less than C$2,500,000.

On May 24, 2023, the Company announced the Issuance of Patent for ATI-1501 Liquid Oral Reformulation of Metronidazole. This patent covers the composition and preparation methods for ATI-1501 through the year 2039.

On May 5, 2023, the Company secured a Cooperative Agreement for ATI-1701 funding from USAFA (the "**USAFA Cooperative Agreement**"). The USAFA Cooperative Agreement provides for funding up to US$7.3 million, which would be used to initiate early-stage development and regulatory activities for ATI-1701.

On April 3, 2023, the Company appointed Dr. Gary Nabors, PhD, to serve as CDO. Dr Nabors leads the advancement of programs through development, regulatory submission and key commercialization milestones.

Fiscal 2023 (April 2022 to March 2023)

On March 20, 2023, the Company entered into an amended and restated secured loan agreement (the "**Amended LZH Loan Agreement**") with LZH, amending and restating the original secured loan agreement by and between Appili and LZH dated March 25, 2022 (the "**Original LZH Loan Agreement**").

On March 10, 2023, Yoav Golan ceased to act as Chief Medical Officer of the Company.

Pursuant to the terms of the Amended LZH Loan Agreement, Appili and LZH have amended the Original LZH Loan Agreement to provide Appili a second tranche loan in the amount of $2.5 million (the "**Second Tranche Loan**") which supplements the first tranche of US$3.6 million advanced pursuant to the Original LZH Loan Agreement (the "**First Tranche Loan**" and collectively with the Second Tranche Loan, the "**LZH Loan**"). The Second Tranche Loan will be used by Appili for working capital purposes.

In connection with the Amended LZH Loan Agreement, LZH was issued 6,930,000 Common Share purchase warrants, exercisable for seven years, with a warrant exercise price of C$0.04 (the "**March 2023 Warrants**").

On February 8, 2023, the Company received notification from the FDA that it had accepted ATI-1501 New Drug Application. The FDA established a Prescription Drug User Fee ("**PDUFA**") action date of September 23, 2023.

On January 4, 2023, the Company terminated and cancelled 4,305,990 options with a strike price in excess of $0.13 to purchase Common Shares.

On November 14, 2022, the Company announced that the USDOD, in partnership USAFA, was expected to provide funding over two years to fund the development of ATI-1701. At the same time, Appili announced leadership changes, promoting Don Cilla to President and CEO and appointing Armand Balboni to Chairman of the Board.

On November 10, 2022, the Company announced plans to focus its resources on advancing its portfolio of infectious disease and biodefense assets, including ATI-1701, ATI-1801, and ATI-1501. At this time, the Company discontinued development of its remaining portfolio programs ATI-2307, a broad-spectrum anti-fungal, and ATI-1503, a broad-spectrum antibiotic targeting multi-drug resistant Gram-negative bacteria.

On May 26, 2022, the Company completed a prospectus offering (the "**May 2022 Public Offering**") of 50,000,000 units at a price of $0.09 per unit, for aggregate gross proceeds of $4,500,000. Each unit consisted of Common Share and one-half of one Common Share purchase warrant, with each whole warrant entitling the holder one additional to acquire Common Share at an exercise price of $0.15 for a period of five years, expiring on May 26, 2027 (the "**May 2022 Warrants**").

In connection with the May 2022 Offering, the Corporation paid commissions of $315,000, and issued 3,500,000 compensation warrants with each such compensation warrant entitling the holder to acquire one Common Share at an exercise price of $0.095 for a period of two years, expiring on May 26, 2024 (the "**May 2022 Broker Warrants**").

On April 13, 2022, the Company announced the addition of ATI-1801 to its development pipeline.

Fiscal 2022 (April 2021 to March 2022)

On March 29, 2022, the Company announced that it had entered into the Original LZH Loan Agreement with LZH, with funds to be used by Appili to retire the previously announced senior convertible funding agreement (the "**Lind Funding Agreement**") with Lind Global Fund II, LP (an investment entity managed by The Lind Partners, a New York based institutional fund manager (together "**Lind**")) and for working capital purposes.

On February 28, 2022, the Company announced that the USDOD had selected for funding an Appili proposal that would provide over US$10 million to advance the Company's biodefense vaccine candidate ATI-1701.

On February 14, 2022, the Company announced that it had discontinued further investment in development activities related to COVID-19 antiviral candidate favipiravir and issued notice of termination of the strategic alliance and equity transaction to AiPharma Global Holdings LLC ("**AiPharma**"), a private pharmaceutical research, development, and commercialization company.

On February 8, 2022, the Company announced that it had amended its agreement with Saptalis to expand the territories in which Saptalis would commercialize ATI-1501, Appili's liquid oral reformulation of the antibiotic metronidazole. Under the terms of the amended agreement, Saptalis would assume responsibility for development and commercialization of ATI-1501 in Europe and Latin America.

On December 22, 2021, the Company announced that the Company and Lind had agreed to amend certain terms of the Lind Funding Agreement. Under the revised terms, Appili made a voluntary prepayment of $1 million towards the principal amount outstanding under the Lind Funding Agreement. In exchange, Lind agreed to a standstill period expiring on March 18, 2022 during which Lind would not be entitled to convert any of the remaining principal amount outstanding into Common Shares.

Under the previously disclosed Lind Funding Agreement, Appili issued to Lind a secured convertible security with a face value of $4.095 million and a 24-month maturity date.

On November 16, 2021, the Company announced the resignation of Kimberly Stephens as CFO and that Kenneth Howling, who has over 25 years of experience in senior financial positions across several healthcare and pharmaceutical companies, would be joining Appili Therapeutics as Acting CFO.

On November 12, 2021, the Company announced that its Phase 3 PRESECO (PREventing Severe COVID-19) clinical trial evaluating oral antiviral favipiravir for the treatment of mild-to-moderate COVID-19 did not achieve statistical significance on the primary endpoint of time to sustained clinical recovery.

On October 14, 2021, the Company completed a prospectus offering (the **"October 2021 Offering"**) of 8,434,000 units (the **"October 2021 Units"**), at a price of $0.83 per October 2021 Unit, for aggregate proceeds of $7,000,220. Each October 2021 Unit consisted of one Common Share and one-half of one Common Share purchase warrant (each whole warrant, a **"October 2021 Warrant"**). Each October 2021 Warrant entitles the holder to acquire one additional Common Share at an exercise price of $1.10 for a period of 3 years, expiring on October 14, 2024. An aggregate of 590,380 broker warrants (the **"October 2021 Broker Warrants"**) were issued as compensation to certain agents in connection with the October 2021 Offering. Each October 2021 Broker Warrant entitles the holder to acquire one Common Share at an exercise price of $0.83 for a period of 2 years, expiring on October 14, 2023.

On September 29, 2021, the Company, together with AiPharma, announced a strategic alliance to advance the global development of favipiravir, which included an equity transaction to establish minority positions in each other's businesses and established of a joint scientific steering committee to coordinate development efforts. Under the terms of the equity transaction, AiPharma would receive that number of Common Shares is equal to 24% of the issued and outstanding Common Shares immediately prior to the agreement (calculated on a non-diluted basis). AiPharma would also be granted certain investor rights, including pre-emptive rights, certain consent rights and registration rights (which rights would be extinguished if the AiPharma holdings fall below 10% of the issued and outstanding Common Shares). Assuming no further equity issuances, it was expected that AiPharma would hold approximately 19.4% of the issued and outstanding Common Shares immediately following closing. In exchange, Appili would receive approximately 6% of the issued and outstanding AiPharma shares (calculated on a non-diluted basis). Closing of the transaction was conditional upon obtaining certain third-party consents and receipt of final TSX approval, which was subject to satisfaction of customary listing conditions (including clearance of requisite personal information forms on behalf of AiPharma).

On September 23, 2021, the Company announced that it had completed enrollment in its Phase 3 PRESECO trial.

On September 20, 2021, the Company announced that it had entered into an agreement with FUJIFILM Toyama Chemical Co., Ltd. (**"FFTC"**), under which FFTC provided Appili US$1 million in funding for which FFTC would receive direct access to PRESECO data in support of local regulatory submissions in Japan.

On September 17, 2021, the Company announced that it had completed patient enrollment in the viral shedding sub-study portion of its Phase 3 PRESECO trial.

On August 18, 2021, the Company announced that it had closed the $3.5 million convertible security Lind Funding Agreement.

On June 17, 2021, the Company announced that it had expanded its ongoing Phase 3 PRESECO trial to Mexico and Brazil. The Company also announced prioritization of the PRESECO trial and that it had ended its Phase 2 CONTROL trial evaluating favipiravir for COVID-19 outbreak control in long-term care facilities.

On May 17, 2021, the Company announced that an independent Data and Safety Monitoring Board has recommended continuation without modification of Appili's ongoing Phase 3 PRESECO trial evaluating favipiravir as a potential oral therapy for patients with mild-to-moderate COVID-19.

Our Business Strategy

The Company was founded to acquire, develop, and commercialize novel therapeutics in the area of infectious disease. The strategic decision to focus on infectious disease and biodefense was driven by the large unmet clinical need in the therapeutic area, as well as the increasing number of regulatory and financial incentives available to support anti-infective R&D. The Company has recruited a team of experienced drug development and commercialization professionals to, among other things: (i) identify high value commercial and R&D anti-infective assets, (ii) leverage available incentive programs to accelerate development, and (iii) maximize market access, reimbursement, and partnerships and alliances to realize stakeholder value. The Appili team has built a portfolio of anti-infective assets through internal innovation and acquisition from partners, and is actively evaluating additional antiviral, antibacterial, antifungal, antiparasitic and vaccine assets for acquisition or partnership.

Our Development Programs

Appili is dedicated to the acquisition, discovery, development, and commercialization of novel infectious disease therapeutics and vaccines. The Company's anti-infective portfolio currently includes three major programs: LIKMEZ (ATI-1501), ATI-1701 and ATI-1801, described below.

LIKMEZ (ATI-1501)

LIKMEZ (ATI-1501) is a liquid oral reformulation of the antibiotic metronidazole, which has been licensed to Saptalis for commercialization in the U.S., and other selected territories.

Metronidazole is a front-line antibiotic for the treatment of anaerobic bacterial and parasitic infections (Quintiles 2016, Solomkin 2010, Flagyl® FDA Label 2018). In many jurisdictions, including the United States and Canada, the only approved oral metronidazole products are in solid dose formats. Elderly and pediatric patients with difficulty swallowing typically crush the tablets to ingest them. Metronidazole has a strong bitter and metallic taste that is exacerbated by crushing and can reduce patient adherence to treatment. ATI-1501 is aimed at making it easier for patients with difficulties swallowing and sensitivity to taste to take metronidazole, improving patient adherence to therapy and clinical outcomes.

In December 2019, Appili entered into a development and commercialization agreement with Saptalis for the manufacturing, development, and commercialization of ATI-1501. Under the terms of the agreement, Appili is eligible to receive multiple milestone and royalty payments on the development and sale of ATI-1501 in the United States. Upon signing the commercialization agreement with Saptalis, the Company received the initial upfront payment of US$150,000 that was recognized as revenue in December 2019.

In February 2022, Appili announced an amendment to its licence with Saptalis to expand the territories in which Saptalis will commercialize ATI-1501 to include Europe and Latin America. Under the terms of the amended agreement, Saptalis will assume all responsibilities related to the development and commercialization of ATI-1501 for European and Latin American markets and Appili will be eligible to receive royalties on sales for a specified term.

Saptalis submitted a 505(b)2 NDA in December 2022 and in September 2023, Saptalis received approval from the FDA for Metronidazole Oral Suspension 500mg/5mL (ATI-1501) in the United States. The FDA also approved LIKMEZ as the brand name for ATI-1501. LIKMEZ is the first and only FDA approved ready-made suspension of metronidazole for the treatment of antimicrobial infections that addresses the unmet need in patients with dysphagia to avoid risks associated with drug compounding, and discontinuation related anti-microbial resistance. Saptalis launched LIKMEZ in November 2023 and commercial sales in the United States are ongoing.

Appili earned US$600,000 in milestone payments from Saptalis in fiscal 2024. Appili expects to receive sales-based milestone payments and royalties from Saptalis based on sale of the product. In May 2023, the United States Patent and Trademark Office published patent claims for ATI-1501 under the US Application No. 18/072,154 filed on

November 30, 2022, and titled "Oral Formulations of Metronidazole and Methods of Treating an Infection Using Same". The patent covers the composition and preparation methods for the drug through 2039.

The sales-based milestone payments set out above are based on management's current expectations with respect to the successful commercialization of ATI-1501 and are subject to certain underlying assumptions and general risks. There is no assurance that these objectives will be achieved and there can be no assurance with respect to the time or resources that may be required. See "Risk Factors"

ATI-1701

Appili licensed the exclusive worldwide rights to biodefense vaccine candidate ATI-1701 from the National Research Council of Canada ("**NRC**") in December 2017.

ATI-1701 is a novel, live-attenuated vaccine for *F. tularensis*. *F. tularensis*, the bacterium which causes tularemia, is a Category A pathogen which can be aerosolized and is over 1,000 times more infectious than anthrax when inhaled (PHAC PSDS Anthrax 2011, PHAC PSDS Tularemia 2011). Category A pathogens are organisms or biological agents that, according to the U.S. National Institutes of Health ("NIH"), pose the highest risk to National Security and public health (NIH website). The signs, symptoms, and prognosis of tularemia depend on the route of infection. Pneumonic tularemia, caused by inhalation of *F. tularensis*, is among the most severe forms of tularemia, causing respiratory issues and difficulty breathing in patients and can be fatal if untreated, (CDC 2018, WHO 2007). Since it is a highly infectious pathogen capable of causing severe illness, medical countermeasures for *F. tularensis* are a top biodefense priority for the United States and allied governments around the world. There is currently no approved vaccine for the prevention of tularemia in the United States or other major global markets. Historical evidence of tularemia outbreaks on Eastern European battlefields suggest that tularemia may be a threat to warfighters in Ukraine.

Preliminary studies in mice conducted by the NRC and colleagues have demonstrated 100% survival of ATI-1701-immunized mice compared to no survival in unvaccinated mice following challenge with virulent *F. tularensis* (Conlan 2010, Shen 2010). Vaccine manufacturing activities have been initiated and animal work commenced in 2019. A non-human primate ("NHP") study showed that vaccination with ATI-1701 provided >88% survival when animals were challenged with a lethal dose of *F. tularensis* at either 28 or 90 days after vaccination. Some of the NHP data have been replicated by a second laboratory, with 87.5% of NHPS surviving a lethal dose of *F. tularensis* 28 days after vaccination. The Company disclosed results from the last cohort of animals challenged 365 days after vaccination, with survival rates of 29% (n = 2/7) reported in the ATI-1701 vaccinated cohort, compared to 0% (n = 0/5) in mock vaccinated controls. Ongoing potency assay development studies have found that as few as 6 CFU of ATI-1701 can provide 100% protection against intradermal challenge in mice. The Company expects to start Phase 1 studies in 2025, with timing to be finalized based on USDOD contracting discussions as described further below. Appili has had interactions with the FDA in the form of a pre-IND meeting, confirming the development pathway for the majority of our efforts and is incorporating suggested changes in the development effort.

In September 2023, Appili sponsored and presented data at the 10th International Conference on Tularemia. The conference hosted the top tularemia physicians and scientists in the world, discussing topics of bacteriology, epidemiology, host immune responses, human infections, pathogenesis, and vaccines. Progress on ATI-1701 was presented and was well received by the scientific community.

The primary focus for commercializing ATI-1701 is targeted towards the United States market, where approval from the FDA is necessary. However, rare and severe diseases such as tularemia present unique challenges during clinical development. These challenges include the inherent risks associated with experimental infection studies in humans, and the impracticality of conducting field efficacy studies due to the low natural attack rate of the disease.

The conventional path for drug development often involves human efficacy studies, which can be impractical for rare diseases like tularemia. The FDA has provided guidance known as the "Animal Rule" (21 CFR 601.90-95) which offers a clear path to approval by relying on well-designed animal studies, potentially expediting the development and availability of this important vaccine. The "Animal Rule" is an alternative product development path for rare and severe diseases like tularemia. According to regulatory guidance from October 2015 titled "Product Development Under the Animal Rule," the FDA may grant marketing approval based on adequate and well-controlled animal efficacy studies for drugs designed to mitigate or prevent serious or life-threatening conditions caused by exposure to toxic substances. This route becomes applicable when human efficacy studies are neither ethical nor feasible, and field

trials are impractical. Under the Animal Rule, drugs must still undergo safety evaluation as per existing requirements for establishing the safety of new drugs.

Appili and its strategic partners are currently assessing the feasibility of seeking approval for ATI-1701 under the FDA Animal Rule. This assessment involves developing appropriate experimental models to demonstrate the efficacy of ATI-1701. Appili aims to complete the necessary preclinical and clinical testing required under the Animal Rule. The objective is to evaluate the immunogenicity, efficacy, and safety of the ATI-1701 vaccine and ultimately submit a Biological License Application (BLA) to the FDA.

Appili's activities related to ATI-1701 have been and continue to be funded through its current resources and largely through USDOD funding.

On May 5, 2023, Appili signed the USAFA Cooperative Agreement with USAFA, who is working in partnership with the Defense Threat Reduction Agency ("**DTRA**"), a department of the USDOD. The initial commitment was US$7.3 million for the ATI-1701 program. On October 25, 2023, Appili secured a further commitment for ATI-1701 from USAFA. With this additional US$6.6 million award Appili's ATI-1701 program has been awarded a total US$14 million in USAFA commitments.

Under the terms of the USAFA Cooperative Agreement, Appili oversees a comprehensive development program for ATI-1701, which includes nonclinical studies, CMC/manufacturing, clinical preparatory, and regulatory activities to support an IND submission in 2025. This adjustment in the timeline for ATI-1701's IND submission was due to the timing of the recent USAFA additional funding agreement which now allows Appili to subcontract other performers to work on the project. Under the terms of the agreement with USAFA, Appili will be reimbursed for the subcontractor and vendor costs necessary to carry out the technical tasks. Additionally, Appili will be reimbursed for direct labour costs associated with budgeted program activities, and a portion of its overhead costs. Appili successfully completed a knowledge transfer and a technology transfer for the ATI-1701 drug substance manufacturing process to our Phase 1 contract manufacturing organization. Engineering and GMP batches are planned for 2024.

In December 2023, Appili announced the issuance of patent for ATI-1701 to protect against tularemia. This patent covers the composition and preparation methods for ATI-1701 through 2039.

It is important to note that access to the funding described above is based on management's current expectations regarding the development and advancement of ATI-1701. Continuous access to funds is subject to certain assumptions and general risks. Due to the nature of the Company's business and stage of operations, there is no guarantee that these objectives will be achieved, and uncertainties remain regarding the required time and resources. Please refer to the "Risk Factors" section for further information.

ATI-1801

Appili licensed the exclusive worldwide rights to topical antiparasitic product ATI-1801 from the US Army Medical Material Development Activity ("**USAMMDA**") in August 2019.

ATI-1801 is a novel topical formulation of paromomycin (15% w/w) under advanced clinical development for the treatment of cutaneous leishmaniasis, a disfiguring infection of the skin that affects hundreds of thousands of people around the world annually and is characterized by the formation of lesions and ulcers that often lead to scarring, disfigurement, disability, and stigmatization of the infected (CDC 2020. WHO 2022, Okwor 2016). The disease is a serious impediment to socioeconomic development, especially for women, and a priority for governments and non-governmental organizations ("**NGOs**") around the word (NIAID 2021, DNDi 2021). Current treatments are often invasive, toxic and/or require hospitalization, limiting access. (Aronson 2016, DNDi 2018).

ATI-1801 has the potential to significantly reduce the burden of the disease by providing patients with a safe and effective therapy that can be used at home. ATI-1801's active ingredient, paromomycin, disrupts protein synthesis within *Leishmania* parasites, effectively stopping their growth and multiplication. Appili licensed the full clinical dossier for ATI-1801 from USAMMDA, including the results of a randomized, vehicle-controlled Phase 3 study which evaluated the safety and efficacy of ATI-1801 for the treatment of cutaneous leishmaniasis in Tunisia. The study met its primary endpoint, with ATI-1801 administered topically once daily for 20 days demonstrating a

significant improvement in the rate of clinical cure of the index lesion compared to vehicle at 6 months (82% vs 58%; p-value < 0.0001).

Appili is currently engaging with the FDA and submitted a type-B meeting request with the FDA in 2024 to discuss the previously generated Phase 3 data and agree on the necessary registration package to support an NDA submission, which the Company expects will include available nonclinical, manufacturing, and clinical data generated to date. Further advancement of this program remains contingent on securing additional funding. Appili expects to pursue non-dilutive funding and partnership opportunities with NGOs and government agencies which share the Company's focus on tropical diseases to help complete remaining development work.

ATI-1801 has received an Orphan Drug Designation ("**ODD**") from the FDA for the treatment of certain forms of cutaneous leishmaniasis.

The milestones set out above are based on management's current expectations with respect to the development and advancement of ATI-1801 and are subject to certain underlying assumptions, future funding requirements and general risks. Due to the nature of the Company's business and stage of operations, there is no assurance that these objectives will be achieved, and there can be no assurance with respect to the time or resources that may be required. See "Risk Factors".

Management and Employees

The drug development and commercialization process are complex and requires expertise in multiple areas. In order to successfully develop a pharmaceutical product, a company must have expertise in the design of preclinical and clinical drug development programs that are in line with regulatory guidelines. A company must also have access to specialized equipment, materials, and scientific personnel to execute experiments at all stages of the development process, which may include chemists, biologists, microbiologists, toxicologists, clinicians, and regulatory affair professionals.

Appili has assembled a team of drug development experts to build high-value anti-infective assets. The Appili executive team has extensive experience in the design and management of both preclinical and clinical stage drug development programs, including regulatory submissions to the FDA and Health Canada. In addition, Appili executives have substantial experience in raising capital through public and private markets for various issuers and private companies to support drug development and commercialization efforts. See "*Executive Officers and Directors*".

The Appili team includes multiple subject matter experts in infectious disease and drug development to advance and grow the R&D pipeline. As of June 25, 2024, Appili has a total of 7 full-time employees, including program management employees, regulatory, clinical, business development and two senior executives (CEO and CDO). The Appili team includes four individuals holding postgraduate doctoral degrees and several holding other professional designations. Appili employees work remotely or out of the head office in Halifax, Nova Scotia. Many of the Company's senior executives are located near Washington, DC. No Appili employees are unionized. The Company expects to grow its workforce gradually as its portfolio expands.

Appili recognizes that continued workforce expansion is dependent on the recruitment of skilled and knowledgeable personnel, which is not assured. However, the Company believes that its geographic footprint, remote work flexibility, and corporate structure are well-suited for future recruitment. With employees present in major academic and biotechnology centers in Eastern Canada and the Northeastern United States, and growing relationships with internationally renowned academic institutions, Appili has access to a large number of highly skilled MSc and PhD level scientists as well as experienced pharmaceutical industry professionals.

Appili enters into subcontracting, consulting, and R&D collaboration agreements as required to supplement core expertise. The Appili team has established relationships with reputable Clinical Research Organizations ("**CRO**"), and consultants in North America and this experience allows the Company to negotiate competitive market rates.

Facilities

Appili's head office is located at 21-1344 Summer Street, Halifax, Nova Scotia. Appili leases office space from Invest Nova Scotia, a Nova Scotia-based crown corporation which promotes innovation in the Atlantic Canada region.

Market Opportunity

Appili has built a diversified portfolio of first-in-class and highly differentiated agents including a vaccine candidate to eliminate a serious biological weapon threat, a topical antiparasitic for the treatment of a disfiguring disease, and a novel easy to use, liquid oral formulation targeting parasitic and anaerobic infections. It is the Company's belief that with existing incentives, these programs address clear unmet needs with well-defined, attractive market opportunities. The Company continues to seek out licensing, partnership, and acquisition opportunities on programs that meet these criteria and expect to generate shareholder value through acquisition and development of such programs, with additional potential upside if additional incentives or long-term demographic, epidemiologic, and socioeconomic trends materialize.

Multiple incentives exist to promote the development of priority anti-infectives, particularly in the US. The Company is proactive in designing its development programs to maximize alignment with existing and potential future incentive programs. One incentive relevant to multiple Appili programs is the PRV program. The PRV program was designed to incentivize industry investment in government priority areas, which currently includes the development of drugs and vaccines for select tropical infectious diseases and biothreats. A PRV is a transferable voucher issued to an innovator company upon approval of an eligible product by the FDA. The PRV can be applied to any subsequent drug development program and reduce the NDA review time to as little as six months. Over 35 PRVs have been sold since the program was initiated in 2007, with recent sale prices routinely exceeding US$100 million.

LIKMEZ (ATI-1501)

Appili originally initiated development of LIKMEZ primarily for use in the United States market. Appili entered into a license agreement with New York-based specialty pharmaceutical company Saptalis on December 3, 2019, in which they were assigned development and commercialization responsibilities. Under the license agreement, Appili is entitled to receive a series of milestone payments and royalties. On February 8, 2022, the Company announced that it had amended its agreement with Saptalis to expand the license to include Europe and Latin America. Appili may pursue additional markets outside of the United States, Europe and Latin America if warranted by market conditions. In some markets, LIKMEZ will likely not be viable due to generic pricing practices and categorization of reformulations against a generic benchmark below Appili's cost of goods. Any future partnering activity conducted by the Company will be focused on markets where the ability to secure premium pricing for the innovation is high and competitive environment is favourable.

As described under "*Our Development Programs* - LIKMEZ *(ATI-1501)*", metronidazole is a front-line antibiotic for the treatment of protozoal and anaerobic bacterial infections including *C. difficile* (Flagyl® FDA Label, 2003; Surawicz, 2013; FDA Orange Book, 2018; Lofmark, 2010). It is estimated that over 10 million prescriptions for oral metronidazole are written in the United States annually, predominantly for confirmed or suspected anaerobic bacterial infections (Quintles, 2016; QuintilesIMS, 2017).

LIKMEZ is designed to facilitate metronidazole ingestion and improve adherence. Appili expects patients of all ages that are prescribed metronidazole to benefit from this product but has identified two enriched segments of patients requiring metronidazole that are most likely to benefit: geriatrics (> 65 years) with dysphagia and pediatrics (< 16 years). These patient populations most often exhibit difficulties with swallowing, and in the case of geriatrics, are also heavily burdened by the anaerobic bacterial infections for which metronidazole is most often prescribed. Appili has commissioned multiple physician and payer surveys to determine potential pricing strategies and guide the Company's overall understanding of the potential market opportunity.

ATI-1701

The objective of the ATI-1701 program is to develop a safe and effective preventative vaccine for tularemia. The Company expects that multiple, international military and government agencies may have an interest in procuring

ATI-1701 for biodefense purposes; however, given existing US military funding for the program and stated biodefense procurement objectives of both civilian and military US agencies, Appili will be focusing initial commercialization efforts on the United States market. The Company also intends to evaluate procurement interest for ATI-1701 in non-US jurisdictions when appropriate, including Canada, Europe, South Korea, Japan, and the Middle East.

US awareness and funding for biodefense initiatives has grown dramatically in the wake of the September 11, 2001, terrorist attacks. The Strategic National Stockpile has been developed in the U.S. as a repository of antibiotics, vaccines, and other critical medical supplies for use in the event of a national or regional public health emergency.

On behalf of the US government, the Biomedical Advanced Research and Development Authority (**"BARDA"**) has deployed significant funds for the stockpiling and development of medical countermeasures. Included below is a non-exhaustive list of contracts issued by BARDA excluding COVID-19 contracts (total potential value listed):

- 2019: US$285 million to Paratek Pharmaceuticals Inc., for development and procurement of Nuzyra® (omadacycline) for the treatment of pulmonary anthrax (announced on December 18, 2019)
- 2018: Up to US$629 million to SIGA Technologies, Inc. ("**SIGA Technologies**") for smallpox antiviral (TPOXX) (designed to maintain stockpile of 1.7M courses)
- 2017: US$539 million to Bavarian Nordic, Inc. ("**Bavarian Nordic**") for smallpox vaccine Imvamune® (also named Jynneos®) (announced on September 27, 2017)
- 2016: US$1.6 billion to Emergent Biosolutions Inc. ("**Emergent Biosolutions**") for anthrax vaccine NuThrax® (50M+ units) (announced on September 30, 2016)
- 2011: US$472 million to SIGA Technologies, Inc. for smallpox antiviral ST-246 (2M courses) (initially disclosed on May 31, 2011, with the total value disclosed on July 13, 2018)

Notably, the United States Department of Health and Human Services and/or BARDA have routinely engaged in medical countermeasure procurement and development in advance of FDA approval, including the SIGA Technologies contract for US$472 million and the Bavarian Nordic contract for US$539 million listed above.

The Company provides no projections on the size or timing of any potential procurement contract. The Company monitors government publications on biodefense to ensure ATI-1701 remains aligned with government interests and a priority for procurement.

In addition to biodefense procurement for civilian populations, United States military agencies may have an interest in procuring additional medical countermeasure supply. The Company is exploring procurement mechanisms in the United States military and will seek out opportunities to maximize revenue potential for the ATI-1701 product.

An additional market consideration for the ATI-1701 program is its potential eligibility to secure a PRV. In 2016, the 21st Century Cures Act (US Public Law 114-255) expanded the PRV eligible program definition to include medical countermeasures. As such, if ATI-1701 is approved by the FDA as a countermeasure for the prevention of tularemia, it is the Company's expectation that the program would be eligible for a PRV, subject to the renewal of certain legislation. The Company may elect to retain or sell the PRV to a third party.

The 21st Century Cures Act includes a sunset clause of October 1, 2023, at which point medical countermeasures may lose PRV eligibility unless the law is renewed. Although rare pediatric priority review vouchers had similar sunset provisions that were subsequently renewed, there is no certainty that this will occur.

ATI-1801

Appili is developing ATI-1801 to meet the need for a safe, non-invasive, and effective topical treatment for cutaneous leishmaniasis. The global burden of cutaneous leishmaniasis is high. The World Health Organization ("**WHO**") estimates that 700,000 to 1 million patients are infected annually with case counts on the rise (WHO, 2020a; WHO, 2020b). There are multiple factors that may contribute to the increase in cases globally, including international travel, globalization, climate change, immigration, civil war and unrest, military operations and conflict, and the refugee crisis (Costa, 2005; Werneck, 2007; Shaw, 2007; Aspock, 2008; Saroufim, 2014; Mansueto, 2014; Du, 2016; Al-salem, 2016; Basher, 2017). Despite the large and growing burden of cutaneous leishmaniasis in many parts of the world, therapeutic options are limited and typically consist of injectables products, heat or cryotherapy, or oral

medicines. The Company believes that ATI-1801 is well positioned to compete with incumbent products based on its tolerability profile and potential for outpatient use.

The burden of cutaneous leishmaniasis is overwhelmingly concentrated in the Middle East, Central and South Asia, North Africa, and Latin America. Cases in the United States and Europe are rare but increasing, the Company intends to work with global partners to pursue multiple market opportunities in parallel to maximize revenues while also ensuring equitable patient access. Appili envisions the total market opportunity for ATI-1801 will include ultra-orphan, premium price US and European travel medicine markets, high volume, low margin procurements from governments, NGOs, or commercial partners for distribution in endemic regions, and potential US military procurement contracts.

The Company also believes that ATI-1801 may be eligible for a PRV if approved for the treatment of cutaneous leishmaniasis. Leishmaniasis has been listed as an eligible tropical disease under the PRV program since inception. The Company intends to further clarify the potential eligibility of ATI-1801 for a PRV in upcoming FDA interactions but does not anticipate a final determination on eligibility until such time that an NDA is approved by the agency.

The Company provides no projections on the size or timing of any potential procurement contract. The Company engages regularly with existing and prospective government and NGO partners to ensure ATI-1801 remains aligned with government interests and pursue non-dilutive funding, partnership, or procurement opportunities.

Competitive Conditions

LIKMEZ™ (ATI-1501)

The US is the primary target market for LIKMEZ. LIKMEZ is the only oral suspension of metronidazole in development for FDA approval in the United States market and no direct competitor is approved and commercially available in the United States, Canada, and many other markets around the world. Competitor products may emerge if LIKMEZ is successful in capturing a significant share of the oral metronidazole market. In addition, a growing number of companies are engaged in reformulation activities for the United States market, including the development of oral liquid formulations. Appili has received patent protection on the LIKMEZ formulation and derivatives. It is expected that this will limit a competitor's room to operate if they were to develop an alternate formulation.

Metronidazole is a multi-sourced, low cost, generic product in the US. LIKMEZ is intended to serve as a substitute for oral metronidazole in patients with difficulty complying with oral solid metronidazole treatment. Substitution of metronidazole with an antibiotic product other than LIKMEZ is likely the major competitive threat to the commercial success of LIKMEZ. The most likely substitution threats identified by Appili are liquid oral forms of antibiotics, such as amoxicillin / clavulanate, and clindamycin, prescribed for swallowing-challenged patients with anaerobic bacterial infections (Bartlett JG 2016). Liquid formulations of drugs are available as generics and are marketed by multiple companies in the United States; however, efficacy of both competitor drugs is limited by gaps in pathogen coverage and/or growing bacterial resistance (Wexler HM, 200; Clin Microb Rev, Snydman DR, 2011; Anaerobe, Hecht DW, 2004; Clin Infect Dis, Nagy E, 2010; Drugs, Koeth LM, 2004; J Antimicrob Ther, Schuetz AN, 2014; Clin Infect Dis). In contrast, metronidazole has comprehensive anaerobe coverage with resistance levels that remain low even after decades of use (Lofmark S, 2010; Clin Infect Dis, Hecht DW, 2004; Clin Infect Dis). The Company expects that ATI-1501 will be preferred over these substitutes due to its lower risk for treatment failure and resistance development.

Physicians in the institutional setting may consider substituting oral metronidazole with the intravenous form for patients with difficulty swallowing. The Company expects that greater convenience, reduced consumable costs, reduced nosocomial infection risk, and reduced nursing time, together with competitive pricing, position LIKMEZ favourably against intravenous competition. Furthermore, the Company does not view intravenous therapy as a credible threat outside of the hospital setting given the safety challenges and costs that would be associated with drug administration, further complicated by metronidazole's frequent dosing schedule (Norris 2018, Flagyl® FDA Label).

As stated above under the heading "*Market Opportunity*", the primary commercial focus for LIKMEZ is the United States market, where no oral suspension product is available. In some other jurisdictions, including Australia, the United Kingdom, and parts of Europe, a metronidazole benzoate prodrug oral suspension product is available. The product exhibits altered pharmacokinetics that may limit utility in the acute setting (Houghton, 1982; Homeida, 1986). In jurisdictions where this product is available, the Company or its partners expect to engage in additional

medical education to ensure the pharmacokinetic advantages of LIKMEZ are well understood by physicians. See also "*Risk Factors*".

ATI-1701

ATI-1701 is a novel, live attenuated vaccine for the prevention of tularemia. The Company has licensed from the NRC a robust intellectual property portfolio relating to composition of matter, methods of synthesis, and methods of use to restrict competitor freedom to operate and maximize product exclusivity. See "*Intellectual Property Rights*". The Company also plans to file additional patents to further strengthen its competitive position. ATI-1701 may be eligible for ODD designation by the FDA, providing Appili with additional mechanisms for extending product exclusivity. Appili does not expect direct competition for the period of exclusivity afforded by the Company's patent position and regional regulatory incentives (e.g., ODD designation). The exact duration of market exclusivity will depend on the patentability of innovations made by Appili and duration of clinical development. To our knowledge, there are no other organizations developing tularemia vaccines based on the same *F. tularensis* genetic backbone with the potential to infringe on the Company's freedom to operate.

There is currently no approved vaccine for the prevention of tularemia either in the United States or in major markets around the world. The most advanced vaccine candidate and greatest competitive threat to ATI-1701 is the LVS vaccine, first developed in Russia and more recently manufactured and stockpiled by the U.S. Army Research Institute of Infectious Diseases ("**USAMRIID**") (Mulligan, 2017). The USAMRIID vaccine ("**USAMRIID-LVS**") was never approved for use by the FDA and previously used by the United States military to vaccinate laboratory workers and other at-risk military personnel under an experimental IND application (Mulligan, 2017). Despite prior military use, clinical data suggest the vaccine only affords incomplete and transient protection in the context of respiratory infection (Pasetti, 2008; Saslaw, 1961; Hornick, 1966). Additional concerns specific to the USAMRIID-LVS vaccine were that it was produced using research-quality standards that do not meet modern GMP criteria for FDA approved products, has an ill-defined mechanism of attenuation, has not been well studied in humans (e.g., safety, efficacy), and that the stockpile is now decades old (Pasetti, 2008).

More recently the US Department of Defense's Joint Vaccine Acquisition Program contracted DynPort Vaccine Company LLC ("**DVC**") to develop a new batch of the LVS vaccine under Good Manufacturing Practices ("**GMP**") conditions. DVC developed a new formulation of the vaccine ("**DVC-LVS**") and performed preclinical and clinical characterization of the new product. Results from a safety and immunogenicity study were reported in 2017 but the Company is not aware of any subsequent development activities (Mulligan 2017).

In addition to the DVC-LVS program, there are multiple earlier stage vaccine development programs targeting tularemia (Sunagar, 2016). The Company is monitoring competitor programs and plans to modify its development program appropriately to maximize procurement opportunities for the product.

ATI-1801

ATI-1801 is a novel, topical formulation of antiparasitic paromomycin that is highly differentiated from products currently on the market. The current formulation is not covered by any active patents; however, Appili holds rights to certain confidential development data. The Company is actively seeking out opportunities to file for new patent protections, restrict competitor freedom to operate, and maximize product exclusivity.

Irrespective of patent status, the Company expects 7 years of regulatory exclusivity in the United States due to its ODD. Appili does not expect direct competition for the period of exclusivity afforded by the Company's patent position and these regional regulatory incentives. The exact duration of market exclusivity will depend on the patentability of innovations made by Appili and duration of clinical development. Regulatory exclusivities in other markets are uncertain.

Incumbent competition for ATI-1801 varies by jurisdiction. The most commonly used agents for the treatment of cutaneous leishmaniasis are injectable antimoniates either administered systemically, which is associated with toxicity and may require hospitalization, or intralesionally, which requires physician administration and can be painful. Heat and cryotherapy are also potential alternatives. The Company believes that ATI-1801 compares favourably to these therapeutic options given its improved tolerability profile and potential for outpatient use.

Miltefosine is an additional therapeutic option that is available only in select jurisdictions, including the United States where it is the only FDA approved therapy for the treatment of cutaneous leishmaniasis and marketed at a premium price under the brand name Impavido®. It is available as an oral formulation and is indicated for the treatment of cutaneous leishmaniasis caused by certain *Lesihmania* species, as well as other forms of leishmaniasis. (Impavido® FDA Label). Miltefosine has been shown to improve outcomes for patients with cutaneous leishmaniasis and its dose format is amenable for outpatient use, however clinical responses vary both by species and also by geography. Gastrointestinal tolerability issues are also frequently reported with miltefosine (Impavido® FDA Label, Ware 2021) and the FDA label includes a warning for potential embryo-fetal toxicity. The Company believes that ATI-1801's safety profile compares favourably to miltefosine providing an opportunity to capture market share in the United States and other jurisdictions where miltefosine is available.

The Company regularly monitors competitor programs in clinical development and will modify its development program appropriately to maximize procurement opportunities for the product.

Intellectual Property Rights

Appili has and will continue to pursue patent protection, register trademarks, and protect other intellectual property through trade secrets, copyright, confidential disclosure agreements, and other mechanisms as appropriate. This includes the use of confidential disclosure agreements with all prospective vendors and partners, reviewed by legal counsel under direction by Appili.

In order to maximize the duration of patent protection during the commercial life a potential product and/or allow the generation of data to strengthen a potential patent, Appili may on occasion delay patent filing, while ensuring it does not risk the product protection during this delay.

To ensure protection of all trade secrets, Appili has put in place strict confidentiality agreements with its directors, executive officers and staff and stores R&D materials and data in secure facilities requiring two level security access.

ATI-1701

Appili has exclusively licensed technology, know how and patents relating to its tularemia vaccine program from the NRC. The licensed patents relate to a vaccine composition comprising an attenuated *F. tularensis* mutant strain, as well as formulations of the vaccine suitable for human administration. The patents have been issued in a number of key commercially relevant jurisdictions, including the United States, Canada and several European countries. A proprietary manufacturing method for the vaccine composition is also licensed and is covered by patent applications, applications currently under review by regional patent offices. The table below summarizes information on the patent portfolio relevant to Canada and the US licensed by Appili (Table 2). Patents issued in other jurisdictions are not listed.

Table 2. – Patents and Patent Applications Licensed by Appili

#	Title	Jurisdiction	Issued Patent or Pending Application Number	Expiry
1	MUTANTS OF FRANCISELLA TULARENSIS AND USES THEREOF	USA	US 8,993,302 (Issued)	2030
		Canada	CA 2,760,098 (Issued)	2030
		Europe	EP 2,424,974 (Issued)	2030
2	A METHOD FOR LYOPHILIZING LIVE VACCINE STRAINS OF FRANCISELLA TULARENSIS	Global (PCT)	PCT/CA2019/050340	-
		USA	US 16/982,322 (Issued)	2039
		CA	CA 3,094,404 (Pending)	2039
		Europe	EP 3,768,820 (Issued)	2039

ATI-1501

An international patent application was filed under the Patent Cooperation Treaty ("**PCT**") on January 16, 2019. The patent application covers oral pharmaceutical compositions, as well as uses of such compositions to treat an infection in a patient. This application entered national phase in various jurisdictions in 2020 and the patent has been issued in the United States, where it is commercially relevant. Other applications are currently under review by regional patent offices. These patents relate to a taste masked formulation of metronidazole directed to patients with the goal of improving compliance with prescribed dosing regimens, a long standing, commercial problem in the United States of metronidazole as a liquid in that patient population. Protection for this formulation involves a combination of regulatory exclusivity strategies and patent protection. A summary of Appili's patent portfolio is provided in the table below (Table 3).

Table 3. – Patents Filed and Held by Appili Therapeutics Relevant to US and Canada

#	Title	Jurisdiction	Patent or Application Number	Expiry
1	ORAL FORMULATIONS OF METRONIDAZOLE AND METHODS OF TREATING AN INFECTION USING SAME	Global (PCT)	PCT/CA2019/050053	-
2	ORAL FORMULATIONS OF METRONIDAZOLE AND METHODS OF TREATING AN INFECTION USING SAME	US	US 11,541,035 (Issued)	2039
3	ORAL FORMULATIONS OF METRONIDAZOLE AND METHODS OF TREATING AN INFECTION USING SAME	Canada	3.087,789 (Pending)	2039
4	ORAL FORMULATIONS OF METRONIDAZOLE AND METHODS OF TREATING AN INFECTION USING SAME	Mexico	MX/a/2020/007494 (Pending)	2039
5	ORAL FORMULATIONS OF METRONIDAZOLE AND METHODS OF TREATING AN INFECTION USING SAME	Brazil	BR1120200143766 (Pending)	2039
6	ORAL FORMULATIONS OF METRONIDAZOLE AND METHODS OF TREATING AN INFECTION USING SAME	Europe	19740911.3 (Pending)	2039
7	ORAL FORMULATIONS OF METRONIDAZOLE AND METHODS OF TREATING AN INFECTION USING SAME	US	18/072,154 (Pending)	2039

ATI-1801

Appili exclusively licensed technology, know how and data relating to its topical paromomycin vaccine program from USAMMDA. No active patents or filings were included in the licence. As outlined above, the Company will seek out opportunities to file for new patent protections as ATI-1801 development progresses.

Regulatory Environment

Drug products must be approved by the appropriate governing body before it can be sold in that country or area. The FDA approves products for the United States market and Health Canada approves products for the Canadian market. The European Medicines Agency ("**EMA**") approves products for the European Union. While the process by which products are approved by the FDA and Health Canada is 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.

United States Government Regulation

In the United States, the FDA regulates drugs under 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 Appili 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, Appili may become subject to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, licence 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 Appili.

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 an NDA or Biological 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 Appili 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 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 IND. An IND must become effective before human clinical trials may begin. 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 an investigational treatment to human subjects under the supervision of qualified investigators in accordance with Good Clinical Practice (GCPs), which ensure ethical and scientific research.

GCPs include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. All participants to fully understand the potential risks and benefits of participating in the trial. Clinical trials typically progress through different phases (I-IV) to thoroughly assess the safety and efficacy of the IND. 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 an IND. Additionally, approval must also be obtained from each clinical trial site's IRB/IEC or ethics committee, before initiating the trial, and the IRB/IEC or ethics committee must monitor the ethical conduct of the clinical trial, ensuring it protects the rights and safety of the human subjects involved. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

The clinical investigation of a drug follows a well-defined progression through different phases. Although the phases are usually conducted sequentially, they may overlap or be combined.

- Phase 1. 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 IND 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 IND 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 halt, 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 (DSMB) or committee. This group works with confidential data and 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. However, successful clinical trials are essential for developing safe and effective new treatments. 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 clinical trial and investigational 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. Applications for ODD products are exempted from the NDA and BLA application user fee, unless the application includes an indication for other than a rare disease or condition and may be exempted from product and establishment user fees under certain conditions.

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 IND 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.

FDA Animal Rule

The FDA has provided guidance known as the "Animal Rule," which offers an alternative product development path for rare and severe diseases like tularemia. According to a report from October 2015 titled "Product Development Under the Animal Rule," the FDA may grant marketing approval based on adequate and well-controlled animal efficacy studies for drugs developed to ameliorate or prevent serious or life-threatening conditions caused by exposure to toxic substances. This approach is applicable when human efficacy studies are not ethical or feasible, and field trials are not practical. Under the Animal Rule, drugs must still undergo safety evaluation according to existing requirements for establishing the safety of new drugs.

Appili and its strategic partners are currently evaluating the feasibility of developing ATI-1701 under the FDA Animal Rule. This evaluation includes the development of appropriate experimental models to demonstrate the efficacy of ATI-1701. Appili intends to collaborate with the NRC and existing partners to complete the necessary preclinical and

clinical testing required under the Animal Rule. The goal is to evaluate the immunogenicity, efficacy, and safety of the ATI-1701 vaccine and ultimately submit a Biological License Application to the FDA.

Canada Drug Products and Biologics Regulation

In Canada, Health Canada's Health Products and Food Branch is the national authority that regulates, evaluates, and monitors the safety, efficacy and quality of drugs and biologics available to Canadians. Drugs and Biologics are regulated according to the *Food and Drugs Regulations*. A Notice of Compliance ("**NOC**") is issued following the satisfactory review of a submission that has met Health Canada's regulatory requirements, and a NOC is required along with a Drug Identification Number before any new unapproved drug can be marketed in Canada. In some cases, post-NOC changes to an approved drug require pre-approval by Health Canada prior to implementation of the changes.

Appili has to comply with all applicable *Food and Drug Act*, the *Food and Drug Regulations* and related policies and Health Canada guidelines. If Appili fails to comply with applicable *Food and Drugs Act* and *Food and Drug Regulations* or other requirements at any time during the product development process, clinical testing or the approval process, Health Canada may refuse to issue a NOC. The outcome after the comprehensive review could be a Notice of Noncompliance ("**NON**") or Notice of Deficiency ("**NOD**") for which a response is permitted. If the response is not deemed to be adequate, a withdrawal letter could be issued. After a NON is issued, Appili may become subject to administrative or judicial sanctions if found to be non-compliant by Health Canada. These sanctions could include marketing licence suspension or revocation, warning letters, product recalls, product seizures, total or partial sale, suspension of production or distribution, civil monetary penalties, or criminal prosecution. Any Health Canada enforcement action could have a material adverse effect on Appili.

The process required by Health Canada before drug products may be marketed in Canada involves the following:

- completion of extensive preclinical laboratory (*in vitro*) tests and preclinical (*in vivo*) animal studies, adherence to GLP;
- submission to Health Canada of a Clinical Trial Application ("**CTA**") (except for Phase IV studies), which must be reviewed and approved by Health Canada with an NOL. Clinical studies must be conducted under principles of good clinical practices, as well as must be approved by a research ethics board ("**REB**") before study can be initiated;
- submission of a drug establishment licence or amend a DEL for new activities on the new drug submission ("**NDS**");
- preparation of and submission to Health Canada of an NDS after completion of all pivotal clinical trials and all preclinical studies that show the drug's potential therapeutic benefit outweighs its risks, and the CMC dossier is complete;
- screening of information related to NDS by Health Canada within 45 calendar days from NDS receipt and if NDS is found to be acceptable on screening, it will be accepted for review within 300 days. If deficiencies are identified during screening, a Screening Deficiency Notice will be issued, and all requested information must be submitted within 45 calendar days from the date of request. If all requested information is not submitted, the NDS will be rejected, and a Rejection Letter will be issued by Health Canada. However, if all requested information is received within 45 calendar days, a new screening period commences with a new performance target;
- satisfactory completion of a pre-approval inspection of the manufacturing facilities where the proposed product is produced to assess compliance with GMP and inspection of clinical sites as per GCP requirements; and
- Health Canada review and authorization of an NDS prior to any commercial marketing or sale of the product in Canada.

Clinical Trials

Appili is required to file a CTA for human drug clinical trials from Phases I to III of development. The CTA consists of administrative, clinical information and detailed quality information about the drug product to be used in the proposed study. The CTA is subject to a 30-day review period and once review is completed, the CTA will either be authorized by Health Canada with a NOL or rejected (with a Not Satisfactory Notice). Post-authorization by Health Canada is required on some changes to a previously authorized CTA.

Clinical trials in Canada involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include IRB approval before the trials may be initiated. Similar to the US, the clinical investigation of a drug is generally divided into three or four phases. Phase IV (post-marketing) studies do not require a CTA however, these studies still require REB approval and must be conducted according to GCPs. Sponsors must follow Health Canada's adverse drug reactions reporting requirements. Division 5 of the *Food and Drug Regulation* mandates sponsors to report adverse drug reactions that are determined to be both serious and unexpected, as per ICH's E2A Guideline: *Clinical Safety Data Management: Definitions and Standards for Expedited Reporting*, which is adopted by Health Canada. Health Canada, the REB, 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 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. Health Canada must be notified: if a trial is prematurely terminated, of resumption of a trial, of completion of a trial or if a clinical site is closed.

Submission of an NDS to Health Canada

Assuming successful completion of all required preclinical studies and clinical testing in accordance with all applicable regulatory requirements, detailed preclinical, clinical, and quality data to support the safe and effectiveness use of an IND product is submitted to Health Canada in the form of an NDS requesting approval to market the product for one or more indications.

Regulatory activities relating to human drugs (and biologics) are subject to fees as per Health Canada's Cost Recovery. The submission of an NDS is subject to Human Drug Submission Evaluation Fee, where Health Canada reviews the drug product information to assess its safety, efficacy, and quality, before issuing a NOC to allow the sale of the drug in Canada. The sponsor of an authorized NDS is also subject to a Drug Establishment Licensing fee for any establishment within Canada and for GMP-related activities covered within the NDS. In addition, the sponsor is subject to the "Annual Right to Sell Drug Fee" to allow Health Canada to monitor drugs through post-market surveillance, compliance, and enforcement activities.

Similar to an NDA/BLA in the United States, a NDS in Canada must include all relevant data available from pertinent preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling (Product Monograph), among other things, to establish the safety and effectiveness of the IND product to meet Health Canada's regulatory requirements. Health Canada supports the use of foreign reviews, which fosters international collaboration among regulatory agencies.

Once an NDS has been submitted, Health Canada's target is to review the application in 300 days. For drugs intended for the treatment of serious or life-threatening conditions, there are alternative Health Canada approval mechanisms with shorter review periods that they may qualify:

- Drugs intended for the treatment, prevention, or diagnosis of serious, life-threatening, or severely debilitating conditions where there is no existing drug on the Canadian market or where the new product represents a significant improvement in the benefit/risk profile over existing products, could qualify under the priority review policy where an NDS will be reviewed in 180 days.
- Drugs intended for the treatment, prevention or diagnosis of a serious, life-threatening or severely debilitating disease or condition for which there is no existing therapy available on the Canadian market which possesses a similar therapeutic profile or for which the new submission demonstrates a significant improvement in the benefit/risk profile over alternate available products, authorization by Health Canada may be granted in 200 days based on promising evidence of clinical effectiveness under a Notice of Compliance with Conditions ("**NOC/c**"). However, the prerequisite is the sponsor's written commitment to pursue undertakings, such as carrying out additional clinical trials to verify the anticipated benefit within an agreed upon timeline *via* a Letter of Undertaking.

During an NDS review, Health Canada typically conducts pre-approval inspection on the facilities where the product is manufactured unless a successful inspection by a recognized foreign regulatory agency is accepted in lieu thereof. Health Canada will not issue a NOC unless it determines that the manufacturing processes and facilities are in compliance with GMP requirements and adequate to assure consistent production of the product within required

specifications and as described in the NDS. Additionally, Health Canada has the authority to inspect clinical sites and other data to assure compliance with GCP and clinical trial regulations.

Health Canada's Decision on an NDS

After Health Canada completes reviewing the NDS and conducts inspections of manufacturing facilities where the product will be produced and clinical sites where clinical efficacy and safety data are generated, Health Canada will issue either a NOC or a NON/NOD. The deficiencies identified in all parts of the review will be specified on the NON/NOD and the sponsor has 90 calendar days to submit all the solicited information. When the response to a NON is received, a second screening period begins (with a new performance target review period). If the response to a NON/NOD is found to be incomplete, the response will be rejected, and the submission will be considered withdrawn without prejudice to a refiling. A NON/NOD-withdrawal letter will be issued to the sponsor.

If an NDS qualifies under the NOC/c policy, a NOC/c-Qualifying Notice will be issued to the sponsor upon completion of the NDS review. The NOC/c-QN will indicate that the submission qualifies for a NOC, under the NOC/c policy, as well as outline the additional clinical evidence to be provided in confirmatory studies, post-market surveillance responsibilities and any requirements related to advertising, labeling or distribution. The sponsor must submit all the appropriate information within the timelines outlined in the NOC/c-QN.

DIVIDENDS AND DISTRIBUTIONS

The Company has not declared dividends or distributions for any of its three most recently completed fiscal years and does not expect to declare dividends or distributions in the foreseeable future. Other than the applicable "solvency test" under the CBCA, there are no restrictions preventing the Company from declaring dividends on its Common Shares, however, any future payment of dividends will be dependent upon the earnings and financial condition of the Company and other factors that the directors may deem appropriate at the time.

DESCRIPTION OF SHARE CAPITAL

The authorized capital of the Company consists of an unlimited number of Common Shares (of which 121,266,120 Common Shares are issued and outstanding as of the date of this AIF), an unlimited number of Non-Voting Shares (of which nil are issued and outstanding) and an unlimited number of Preferred Shares (of which nil are issued and outstanding).

The following summarizes the rights attached to each class of shares of the Company.

Common Shares

Each Common Share entitles the holder thereof to one vote at any meeting of our shareholders. Subject to the rights of the holders of any Preferred Shares, the holders of Common Shares are entitled to receive equally with the holders of the Non-Voting Shares if, as and when declared by our Board, dividends in such amounts as shall be determined by our Board. Subject to the rights of the holders of any Preferred Shares, in the event of the liquidation, dissolution or winding up of the Company, whether voluntary or involuntary, the holders of the Common Shares shall be entitled to receive equally with the Non-Voting Shares the remaining property and assets of the Company.

Non-Voting Shares

Subject to the rights of the holders of any Preferred Shares, the holders of the Non-Voting Shares shall be entitled to receive equally with the Common Shares, as and when properly declared by the Board, dividends on the Non-Voting Shares at any time outstanding which the directors may determine to declare and pay in any fiscal year of the Company. Subject to the rights of the holders of the Preferred Shares, in the event of the liquidation, dissolution or winding up of the Company, whether voluntary or involuntary, the holders of the Non-Voting Shares shall be entitled to receive equally with the Common Shares the remaining property and assets of the Company. The holders of Non-Voting Shares shall not be entitled to vote at any meeting of our shareholders; provided, however, that any amendment to the articles of the Company to delete or vary any right, privilege, restriction or condition attaching to the Non-Voting Shares or to create shares ranking in priority to or on a parity with the Non-Voting Shares, in addition to the

authorization by special resolution, shall be authorized by at least two-thirds of the votes cast at a meeting of the holders of the Common Shares duly called for that purpose.

Preferred Shares

The Preferred Shares may include one or more series of shares. Subject to the provisions of the CBCA, the directors may, by resolution, if none of the shares of any particular series are issued, alter the Articles to: (i) determine the maximum number of shares of that series that the Company is authorized to issue, determine that there is no such maximum number, or alter any such determination; (ii) create an identifying name by which the share of that series may be identified, or alter any such identifying name; and (iii) attach special rights or restrictions to the shares of that series, including, but without limiting or restricting the generality of the foregoing, the rate or amount of dividends (whether cumulative, non-cumulative or partially cumulative), the dates and places of payment thereof, the consideration for, and the terms and conditions of, any purchase for cancellation or redemption thereof (including redemption after a fixed term or at a premium), conversion or exchange rights into other shares, bonds, debentures, securities or otherwise, the terms and conditions of any share purchase plan or sinking fund, restrictions respecting payment of dividends on, or the repayment of capital in respect of, any other shares of the Company and voting rights and restrictions; or alter any such special rights or restrictions.

MARKET FOR SECURITIES

Prior Sales

During the fiscal year ended March 31, 2024, the Company issued the following securities that are not listed or quoted on a marketplace:

Date of Issuance/Grant	Type of Security	Number of Securities Issued	Issue/Exercise Price
May 05, 2023	Stock Options	4,673,250	$0.04
November 11, 2023	Stock Options	140.000	$0.04

Trading Price and Volume

The Common Shares are traded on the TSX, under the symbol "APLI". The following table sets forth the reported intraday high and low prices and the monthly trading volumes of the Common Shares for the Company's most recent completed financial year (Sources: TMX data):

	TSX		
Calendar Period	High ($)	Low ($)	Volume
April 2023	0.040	0.035	235,530
May 2023	0.040	0.030	2,307,730
June 2023	0.040	0.030	1,501,350
July 2023	0.075	0.025	8,099,950
August 2023	0.065	0.045	3,651,741
September 2023	0.080	0.045	9,226,092
October 2023	0.060	0.035	5,034,211
November 2023	0.040	0.030	1,531,201
December 2023	0.040	0.030	1,285,010
January 2024	0.035	0.025	3,237,584
February 2024	0.035	0.025	1,557,111
March 2024	0.040	0.025	1,361,158

ESCROWED SECURITIES AND SECURITIES SUBJECT TO CONTRACTUAL RESTRICTION ON TRANSFER

As at March 31, 2024, the Company did not have any securities that were subject to escrow or to the knowledge of the Company any securities subject to any contractual restrictions on transfer.

EXECUTIVE OFFICERS AND DIRECTORS

The following table sets forth the names and municipalities of residence of our directors and executive officers as well as their positions with the Company and principal occupations for the previous five years. Appili's directors, officers and employees are required to sign standard confidentiality and non-disclosure agreements with the Company.

Name, Age and Residence	Position[1]	Principal Occupation in the Past Five Years
Don Cilla, 63[2] Maryland, United States	President, CEO and Director (since November 2022)	President and CEO of Appili (since November 2022) CDO of Appili (since November 2020) Consultant (November 2019 to November 2020) Head of Global Program Management Operations at Shire (June 2015 to November 2019)
Kenneth Howling 66[2] Ontario, Canada	Acting CFO (since November 2021)	President and CEO of Pinnacle Financial Corporation (since September 2015)
Armand Balboni, 57[2] Virginia, United States	Director (since February 2019)	LT. Colonel, faculty member and Director of the Life Sciences Research Center at United States Air Force Academy (since November 2022) CEO of Appili (December 2019 to November 2022) CDO of Appili (April 2019 to December 2019) Chief Scientific Officer of Appili (October 2018 to April 2019) Assistant Professor, US Military Academy[5]
Brian Bloom, 48 Ontario, Canada	Director (since May 2015)	CEO and Chairman of Bloom Burton & Co.[5] (since November 2008)
Theresa Matkovits, 56[3][4] New Jersey, United States	Director (since October 2018)	CDO of Matinas Biopharma (since October 2018) COO of ContraVir (December 2017 October 2018)
Juergen Froehlich, 68[3][4] Massachusetts, United States	Director (since January 2020)	CMO of Arcturus Therapeutics Holdings Inc. (since March 2023) Acting CMO of EnBiotix, Inc. (January 2022-April 2023)

Name, Age and Residence	Position[1]	Principal Occupation in the Past Five Years
Prakash Gowd, 60[3][4] Ontario, Canada	Director (since November 2023)	Vice President of Toronto Innovation Acceleration Partners (since December 2023) Chief Operating Officer of Novamind Inc. (August 2020 – August 2023)

Notes:

(1) All of the directors' appointments expire at the next annual meeting of the shareholders of the Company.
(2) Each member of management listed in the table above is either a full-time or part-time employee or Consultant of the Company or its subsidiary and is subject to customary non-competition and non-disclosure restrictions pursuant to their employment/consulting agreements with the Company.
(3) Member of the Audit Committee.
(4) Member of the Nominating, Corporate Governance and Compensation Committee.
(5) In addition, (a) Mr. Bloom is a director of BBDC and a director and officer of BBSI; and (b) Mr. Balboni is partner, senior advisor, and member of the board of directors of Bloom Burton & Co., and a director of BBSI.

Biographies

Don Cilla, PharmD, MBA
Dr. Cilla brings to Appili over 35 years of experience in the pharmaceutical industry, with extensive clinical and regulatory expertise that includes direct involvement with developing products, including Lipitor™ and Difcid™. His career includes positions in key leadership, scientific, and program management roles in research and development in pharmaceutical, biotech, and generic drug companies, including Takeda (Shire Pharmaceuticals) and AstraZeneca (MedImmune). In prior roles, Dr. Cilla led and / or participated in the global development of more than 40 products, with six products having made it through regulatory approval to be commercialized. He also has held multiple consulting roles, outsourcing his drug development expertise to help build and lead teams for companies in need of functional area expertise. Dr. Cilla earned his Doctor of Pharmacy from the University of Michigan and an MBA from the University of Phoenix.

Kenneth Howling, Acting CFO
Mr. Howling has over 25 years of healthcare industry experience in senior financial positions; including 11 years with Bausch Health (formerly Biovail Corporation), as CFO, and Senior Vice President, Finance and Corporate Affairs; five years as CFO of Acerus Pharmaceuticals Corporation; and five years as CFO with Pharma Patch PLC. During his career, Mr. Howling has contributed to the success of multiple start-up companies, taken companies through the IPO process, and has collectively raised over US$2.5 billion in various forms of capital. Earlier in his career, Mr. Howling worked in senior financial management positions at Roberts Company Canada Limited, including roles of General Manager, Corporate Secretary and Controller, at GlaxoSmithKline (formerly Beecham Pharmaceuticals Ltd), and as an auditor with PricewaterhouseCoopers. Mr. Howling is a graduate of the ICD/Rotman Director Program and formerly a Certified Public Accountant (inactive licence).

Armand Balboni, MD, PhD, JD, Chair
Dr. Armand Balboni's career includes medical research and drug development experience in civilian, academic, and military organizations, most recently as a partner at Bloom Burton & Co. where he was the firm's senior advisor for regulatory and medical affairs. He has 20 years of active duty and reserve service in the U.S. Army where he spent most of his career in the Chem Bio Defense and emerging infectious disease community. As an Army Officer, he worked as a scientist, clinical and regulatory expert, and in DoD S&T development broadly. Dr. Balboni spent time as an officer at USAMRIID, the U.S. Food and Drug Administration, and USAMMDA as deputy director of clinical and regulatory affairs for the U.S. Army. LTC Balboni currently acts as a medical staff officer with the Allies and Foreign Partners Division within the Joint Chiefs of Staff, Joint Staff J7, in Virginia. Armand completed his doctoral work in the MD/PhD program at the Icahn School of Medicine at Mount Sinai and earned his law degree at Brooklyn Law School. His faculty appointments have included Westfield State University, the United States Military Academy at West Point, and currently at the United States Air Force Academy.

Brian Bloom, Director
Brian Bloom is a co-founder of healthcare investment banking firm Bloom Burton & Co. and serves as the firm's Chairman and Chief Executive Officer. Brian serves on the Board of Directors of Satellos Bioscience and Appili Therapeutics. Brian was formerly the Chairman of the Board of Grey Wolf Animal Health and Triumvira Immunologics, a member of the Life Sciences Advisory Board at the National Research Council of Canada, the Dean's Advisory Board at McMaster University and on the Board of Directors of BIOTECanada, the Baycrest Foundation and Qing Bile Therapeutics.

Before co-founding Bloom Burton in 2008, Brian spent six years at an independent investment dealer in the healthcare and biotechnology institutional sales and equity research groups. Brian started his career at New York-based investment banking firms SCO Financial Group and Molecular Securities. Brian received an Honours Bachelor of Science in Biochemistry from McMaster University and subsequently studied at the Mount Sinai Graduate School for Biological Sciences of New York University, with a focus in molecular endocrinology and biophysics. Brian is the proud recipient of the McMaster University 2017 Distinguished Alumni Award in Science and the co-recipient of the 2023 Life Sciences Ontario Community Service Award. In 2023, Bloom Burton celebrated its 15-year anniversary with an Ecosystem Builder Award from BIOTECanada.

Theresa Matkovits, PhD, Lead Independent Director
Dr. Theresa Matkovits has more than 20 years of experience as a leader in global drug development and commercialization, with extensive expertise in infectious disease. She currently serves as the Chief Development Officer at Matinas Biopharma where she serves as an Executive Leadership Team member, joining the company in October 2018. Dr. Matkovits is responsible for leading the Global Development efforts of the company's development pipeline products, including their Infectious Disease products. Prior to this role, she was the Chief Operating Officer at ContraVir (Nasdaq: CTRV) now Hepion, where she led global development of the company's clinical-stage antiviral portfolio. She also served as ContraVir's Executive Vice President, Head of Drug Development, where she was responsible for leading all global drug development functional areas for the company's infectious disease programs. Dr. Matkovits' career also includes steering the clinical development and approval efforts for Natpara® at NPS Pharmaceuticals; serving as a Vice President and Innovation Leader at The Medicines Company (Nasdaq: MDCO), where she managed global development and commercialization efforts for the Company's infectious disease franchise; and several leadership positions at Novartis in its U.S. Medical and Drug Regulatory Affairs and Global Development Divisions. Dr. Matkovits is a member of the Board of Directors for BioSurplus and Chairperson of Good Cap Pharmaceuticals, and previous director of Aradigm Corporation (Nasdaq: ARDM). Dr. Matkovits earned her PhD in Biochemistry and Molecular Biology from the University of Medicine and Dentistry of New Jersey - New Jersey Medical School.

Juergen Froehlich, Director
Dr. Froehlich's career spans multiple decades and covers a broad range of drug development successes. It includes strategic planning and execution of all phases of drug development and regulatory interactions across therapeutic areas such as cystic fibrosis, bronchiectasis, and hepatitis C. He has worked with biologics, peptides, small molecules and RNA therapeutics at companies including Boehringer Ingelheim, Genentech, Quintiles, Bristol-Myers-Squibb, Ipsen, Vertex, Aradigm Corporation, EnBiotix, Genevant and Spexis AG. He was instrumental in obtaining successful marketing authorizations worldwide, including the U.S., Canada, and the E.U. As CMO and Head of Regulatory Affairs of Aradigm Corporation, he conducted a Ph 3 trial program with a liposomal formulation of ciprofloxacin for inhalation in patients with non-cystic fibrosis bronchiectasis (NCFBE) and chronic Pseudomonas aeruginosa (PA) lung infections. He was an invited panel member at a U.S. Food and Drug Administration workshop in 2018 for inhaled antibiotics in cystic fibrosis and NCFBE. As CMO of Arcturus Therapeutics Holdings, Juergen currently oversees mRNA therapeutics targeting root causes for cystic fibrosis as well as inborn errors of metabolism and is involved in strategic planning for other therapeutic uses.

Prakash Gowd, Director
An accomplished healthcare executive, Mr. Gowd brings over 25 years of extensive experience in biopharma, capital markets, and entrepreneurship, including leadership roles in startups, publicly-traded and private companies. He currently serves as Vice President at TIAP, a not-for-profit organization that identifies, funds, and accelerates transformative, member-sourced, early-stage medical innovation into successful Canadian companies. Before joining TIAP, Mr. Gowd was Chief Operating Officer and Head of Corporate Development at a mental health and psychedelic medicine company where he played pivotal roles in building a network of clinics, bringing the company public,

optimizing value of the U.S. operations, executing acquisitions, and managing the sale of the business. Previously, as Co-founder of a genetic testing company in medical cannabis, he worked collaboratively to assemble the team, develop and market the test, and eventually sell the company. He is also a seasoned capital markets professional, having served in senior equity research and investment banking roles at CIBC World Markets, National Bank Financial, and Canaccord Capital. The foundation of his career was built in commercial operations and new product development in the pharmaceutical industry.

Mr. Gowd served as Audit Chair and Director at FendX Technologies and at Isotechnika Pharma, the predecessor company to Aurinia Pharmaceuticals. He holds an MBA from McGill University, undergraduate degrees in Pharmacy and Zoology from the University of British Columbia, and a Chartered Director designation.

Share Ownership by Directors and Officers

As at the date of this AIF, as a group, the Company's directors, and executive officers beneficially own, directly, or indirectly, or exercise control over, 14,433,611 Common Shares, as well as warrants and options to purchase up to 11,011,754 Common Shares.

Corporate Cease Trade Orders, Bankruptcies, Penalties and Sanctions

No director or executive officer of Appili is, as at the date of this AIF, or was, within 10 years before the date of this AIF, a director, CEO or CFO of any company (including Appili), that 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, CEO or CFO, or
- that was issued after the director or executive officer ceased to be a director, CEO or CFO and which resulted from an event that occurred while that person was acting in the capacity as director, CEO or CFO.

Except as disclosed herein, no director or executive officer of Appili, or a shareholder holding a sufficient number of securities of the Company to affect materially the control of Appili:

- is, as at the date of this AIF, or has been within the 10 years before the date of the 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
- has, within the 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 director, executive officer, or shareholder.

Dr. Froehlich was the CMO and Dr. Matkovits was a director of Aradigm until February 2019. In February 2019, Aradigm filed for protection under Chapter 11 of the U.S. Bankruptcy Code in Alameda County Court District to facilitate the sale of its assets.

Mr. Howling was previously an officer of Biovail Corporation ("**Biovail**"), a speciality pharmaceutical company, engaged in the formulation, clinical testing, registration, manufacture and commercialization of pharmaceutical products. In March 2008, the Ontario Securities Commission (the "**OSC**") alleged certain public disclosures made by Biovail were misleading or untrue in a material respect and in contravention of the *Securities Act* (Ontario). A number of officers of Biovail, including Mr. Howling, were involved to various degrees in these disclosures. In January 2009, the OSC sought and obtained enforcement penalties against the officers involved, including Mr. Howling who was responsible for investor relations at the time. Mr. Howling agreed to a settlement with the OSC which resulted in a reprimand for Mr. Howling, an order to pay $20,000 in respect of the costs of the investigation, and a prohibition against Mr. Howling being or becoming an officer or director of a public company for two years. A complaint was also filed by the United States Securities and Exchange Commission and a settlement was reached in which Mr. Howling was permanently restrained and enjoined from violating Section 10(b) of the Securities and Exchange Act of 1934 and ordered to pay a civil penalty in the amount of US$50,000.

Other than as disclosed, no director or executive officer of Appili, or a shareholder holding a sufficient number of securities of the Company to affect materially the control 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 investor in making an investment decision.

Conflicts of Interest

Other than as disclosed herein, including with respect to the fact that Brian Bloom is a director and officer of Bloom Burton Securities Inc. ("**BBSI**") and Armand Balboni is a director of BBSI, one of the agents in the October 2021 Offering and May 2022 Offering and a party to certain bridge loans as described herein, none of our directors, officers or principal shareholders and no associates or affiliates of any of them, have or have had any material interest in any transaction which materially affects us. There are potential conflicts of interest to which our directors and officers will be subject in connection with our operations. In particular, certain of our directors are involved in managerial and/or director positions with other companies whose operations may, from time to time, be in direct competition with our operations or with entities which may, from time to time, provide financing to, or make equity investments in, our competitors. See "*Risk Factors*" and "*Promoters*".

Conflicts, if any, will be subject to the procedures and remedies available under the CBCA. The CBCA generally provides that in the event that a director has an interest in a material contract or proposed contract or transaction, the director shall disclose his interest in such contract or transaction and shall refrain from voting on any matter in respect of such contract or transaction unless otherwise provided by the CBCA.

AUDIT COMMITTEE

Composition of the Audit Committee

The Audit Committee of the Board (the "**Audit Committee**") is comprised of Prakash Gowd (Chair), Theresa Matkovits and Juergen Froelich, all of whom are "financially literate" as defined in National Instrument 52-110 – *Audit Committees* ("**NI 52-110**"). All three Committee members are considered independent pursuant to NI 52-110. A description of the education and experience of each Audit Committee member that is relevant to the performance of their responsibilities as an Audit Committee member may be found above under the heading "*Executive Officers and Directors*".

The Audit Committee is responsible for reviewing the Company's financial reporting procedures, internal controls and the performance of the financial management and the auditor. The Audit Committee also reviews the annual audited financial statements and makes recommendations to the Board. The Company is relying on the exemption set out in Section 6.1 of NI 52-110.

Audit Committee Charter

A copy of the charter of the Audit Committee is attached as Appendix A.

Audit Committee Oversight

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

Pre-Approval Policies and Procedures

The Audit Committee has authority and responsibility for pre-approval of all non-audit services to be provided to the Company or its subsidiary entities by the external auditor or the external auditor of the Company's subsidiary entities

unless such pre-approval is otherwise appropriately delegated or if appropriate specific policies and procedures for the engagement of non-audit services have been adopted by the Audit Committee.

External Auditor Service Fees by Category

The aggregate fees billed by our current auditor in each of the last two fiscal years are set out in the table below.

Financial Year Ending	Audit Fees	Audit-Related Fees	Tax Fees	All Other Fees
March 31, 2024	$89,000	$56,700	$30,000	$nil
March 31, 2023	$75,500	$68,950	$17,900	$nil

Notes:

(1) *Audit Fees* consist of the aggregate fees billed by the auditor for audit services.
(2) *Audit-Related Fees* consist of the aggregate fees billed for assurance and related services that are reasonably related to the performance of the audit or review of the financial statements and are not reported under "Audit Fees" above and may include the provision of comfort letters and consents, the consultation concerning financial accounting and reporting of specific issues and the review of documents filed with regulatory authorities.
(3) *Tax Fees* include fees billed for tax compliance, tax advice and tax planning services, including the preparation of original tax returns and claims for refund; tax consultations, such as assistance and representation in connection with tax audits and appeals, tax advice related to mergers and acquisitions, and requests for rulings or technical advice from taxing authorities; tax planning services; and consultation and planning services.
(4) *All Other Fees* include the aggregate fees billed for products and services provided by the auditor, other than the services reported above.

RISK FACTORS

The Company is subject to a number of risks, including the risks described below. The risks and uncertainties described below are those believed to be material, but they may not be the only ones faced by the Company. Additional risks and uncertainties not presently known to us or that we believe to be immaterial may also adversely affect our business. If any of these risks actually occur or become material risks, our business, prospects, financial condition and results of operations could be seriously harmed.

Risks Related to the Company and our Business

While the Company has potential sources of cash of approximately $1.3 million as at March 31, 2024, as well as access to potentially the remaining USAFA funding, management does not believe these resources will be sufficient to fund operations and current working capital requirements, for the next twelve months, unless further financing is obtained in the near term. The ability of the Company to continue as a going concern and finance its current working capital requirements in the near term is dependent upon raising additional capital to fund the Company's R&D activities, general and administration expenses, and any expansion of operations through equity financings, non-dilutive funding, and partnerships. As there can be no assurance that the Company will be successful in its efforts to raise additional financing or secure alternative funding on terms satisfactory to the Company, there is substantial doubt about the Company's ability to continue as a going concern. The Company is currently analyzing financing alternatives that could include equity and/or debt financings, government, or other non-dilutive funding and/or new strategic partnership agreements to fund some or all costs of development. There can be no assurance that the Company will be able to obtain capital sufficient to meet any or all of its needs, including accessing all expected USDOD funding pursuant to the USAFA Cooperative Agreement in a timely manner or at all. The availability of equity or debt financing will be affected by, among other things, R&D activity, the Company's ability to obtain regulatory approvals, the market acceptance of the Company's products, the state of the capital markets generally, strategic alliance agreements and other relevant commercial considerations. In addition, if the Company raises additional funds by issuing equity securities, the existing security holders will likely experience dilution, and any incurring of indebtedness would result in increased debt service obligations and could require the Company to agree to operating and financial covenants that would restrict the Company's operations. There can be no assurance that the Company will have sufficient capital to fund its ongoing operations, develop or commercialize any products without future financings. Any failure on Appili's part to raise additional funds on terms favourable or at all may require the Company to significantly change or curtail the current or planned operations in order to conserve cash until such time, if ever, that

sufficient proceeds from operations are generated, and could result in the Company not taking advantage of business opportunities, the termination or delay of clinical trials for our products, curtailment of product development programs. Such adjustments or delays could be material. In addition, failure to secure additional financing as required to fund current working capital requirements and to satisfy certain obligations to secure additional funding (as required pursuant to the amended loan agreement with LZH) may result in the Company defaulting under its existing long term debt arrangements, which may result in the acceleration of obligations under such arrangements. In particular, any delays in either (i) the reimbursement by USAFA of previously submitted expenses pursuant to the USAFA Cooperative Agreement in the near term or (ii) complying with the obligations to secure additional funding (as required pursuant to the amended loan agreement with LZH) may, in the absence of the Company securing satisfactory alternative funding arrangements, result in the Company not being able to satisfy its covenants to maintain a minimum cash balance pursuant to the amended loan agreement with LZH. Such default under the amended loan agreement may result in the acceleration of all obligations owing to LZH under such agreement. Delays in future expense reimbursements by USAFA in the near term may also materially and adversely impact the Company's working capital requirements in the absence of securing satisfactory alternative funding arrangements.

History of negative cash flow

Appili has a history of negative cash flow from operating activities. To the extent that Appili has negative cash flow in future periods, Appili may need to allocate a significant portion of any net proceeds from future financings to fund such negative cash flow and rely principally on non-dilutive financing (e.g., grants) to funds and advance its R&D programs. There can be no assurance that additional capital or other types of financing will be available when needed or that these financings will be on terms at least as favourable to Appili as those previously obtained, or at all.

Transaction with Aditxt

Appili has previously announced the proposed Aditxt Arrangement. There is no guarantee that the Aditxt Arrangement will be completed on the terms as set out in the Arrangement Agreement or at all.

Delays in Accessing the USAFA Funding are expected to Negatively Impact the Company's Working Capital

The arrangement with USAFA requires that the Company incur upfront costs relating to the development of ATI-1701 and submit expenses for reimbursement by USAFA from the DTRA funding. Expenses are expected to be reimbursed within a prescribed period of time. Any material delays in reimbursement are expected to negatively impact the Company's working capital position and may negatively impact the Company's ability to advance ATI-1701 or its other programs, absent securing additional financing. Any additional financing may not be obtained on favourable terms, if at all. If the Company cannot obtain sufficient funding on reasonably acceptable terms, it may terminate or delay clinical trials, decrease R&D costs, scale-back on regulatory plans, and/or sell or assign rights to its technologies, products, or product candidates. There may also be substantial doubt about Appili's ability to continue as a going concern and realize assets and pay liabilities as they become due if the Company is not successful in accessing additional capital. In particular, Appili may fall offside its minimum cash requirement covenants under the Amended LZH Loan Agreement and/or be in breach of other related covenants, which may give LZH the right to enforce its security under the Amended LZH Loan Agreement. See "*Risk Factors – Restrictive Covenants*".

Share price fluctuations

The market price of securities of many companies, particularly development stage pharmaceutical companies, experience wide fluctuations in price that are not necessarily related to the operating performance, underlying asset values or prospects of such companies, including:

- Appili's financial condition and operating results;
- actual or anticipated changes in Appili's growth rate relative to its competitors;
- adverse results or delays in any of the current or project clinical trials Appili will undertake to develop its products;
- regulatory actions with respect to Appili's programs;
- unanticipated efficacy, safety or tolerability concerns related to any of Appili's product candidates;
- changes in laws or regulations applicable to Appili's current product candidates or any future product candidates, including but not limited to clinical trial requirements for approvals;

- the Company's inability to effectively promote and market any of its product candidates once approved;
- competition from other Company's existing products or new products that they are developing;
- failure to meet or exceed financial estimates and projections of the investment community;
- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of competitive companies to Appili;
- share price and volume fluctuations attributable to inconsistent trading volume levels of the Company's shares;
- additions or departures of key management or scientific personnel;
- acquiring additional debt or equity financing efforts;
- sales of the Company's Common Shares by the Company, its insiders or Appili's other shareholders; and
- general economic and market conditions.

These as well as other market and industry factors may cause the market price and demand for the Common Shares to fluctuate substantially, regardless of the Company's actual operating performance, which may limit or prevent investors from readily selling their Common Shares and may otherwise negatively affect the liquidity of the Common Shares. In addition, the stock market in general has experienced extreme price and volume volatility.

Potential dilution

The Company's Articles allow it to issue an unlimited number of Common Shares, Non-Voting Shares and Preferred Shares for such consideration and on such terms and conditions as established by the Board, in many cases, without the approval of the Company's shareholders. The Company may issue additional Common Shares, Non-Voting Shares or Preferred Shares in subsequent offerings (including through the sale of securities convertible into or exchangeable for Common Shares, Non-Voting Shares or Preferred Shares). The Company cannot predict the size of future issuances of Common Shares, Non-Voting Shares or Preferred Shares or the effect that future issuances and sales of such securities will have on the market price of the Common Shares, should such a market develop. Issuances of a substantial number of additional Common Shares, Non-Voting Shares or Preferred Shares or the perception that such issuances could occur, may adversely affect prevailing market prices for the Common Shares, if any. With any additional issuance of Common Shares investors will suffer dilution to their voting power and the Company may experience dilution in its earnings per share.

No dividends have been paid on the Common Shares and the Company does not intend to pay dividends in the foreseeable future although it may ultimately do so in the appropriate circumstances

The Company has paid no cash dividends on any of its Common Shares to date and currently intends to retain its future earnings, if any, to fund the development growth of its businesses. In addition, the terms of any future debt or credit facility may preclude the Company from paying any dividends unless certain consents are obtained, and certain conditions are met.

The Company has incurred significant losses since inception and expects to incur losses for the foreseeable future and may never achieve or maintain profitability

Appili has a history of losses and may never achieve or maintain profitability. Since inception, the Company has incurred significant losses each year and expects to incur significant losses in the coming years as the Company continues to spend resources on R&D activities, clinical trials, and other regulatory and commercialization costs for its product candidates. The net loss was $3.8 million for the year ended March 31, 2024, and $9.2 million for the year ended March 31, 2023. As of March 31, 2024, Appili had an accumulated deficit of $69.1 million. The Company has dedicated its efforts to R&D and expects that its expenses will substantially increase if and as the Company expands its product pipeline and moves its product candidates through one stage of development to the next. To become and remain profitable, Appili must either develop and eventually commercialize a product or products with significant market potential on their own, or in collaboration with a partner. These development and commercialization activities are challenging, including successfully completing the preclinical activities, the clinical trials, obtaining regulatory approval and being able to market successfully approved products. The Company may never realize revenue from its products and even if it does, it may not generate sufficient revenue to be profitable. Profitability may not be sustainable or be able to be increased once achieved.

The Company depends heavily on the success of its product candidates

Appili's product candidates are at various stages of development; risk decreases as the product progresses through the various stages of preclinical and clinical development. Clinical trials of the product candidates may not be successful or may result in unfavourable target product profiles, resulting in significantly lower commercial opportunity than currently anticipated. Significant delays and inability to fully realize the value of the product candidates may materially harm the business. The Company may never be able to obtain regulatory approval for any of its product candidates. Appili has committed significant resources, both human and financial, to the acquisition and development of products. The ability to generate revenues from any of these current or future product candidates will depend heavily on the successful development and eventual commercialization of these product candidates.

Some programs are at an early stage of development. There is no guarantee that any pre-IND-enabling studies will be successful, and that a pre-clinical or clinical candidate will ever be identified. Even if the Company identifies an efficacious clinical candidate for any of its programs, there is no guarantee such product will be considered safe for clinical use. Preclinical studies conducted with clinical candidate may demonstrate dose-limiting toxicities, precluding clinical evaluation of safety and efficacy in clinical trials. Other features of the products may hinder regulatory approval that are related to safety but are not an outcome of a clinical study such as the theoretical risk that the clpB gene deletion mutant live attenuated bacterial vaccine (otherwise known as ATI-1701) could revert to its pathogenic form. Studies have been done to characterize this risk and no reversions were noted, however regulatory authorities may require additional studies, and the outcome of those studies is not certain. These risks could impact ability to secure non-dilutive funding for the program.

Product candidates may be inherently challenging to synthesize, manufacture and/or formulate. Production of sufficient active pharmaceutical ingredient or final drug product may not be feasible for conduct of clinical trials or supply of commercial product. Furthermore, the drug product may prove unstable under appropriate storage and/or use conditions for the proposed indication. If stability studies of the product candidates fail to demonstrate stability to the satisfaction of the FDA or similar regulatory authorities outside the US or do not otherwise produce positive results, the Company may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and subsequent commercialization of the product candidates.

If clinical trials of the product candidates fail to demonstrate safety, efficacy, or stability to the satisfaction of the FDA or similar regulatory authorities outside the US or do not otherwise produce positive results, the Company may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and subsequent commercialization of the product candidates

The Company must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans before it can obtain regulatory approval for the sale of its product candidates. These types of human clinical testing can be very expensive, challenging to design and implement, take significant time to complete and are at risk of achieving the desired outcome. It is common that a company can experience failure of one or more of its products during any one of the stages of testing in a clinical trial. The results of preclinical and early clinical trials may not be indicative of the success of later clinical trials. Furthermore, preclinical, and clinical data are often susceptible to different interpretations and analyses, and many companies that have thought their products performed well in preclinical and clinical trials unfortunately failed to obtain marketing approval of their products.

Appili may also experience various unexpected events during, or as a result of, clinical trials that could delay or prevent the Company's ability to receive regulatory approval or commercialize its product candidates.

If clinical trials of the product candidates fail to demonstrate safety, efficacy, or stability to the satisfaction of the FDA or similar regulatory authorities outside the US or do not otherwise produce positive results, the Company may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and subsequent commercialization of the product candidates.

If the Company experiences delays or difficulties in the enrollment of volunteers or patients in the clinical trials, receipt of necessary regulatory approvals could be delayed or prevented

Clinical trials for drug candidates require identification and enrollment of a large number of volunteers or eligible patients. The Company may not be able to enroll sufficient volunteers or eligible patients to complete clinical trials in a timely manner or at all. Patient enrollment is a function of many factors, including the following: design of the protocol, size of the patient population, eligibility criteria for the study in question, perceived risks, and benefits of the drug under study, availability of competing therapies, efforts to facilitate timely enrollment in clinical trials, patient referral practices of physicians, and availability of clinical trial sites. If Appili has difficulty enrolling sufficient volunteers or patients to conduct its clinical trials as planned, it may need to delay, forego, or terminate ongoing clinical trials.

If serious adverse or intolerable side effects are identified during the development of the product candidates, the Company may need to abandon or limit the development and expected commercial value of some of its product candidates

The Company's product candidates are still in preclinical or clinical development and as such, they have a high risk of failure. If serious adverse or intolerable side effects are identified during the development of the product candidates, the Company may need to abandon their development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe, or more acceptable from a risk-benefit perspective. It is impossible to predict when or if any of the Company's product candidates will prove effective or safe in humans or will receive regulatory approval.

If serious adverse or intolerable side effects are identified post-approval, the Company may need to recall its products and depending on the serious adverse event or intolerable side effects, the Company may have to abandon the product completely and could be subject to substantial product liability claims. The Company may be able to limit sales to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe, or more acceptable from a risk-benefit perspective.

*Even if any of the Company's product candidates receive regulatory approval, they may fail to achieve market access, reimbursement and pricing approval and be incorporated into medical guidelines supported by public or private insurers ("**Payers**") and health care practitioners necessary for commercial success*

Even if any of the Company's product candidates receive marketing approval by the FDA, there is no guarantee they will gain sufficient market acceptance by physicians, patients, healthcare practitioners and others in the medical community. If the Company's product candidates do not achieve sufficient level of acceptance, the Company may not generate sufficient revenues and may not become profitable. The degree of market acceptance of the Company's product candidates will depend on a number of factors, including the potential advantages the Company's product candidate provides compared to alternative treatments, the price, the convenience and ease of administration compared to alternative treatments, the willingness of the physicians to prescribe the Company's new products, the strength of marketing and distribution support through its partners, sufficient third party coverage or reimbursement and the prevalence and severity of any side effects.

If the Company is unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market its product candidates, the Company may not be successful in commercializing its product candidates if and when they are approved

The Company intends to establish commercialization arrangements with third parties. The Company's likely collaborators for any development, distribution, marketing, licensing, or broader collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies, and biotechnology companies. The Company may not be successful in establishing these agreements with third parties and may not be successful in commercializing its products at all or to the extent required to be profitable.

If a licensing partner is not contracted, the Company must establish commercial reimbursement, contracting and sales/marketing capabilities or enter into agreements with Contract Sales Organizations to provide this service at a cost. This would impact the Company's resources and opportunities and the Company may still not be successful in commercializing its product candidates if and when they are approved

For some of the Company's products, the Company intends on licensing the rights to a partner to take over the commercialization activities of the product. If the Company is not successful in finding a licensing partner, Appili may have to establish its own commercialization activities, either on its own which includes commercial reimbursement activities, contracting and sales and marketing activities, or through a Contract Sales Organization. The Company currently does not have these capabilities and such efforts would lead to significant additional costs which the Company may not be in a position to fund. Failure to secure additional funding may result in material delays and there is no certainty that the Company would attain successful commercialization of its products in a reasonable timeframe or at all.

The Company faces substantial competition, which may result in others discovering, developing, or commercializing products before or more successfully resulting in reduced market opportunity for the product and Company

The Company faces competition with respect to its product candidates from pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies around the world. Many of Appili's competitors have greater financial resources and development and selling and marketing capabilities. The Company may face further competition from both pharmaceutical and biotechnology companies that focus their efforts on developing and marketing products that are similar in nature to its products, but may offer improvements over the Company's product candidates, in either effectiveness or price. Appili's success will partly depend on its ability to secure superiority in its product and operations and maintain such superiority in the face of new products and competition. If the Company's products are not competitive, it would negatively affect Appili's business, prospects, financial condition, and operating results.

Despite launching products, the Company may experience limits in market access, unfavourable reimbursement or pricing, healthcare policy reform initiatives, which would limit the value of the portfolio and harm the business

The Company's ability to commercialize any products successfully will depend, in part, on the extent to which coverage and reimbursement for these products and related treatments will be available from government healthcare programs, private health insurers, managed care plans, and other organizations. Government authorities and third-party Payers, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry is cost containment. Government authorities and third-party Payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third party Payers are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. The Company cannot be sure that coverage and reimbursement will be available for any product that Appili or any partner commercializes and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which Appili obtains marketing approval. Obtaining reimbursement for some of the Company's products may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, Appili may not be able to successfully commercialize any product candidate for which the Company obtained marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA, EMA, or other regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also be insufficient to cover our and any collaborator's costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private Payers and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. Third party Payers often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. The Company's inability to promptly obtain coverage and profitable payment rates from both government-funded and private Payers for any approved products that we or our collaborators develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

The Company's reliance on government funding adds uncertainty to the Company's research and commercialization efforts of its government-funded product candidates

The Company has received significant funding from government organizations either directly or indirectly since its inception totaling over $32.6 million. There is no guarantee the Company will continue to be eligible and/or successfully awarded additional government funding in the future. If Appili is unsuccessful in obtaining additional government funding, the Company will have to either obtain future financing through issuing additional equity, debt financing or licence arrangements with strategic partners or others, if available, that may require the Company to surrender material rights to certain technologies or potential markets, or not complete certain R&D activities as planned. There is no certainty that financing will be available in amounts the Company requires to pursue the planned activities or on acceptable terms, if at all.

Products for which the primary customer will be the government, either through civilian or military contracts, are at risk of changes in policy, strategic priorities and funding commitments tied to political timelines (i.e. elections)

Appili's product pipeline includes a product candidate, ATI-1701, whose primary customer will be the government, either through civilian or military contracts. If the Company is unable to hire and retain the appropriate employees or engage third party contractors with a specialized skill set to contract with government agencies, the Company may not be able to successfully commercialize the product at all or to the extent required to be profitable. If the Company is able to secure a further government contract or renegotiate the USAFA Cooperative Agreement, there is no guarantee it will be at optimal terms, including with respect to volume, price and terms. Any changes in policy, strategic priorities or funding commitments with these government agencies increase the risk that the Company may not be able to secure a government contract and successfully commercialize the product.

Product liability lawsuits against the Company could cause the Company to incur substantial reputational risk and legal liabilities limiting commercialization of the Company's portfolio

There is an inherent risk of product liability exposure related to the testing of the Company's product candidates in human clinical trials and Appili will face an even greater risk if it commercially sells any products that it may develop. The Company's current product candidates have not been widely used over an extended period of time, and therefore, safety data is limited.

If the Company cannot successfully defend itself against claims that its product candidates or products caused injuries, it will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in decreased demand for any product candidates or products that the Company may develop, injury to the Appili's reputation and significant negative media attention, withdrawal of clinical trial participants, significant costs to defend the related litigation, substantial monetary awards to trial participants or patients, loss of revenue and the inability to commercialize any products that the Company may develop.

When Appili begins to commercialize its product candidates, the Company will need to increase its insurance coverage, which is increasingly expensive. The Company may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

PRV Eligibility

Certain PRV programs that our products have been eligible for may cease to exist, absent a change in law.

The PRV program was designed to incentivize industry investment in government priority areas, which currently includes the development of drugs and vaccines for select tropical infectious diseases and biothreats. A PRV is a transferable voucher issued to an innovator company upon approval of an eligible product by the FDA. The PRV can be applied to any subsequent drug development program by the holder and can reduce the NDA review time to as little as six months.

In 2016, the 21st Century Cures Act (US Public Law 114-255) expanded the PRV eligible program definition to include medical countermeasures, of which certain of the Company's products may be eligible. The 21st Century Cures Act included a sunset clause of October 1, 2023, and was not renewed prior to such sunset date, meaning that

the FDA is not authorized to issue PRVs for these approved products, absent an update in law. The U.S. Congress is working to remedy this. In particular, S.2333 the Pandemic and All-Hazards Preparedness and Response Act (PAHPA) includes language to amend the sunset date of the Medical Countermeasures Priority Review Voucher program included in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-4a) from "2023" to "2028". This bill reported out of committee in July 2023 after bipartisan agreement on its inclusion in the PAHPA reauthorization package, which is anticipated to pass Congress this fall. There can be no certainty that this bill (or any similar future bills) will pass on the anticipated timeline, whether in its current format or at all. Accordingly, there can be no certainty that one or more of the Company's current products can once again meet the criteria for PRV eligibility.

The Company may expend its limited resources to pursue a particular product candidate but fail to unlock the value due to market, reimbursement or healthcare practitioner use. This would limit capitalizing on product candidates or indications that may be more profitable or for which there is a greater likelihood of success

The Company has limited financial and managerial resources to expend on research programs and product candidates. As a result, the Company may sacrifice or delay pursuit of opportunities with certain product candidates or for other indications that later prove to have a greater commercial potential. Appili may make decisions to allocate resources on product candidates that may not be viable commercial products or profitable market opportunities and as a result, may fail to capitalize on other product candidates that could be commercially viable products.

The Company's strategy is to develop a pipeline of balanced-risk products to meet the unmet medical needs of patients in the infectious disease space. As such, the Company evaluates multiple opportunities to potentially acquire and further develop new product candidates and makes decisions based on the scientific merit, commercial opportunity, and the Company's current resources. Notwithstanding the large investment to date and anticipated future expenditures in its current product candidates, the Company has not yet developed, and may never successfully develop, any marketed drugs using this approach. As a result of pursuing the development of product candidates using this business strategy, the Company may fail to acquire and/or develop product candidates based on other scientific approaches that may offer greater commercial potential or for which there is a greater likelihood of success.

Research and business development programs to identify new product candidates require substantial technical, financial, and human resources. These research programs may initially show promise in identifying potential product candidates yet fail to yield product candidates for clinical development.

If the Company does not accurately evaluate the commercial potential or target market for a particular product candidate, the Company may relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements in cases in which it would have been more advantageous for the Company to retain sole development and commercialization rights to such product candidate.

Failure to maintain adequate internal controls over financial processes and reporting may negatively impact the Company's results of operations or its ability to comply with its reporting obligations

Effective internal controls are necessary for the Company to provide reliable financial reports and to help prevent fraud. Although the Company has implemented a number of internal control procedures in order to help ensure the reliability of its financial reports, including those imposed on it under Canadian securities laws, the Company cannot be certain that such measures will ensure that the Company will maintain adequate control over financial processes and reporting. Failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm the Company's results of operations, or cause it to fail to meet its reporting obligations once it becomes a reporting issuer.

Restrictive covenants

The Amended LZH Loan Agreement contains restrictive covenants that may restrict the Company's discretion with respect to certain business matters, including a covenant to maintain a minimum cash balance. These covenants may place significant restrictions on, among other things, the Company's ability to obtain additional debt financing, create liens or other encumbrances, to pay distributions or make certain other payments, enter into certain agreements, investments, loans and guarantees, and to sell or otherwise dispose of assets, or otherwise operate the business in the

ordinary course. If the Company breaches any of these covenants, it may constitute an event of default under the Amended LZH Loan Agreement entitling LZH to accelerate the outstanding indebtedness thereunder unless such event of default is cured as required by the Amending LZH Loan Agreement. The Company's ability to comply with these covenants in future periods will depend on its ongoing financial and operating performance, which in turn will be subject to economic conditions and to financial, market and competitive factors, many of which are beyond its control. The restrictions in the Amending LZH Loan Agreement governing the Company's loan with LZH may prevent the Company from taking actions that it believes would be in the best interest of its business and may make it difficult for it to execute its business strategy successfully or effectively operate in comparison to companies that are not similarly restricted. The Company may also incur future debt obligations that might subject it to additional restrictive covenants that could affect its financial and operational flexibility. The Company's ability to comply with the covenants and restrictions contained in any existing or future loan agreements may be affected by economic, financial and industry conditions beyond its control. In particular, as noted above, Appili's ability to comply with minimum cash balance covenant may be impacted by the failure (or delay) of USAFA to reimburse submitted expenses under the USAFA Cooperative Agreement. The breach of any of these covenants or restrictions could result in a default under the loan agreements that would permit the applicable lenders to declare all amounts outstanding thereunder to be due and payable, together with accrued and unpaid interest, or cause cross-defaults under the Company's other debts. If the Company is unable to repay its secured debt, the applicable lenders could proceed against the collateral securing the loans. This could have serious consequences to the Company's financial condition and results of operations and could cause it to become bankrupt or insolvent.

Regulatory Matters

As a U.S. government contractor, Appili business is heavily regulated and, as a result, our need for compliance awareness and business and employee support is significant.

Appili's industry is governed by various laws and regulations, including but not limited to laws and regulations relating to: the formation, administration, and performance of contracts; the security and control of information and information systems; international trade compliance; human trafficking; and the mandatory disclosure of "credible evidence" of a violation of certain criminal laws receipt of significant overpayments, or violations of the civil False Claims Act. In addition, U.S. government contractors are generally subject to other federal and state laws and regulations, including:

- the Federal Acquisition Regulation ("**FAR**"), agency supplements to the FAR, and related regulations, which regulate the formation, administration, and performance of U.S. federal government contracts;
- the False Claims Act, which allows the government and whistleblowers filing on behalf of the government to pursue treble damages, civil penalties, and sanctions for the provision of false or fraudulent claims to the U.S. federal government.
- the Truth in Negotiations Act, which requires certification and disclosure of cost and pricing data in connection with the negotiation of certain contracts, modifications, or task orders;
- the Procurement Integrity Act, which regulates access to competitor bid and proposal information, as well as certain internal government procurement sensitive information, and regulates our ability to provide compensation to certain former government procurement officials;
- laws and regulations restricting the ability of employees of the U.S. government to accept gifts or gratuities from a contractor;
- post-government employment laws and regulations, which restrict the ability of a contractor to recruit and hire current employees of the U.S. government and deploy former employees of the U.S. government;
- laws, regulations, and executive orders requiring the safeguarding of and restricting the use and dissemination of information classified for national security purposes or determined to be "controlled unclassified information," "covered defense information," or "for official use only";
- laws and regulations relating to the export of certain products, services, and technical data, including requirements regarding any applicable licensing of our employees involved in such work;

•laws, regulations, and executive orders regulating the handling, use, and dissemination of personally identifiable information in the course of performing a U.S. government contract;

•laws, regulations, and executive orders governing organizational conflicts of interest that may prevent us from bidding for or restrict our ability to compete for certain U.S. government contracts because of the work that we currently perform for the U.S. government;

•laws, regulations, and executive orders that mandate compliance with requirements to protect the government from risks related to our supply chain;

•laws, regulations, and mandatory contract provisions providing protections to employees or subcontractors seeking to report alleged fraud, waste, and abuse related to a government contract;

•the DoD's "Contractor Business Systems Rule," which authorizes DoD agencies to withhold a portion of our payments if we are determined to have a significant deficiency in any of our accounting, cost estimating, purchasing, earned value management, material management and accounting, or property management systems; and

•the Cost Accounting Standards and the Cost Principles, which impose accounting requirements that govern our right to reimbursement under certain cost-based U.S. government contracts and require consistency of accounting practices over time.

We are also subject to oversight by the U.S. Office of Federal Contract Compliance Programs ("**OFCCP**") for federal contract and affirmative action compliance, including the following areas:

•affirmative action plans;
•applicant tracking;
•compliance training;
•customized affirmative action databases and forms;
•glass ceiling and compensation audits;
•desk and on-site audits;
•conciliation agreements;
•disability accessibility for applicants and employees;
•diversity initiatives;
•equal employment opportunity compliance;
•employment eligibility verification (known as "E-Verify");
•internal affirmative action audits;
•internet recruiting and hiring processes;
•OFCCP administrative enforcement actions;
•record-keeping requirements; and
•Sarbanes-Oxley Act of 2002 compliance.

The U.S. federal government routinely revises its procurement practices and adopts new contract statutes, rules and regulations. In order to anticipate compliance with changes to laws and regulations, we participate in industry-wide associations that represent the industry perspectives on proposed regulations to the government, monitor proposed regulatory changes to adapt our policies and processes to accommodate the changes when they become effective, maintain compliance staff in our corporate departments, and conduct awareness and training for affected employees, such as our contracts staff and government compliance team.

The U.S. federal government has a broad range of tools available to enforce its procurement law and policies. These include debarring or suspending a particular contractor, certain of its operations and/ or individual employees from future government business. Individuals, on behalf of the federal government, may also bring qui tam suits against us for any alleged fraud related to payments under a U.S. federal government contract or program.

Dependence on USAFA funding for most of our operating cash inflows. If our relationships with such agencies are harmed, our future revenue and operating profits could materially decline

USAFA is our primary customer accounting for substantial our revenue. We believe the performance of our business will continue to depend primarily on our ability to be awarded work under U.S. government contracts, as we expect this will be the primary source of substantially all of our operating cash inflows in the foreseeable future.

For this reason, any issue that compromises our relationship with the U.S. government generally or any U.S. government agency that we serve could cause our revenue to materially decline. Among the key factors in maintaining our relationship with U.S. government agencies are our performance on contracts, the strength of our professional reputation, compliance with applicable laws and regulations, and the strength of our relationships with customer personnel. In addition, the failure to maintain adequate protection against security breaches, including from cyber-attack, or the mishandling or perceived mishandling of sensitive information, could harm our relationship with U.S. government agencies. This could include, for example, our failure to maintain the confidentiality of sensitive information associated with the work we perform for our customers, or even disclosure of the existence of our business relationships with certain of our customers, including as a result of misconduct or other improper activities by our employees or subcontractors. Our relationship with the U.S. government could also be damaged as a result of an agency's dissatisfaction with work performed by us, a subcontractor, or other third parties that provide services or products for a specific project for any reason, including due to perceived or actual deficiencies in the performance or quality of our work. In such case, we may incur additional costs to address any such situation and the profitability of that work might be impaired. In addition, to the extent our performance under a contract does not meet U.S. government agency's expectations, such agency customer may seek to terminate the contract prior to its scheduled expiration date, provide a negative assessment of our performance to government-maintained contractor past-performance repositories, fail to award us additional business under existing contracts or otherwise, and direct future business to our competitors. Further, negative publicity concerning government contractors in general or us in particular may harm our reputation with U.S. government contractors. To the extent our reputation or relationships with U.S. government agencies is impaired, our revenue and operating profits could materially decline.

A delay in the completion of the U.S. federal government's budget process and statutory debt limit could have a material adverse effect on our operating cash inflows and operating results

On an annual basis, the U.S. Congress must approve budgets that govern spending by each of the federal agencies we support. When the U.S. Congress does not pass the annual budget on a timely basis, it may enact a continuing resolution that allows U.S. federal government agencies to operate at spending levels approved in the previous budget cycle. Under a continuing resolution, funding may not be available for new projects. In addition, when U.S. federal government agencies operate on the basis of a continuing resolution, they may delay funding we expect to receive on contracts we are already performing. Any such delays would likely result in new business initiatives being delayed or canceled and could have a material adverse effect on our revenue, cash flows and operating results. Furthermore, a failure to complete the budget process and fund government operations pursuant to a continuing resolution may result in a U.S. federal government shutdown, such as the recent partial shutdown in December 2018 and January 2019. Finally, while the U.S. Congress may pass a continuing resolution, it is possible no agreement on the annual budget may be reached and the U.S. government could shut down again following the expiration of the continuing resolution that acted largely as a stopgap measure. A shutdown may result in us incurring substantial costs without reimbursement under our contracts and the delay or cancellation of key programs, which could have a material adverse effect on our revenue, cash flows and operating results.

We are subject to extensive and complex laws and regulations relating to award, administration and performance of U.S. government contracts. Our business and reputation could be adversely affected by the application of these laws.

We must comply with and are affected by laws and regulations relating to the award, administration and performance of U.S. government contracts. Government contract laws and regulations affect how we do business with our customers and impose certain risks and costs on our business. U.S. government contractors are subject to a greater risk of investigation, criminal prosecution, civil fraud, whistleblower lawsuits and other legal actions and liabilities than companies with solely commercial customers. A violation of specific laws and regulations, by us, our employees, others working on our behalf, a supplier or a venture partner, could harm our reputation and result in the imposition of fines and penalties, the termination of our contracts, suspension or debarment from bidding on or being awarded contracts, loss of our ability to export products or services, and civil or criminal investigations or proceedings. In some

instances, these laws and regulations impose terms or rights that are different from those typically found in commercial transactions.

Our business is subject to reviews, audits and cost adjustments by the U.S. federal government, which, if resolved unfavorably to us, could adversely affect our profitability, cash flows or growth prospects.

Government audits and reviews may conclude that our practices are not consistent with applicable laws and regulations and result in adjustments to contract costs and mandatory customer refunds. U.S. federal government agencies, including the Defense Contract Audit Agency, the Defense Contract Management Agency ("**DCMA**") and various agency Inspectors General, routinely audit and investigate government contractors. These agencies review a contractor's performance under its contracts, its cost structure, its business systems, and compliance with applicable laws, regulations and standards. A finding of material weakness or significant control deficiencies in a contractor's business systems or a finding of noncompliance with the CFR, FAR or Cost Accounting Standards can result in reduced billing rates to U.S. government customers until the material weakness or control deficiencies are corrected and their remediation is accepted by the DCMA. The U.S. federal government has the ability to decrease or withhold certain payments when it deems systems subject to its review to be inadequate. Additionally, any costs found to be misclassified may be subject to repayment.

If an audit or investigation uncovers improper or illegal activities, we may be subject to civil or criminal penalties and administrative sanctions, including reductions of the value of contracts, contract modifications or terminations, forfeiture of profits, suspension of payments, penalties, fines and suspension, or prohibition from doing business with the U.S. government. In addition, we could incur significant legal costs and suffer serious reputational harm if allegations of impropriety were made against us. The agencies conducting these audits and reviews have come under increased scrutiny. As a result, audits and reviews have become more rigorous and the standards to which we are held are being more strictly interpreted which has increased the likelihood of an audit or review resulting in an adverse outcome.

The U.S. government's organizational conflict of interest rules could limit our ability to successfully compete for new contracts or task orders or may require us to exit or wind down certain existing contracts or task orders, any of which could adversely affect our results of operations and prospects.

Future legislation and regulations may increase the restrictions in current organizational conflicts of interest regulations and rules. To the extent that organizational conflicts of interest laws, regulations and rules limit our ability to successfully compete for new contracts or task orders with the U.S. government and/or commercial entities, or require us to exit certain existing contracts or task orders or winding down certain existing contracts or task orders, either because of organizational conflicts of interest issues arising from our business or because companies with which we are affiliated or with which we otherwise conduct business create organizational conflicts of interest issues for us, our results of operations and prospects could be materially and adversely affected.

Risks Related to the Company's Dependence on Third Parties

Reliance on USAFA Cooperative Agreement

We currently rely on the USAFA Cooperative Agreement for the Company's current sole revenue stream. In the event that the USAFA Cooperative Agreement is terminated or either the Company or USAFA is unable to perform its obligations thereunder, this would be expected to negatively impact the Company's working capital position and may negatively impact the Company's ability to advance ATI-1701 or its other programs, absent securing additional financing (see "*The Company will need substantial additional funding. Raising additional capital may cause dilution to existing shareholders, restrict operations, or require the Company to relinquish rights to its technologies or product candidates*"). Furthermore, if the USAFA Cooperative Agreement is terminated, there are a limited number of parties who would be able to provide the Company the opportunities contemplated thereunder. Such loss would require significant time and effort to locate an equally qualified party to contract and there is no guarantee that the Company would be able to enter into an agreement with such party or on terms acceptable to the Company.

Milestone Payments

The development and commercialization agreement with Saptalis sets out milestones for certain payments from Saptalis to the Company. In the event such milestones: (a) are not achieved; or (b) are achieved and the corresponding payments are not made to the Company or are not made to the Company in a timely manner, such outcome could have a material adverse effect on the Company.

If the Company is not able to establish collaborations, the Company may have to alter its development and commercialization plans

For some of Appili's product candidates, the Company plans to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates. For instance, the Company has partnered with Saptalis to advance the development and commercialization of ATI-1501 in certain jurisdictions. The Company faces significant competition in seeking appropriate collaborators. Whether the Company reaches a definitive agreement for a collaboration will depend, among other things, upon its assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator's evaluation of a number of factors. Those factors may include the likelihood of approval by the FDA, Health Canada or similar regulatory authorities outside the United States and Canada, the potential market for the product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, and the potential of competing products. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with Appili for its product candidate. The Company may also be restricted under existing licence agreements from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. Appili may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all.

The Company intends to develop collaborations with third parties to commercialize some of its products. If the Company is not able to enter into collaborations for any such product candidate, the Company may have to curtail the development of such product candidate, reduce or delay its development program or one or more of its other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase its expenditures and undertake development or commercialization activities at the Company's own expense. If Appili elects to increase its expenditures to fund development or commercialization activities on its own, the Company may need to obtain additional capital, which may not be available to the Company on acceptable terms or at all. If the Company does not have sufficient funds, the Company may not be able to further develop these product candidates or bring these product candidates to market and generate product revenue.

The Company may depend on collaborations with third parties for the development and commercialization of its product candidates. If those collaborations are not successful, the Company may not be able to capitalize on the market potential of these product candidates

The Company's collaborators may fail to meet contractual obligations. Potential delays include delays in manufacturing for clinical trials, failure to produce sufficient quantities of product to conduct trials, or failure to complete trials. They could also pursue other technologies or develop alternative products that could compete with the products the Company is developing. If the Company does enter into any such arrangements with any third parties, the Company will likely have limited control over the amount and timing of resources that its collaborators dedicate to the development or commercialization of its product candidates. The Company's ability to generate revenues from these arrangements will depend on its collaborators; abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving the Company's product candidates would pose the following risks to the Company:

(a) collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;

(b) collaborators may not pursue development and commercialization of the Company's product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial

results, changes in the collaborator's strategic focus or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;

(c) collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

(d) collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with the Company's products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than those of the Company;

(e) a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;

(f) collaborators may not properly maintain or defend the Company's intellectual property rights or may use the Company's proprietary information in such a way as to invite litigation that could jeopardize or invalidate the Company's proprietary information or expose the Company to potential litigation;

(g) disputes may arise between the collaborators and the Company that result in the delay or termination of the research, development or commercialization of the Company's products or product candidates or that result in costly litigation or arbitration that diverts management's attention and resources; and

(h) collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates. For example, the Company could have to build a sales force.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner, or at all. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

The Company relies on third parties to conduct its clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials

The Company must rely on third parties including academic institutions, CROs, clinics, and other third-party collaborators, to monitor, support, conduct and/or oversee preclinical and clinical studies of the Company's current and potentially future product candidates. If Appili is unable to maintain or enter into agreements with these third parties on acceptable terms, or if any such engagement is terminated prematurely, the Company may be unable to enroll patients on a timely basis or otherwise conduct the preclinical and clinical trials in the manner and timeframe originally agreed to. There is no guarantee that these third parties will devote adequate time and resources to the Company's clinical studies or perform as required by the agreed terms in the contract or in accordance with regulatory requirements. If these third parties fail to meet expected deadlines, fail to transfer to the Company's regulatory information in a timely manner, fail to adhere to protocols or fail to act in accordance with regulatory requirements or fail to perform under the agreed contract terms, or if they otherwise perform in a substandard manner or in a way that compromises the quality or accuracy of their activities or the data they obtain, then clinical trials of the Company's product candidates may be extended or delayed with additional costs incurred, or the Company's data may be rejected by the FDA, Health Canada or other regulatory agencies.

The Company and its third party CROs are required to comply with cGCP regulations and guidelines enforced by the FDA, Health Canada, and comparable foreign regulatory authorities for products in clinical development. Regulatory authorities enforce these cGCP regulations through periodic inspections of clinical trial sponsors, principal investigators, and clinical trial sites. Failure to comply with applicable cGCP regulations may result in the clinical data generated in the Company's clinical trials being deemed unreliable and Appili's submission of marketing applications may be delayed or the FDA, EMA or another regulatory authority may require the Company to perform additional clinical trials before approving Appili's marketing applications. In addition, the clinical trials must be conducted with product produced under the cGMP regulations enforced by the FDA, Health Canada, and other

regulatory authorities. Failure to comply with either of these regulations may require the Company to repeat clinical trials, which would delay the regulatory approval process and increase costs. In addition, the Company's reputation may be negatively affected if any of the Company's CROs violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws. If any of the clinical trial sites terminates for any reason, the Company may lose follow-up information on patients enrolled in Appili's ongoing clinical trials unless the Company is successfully able to transfer the care of those patients to another qualified clinical trial site, which is not guaranteed. Further, if the Company must terminate the agreements with any of the Company's CROs, the Company may not be able to enter into arrangements with alternative CROs on commercially reasonable terms, or at all. Finally, if the Company is required to switch or add new CROs or other suppliers, it will significantly impact management's resources, potentially significantly delay the timeline, and can result in substantial costs.

The Company depends on third party suppliers to obtain the Company's raw ingredients, intermediate drug substances and specialized equipment, which are necessary for the production of the Company's products

Appili currently obtains ingredients and API for the manufacturing of the Company's pipeline products from specialized suppliers. For some components, including raw ingredients, the Company has so far identified only one supplier which is qualified for the Company's outsourcing and/or cGMP process. If that supplier were to stop supplying the required ingredient(s), the Company would need to identify an alternative source of such components, if possible, and may need to wait until it is qualified for the Company's outsourcing and/or cGMP process before procuring the components, which may cause substantial delays to one or all of the Company's development programs, as well as a significant increase in costs. If no alternate suppliers were identified, such supply issues could terminate the program.

Risks Related to the Manufacturing of the Company's Product Candidates

If the Company is unable to manufacture its products, the Company could face delayed trial approvals, revenues from marketed sales and be in default to supply a partner obligation

Appili has no experience manufacturing commercial quantities of products and does not currently have the resources to commercially manufacture any products that the Company may develop. Accordingly, if the Company becomes successful in developing any product with commercial potential, the Company would either have to build the facilities to manufacture the product independently or secure a contract manufacturer or enter into another arrangement with third parties to manufacture the products. If Appili is unable to develop such capabilities or enter into any such arrangement on reasonably favourable terms, the Company may be unable to offer the product at a competitive rate, if at all. If the Company is unable to manufacture or contract for a sufficient supply of product on acceptable terms, or if the Company encounters delays or difficulties in its relationships with manufacturers or collaborators, its preclinical, clinical testing and/or product sales could be delayed, thereby delaying the submission of products for regulatory approval and/or market introduction and subsequent sales of such products.

Currently Appili is utilizing the GMP services of a CMO located in India for one of its clinical drug product manufacturing, and indirectly a CMO in the United States for another one of its product candidates and does not have fully qualified and approved backup facilities for either one of these products. The Company may need to approve an alternative CMO to avoid delays in planned clinical programs should there be any issues with the current CMO. Some of the Company's products require a unique manufacturing process that is not easily replicated by a third-party manufacturer.

*If a contract manufacturer of the Company s products or the Active Pharmaceutical Ingredient ("**API**") or excipient supplier to the Company experiences quality assurance/quality control issues or receives an inspection by a regulatory authority and is required to enact remediation which delay supply, it may impact the supply and timing of clinical or commercialized products, the potential for product recall and expose the Company to risk*

The Company currently does not own or operate any manufacturing facilities and does not have any significant in-house manufacturing experience or personnel. As such, the Company relies on third party contract manufacturers to manufacture product candidates and work with multiple third-party suppliers to produce sufficient quantities of

materials, including API and excipients, required for the manufacture of Appili's product candidates for preclinical testing and clinical trials and intends to do so for the commercial manufacture of the Company's products.

Reliance on third party manufacturers entails risks to which Appili would not be subject if the Company manufactured its product candidates, including the following:

- reliance on the third party for regulatory compliance and quality control and assurance;
- the possibility of breach of the manufacturing agreement by the third party because of factors beyond the Company's control (including a failure to synthesize and manufacture the Company's product candidates in accordance with the product specifications); and
- the possibility of termination or nonrenewal of the agreement by the third party at a time that is costly or damaging to us.

In particular, the Company relies upon a contract manufacturer to manufacture the API for some or all of its product candidates. The manufacturers may encounter difficulties in scaling up production, including production yields, quality control and quality assurance. There may only be a limited number of manufacturers can supply API for the Company's product candidates, and failure by the manufacturer to deliver the required quantities of API on a timely basis and/or at commercially reasonable prices, may have a material adverse effect on the Company. In the event that a manufacturer stops supplying the required ingredient(s), including API, the Company may need to identify an alternative source of such components and may need to wait until it is qualified for the Company's GMP process before procuring the components, which may cause substantial delays to one or all of the Company's clinical programs.

In addition, the FDA, Health Canada, EMA, and other regulatory authorities require that Appili's product candidates be manufactured according to cGMP and similar foreign standards. Pharmaceutical manufacturers and their subcontractors are required to register their facilities and/or products manufactured at the time of submission of the marketing application and then annually thereafter with the FDA, EMA, and other regulatory agencies. They are also subject to periodic unannounced inspections by the FDA, EMA, and other regulatory agencies. Any subsequent discovery of problems with a product, or a manufacturing or laboratory facility used by the Company or Appili's collaborators, may result in restrictions on the product or on the manufacturing or laboratory facility, including product recall, suspension of manufacturing, product seizure or a voluntary withdrawal of the drug from the market. Any failure by our third-party manufacturers to comply with cGMP or any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of the Company's product candidates.

Once the Company has products on the market, delays in supply due to manufacturing require a high frequency of public reporting on government drug shortage databases, increasing the workload and risk to the Company

The Company intends to take every precaution with commercial manufacturing to ensure continuity of the market supply through Appili or its commercial partners. Contracting API and excipients from suppliers with proven track records for quality and partnering with manufacturing sites with established audit records by regulatory authorities will both aid in minimizing this risk. Shortage of API and key excipients from approved vendors or delays in manufacturing would require Appili or its commercial partner to meet compliance standards for reporting on government drug shortage databases. In the United States, manufacturers of all covered prescription drugs are required to notify the FDA of a temporary interruption in manufacturing that is likely to lead to a meaningful disruption in the supply of a covered drug in the United States. The notification is required six months in advance, or if that is not possible, as soon as practicable thereafter, but in no case later than five business days after the discontinuance or interruption in manufacturing. The FDA is required to send a noncompliance letter to firms that fail to so notify the FDA. Similar requirements exist in other target markets. This increased workload for reporting would significantly increase resources to ensure compliance limiting ongoing business development activities. The added risk for noncompliance with communications to the regulatory authority poses the risk of the Company being cited publicly for non-compliance with the FDA. This may impact Appili's corporate reputation with the FDA, delay review of other submissions and expose Appili to contract penalties with its commercial partner.

If the Company has to make changes in methods formulation or manufacturing of the product candidates, it may result in additional costs or delay

As product candidates are developed through pre-clinical to late-stage clinical trials towards approval and commercialization, various aspects of the development program, such as manufacturing methods and formulation, may be altered in an effort to optimize processes, product stability and results. There is no certainty that these changes will achieve the intended objectives. Any of these changes could cause a significant delay in product candidates' development timeline and/or cause the product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and/or jeopardize our or our collaborators' ability to commence product sales and generate revenue.

Risks Related to the Company's Intellectual Property, Personally Identifiable Information ("PII") and Sensitive Personally Identifiable Information ("sPII")

If the Company fails to comply with its obligations under its intellectual property licenses with third parties, the Company could lose license rights that are important to its business

The Company is party to an intellectual property license agreement with the NRC and expects to enter into additional license agreements in the future. Appili's existing license agreement imposes, and future license agreements, will most likely impose various milestone payments, royalties, insurance, indemnification, and other obligations on the Company.

The Company's current agreement with the NRC requires the Company to maintain its patents and pay annual license fees and research fees. If Appili fails to comply with its obligations under this license, the NRC may have the right to terminate this license agreement. In such an event, the Company might not be able to market any product that is covered by such license, or to convert such license to a non-exclusive license. This could materially adversely affect the value of the product candidate being developed under the NRC license agreement.

Termination of any license agreement or reduction or elimination of the Company's licensed rights may result in Appili having to negotiate new or reinstated licenses with less favourable terms.

If the Company is unable to obtain and maintain patent protection for its technology and products, or if the Company s licensors are unable to obtain and maintain patent protection for the technology or products that it licenses from them, or if the scope of the patent protection obtained is not sufficiently broad, the Company's competitors could develop and commercialize technology and products similar or identical to that of the Company's, and its ability to successfully commercialize its technology and products may be adversely affected

Appili's success will depend on its ability to obtain and maintain patent and other intellectual property protection with respect to its product candidates. The Company and its licensors have sought to protect the Company's proprietary position by filing patent applications in the United States and abroad related to its novel technologies and products that are important to its business. This process is expensive and time-consuming, and the Company may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, patents might not be issued or granted with respect to Appili's patent applications that are currently pending and issued or granted patents might later be found to be invalid or unenforceable, be interpreted in a manner that does not adequately protect the Company's current product or any future products or fail to otherwise provide us with any competitive advantage. The patent position of biotechnology and pharmaceutical companies is generally uncertain because it involves complex legal and factual considerations and in recent years has been the subject of much litigation. The standards applied by the U.S. Patent and Trademark Office and foreign patent offices in granting patents are not always applied uniformly or predictably. As a result, the issuance, scope, validity, enforceability and commercial value of the Company's and its licensors' patent rights are highly uncertain. The degree of future protection that Appili will have on its proprietary products and technology, if any, is uncertain and a failure to obtain adequate intellectual property protection with respect to the Company's product candidates and proprietary technology could have a material adverse impact on the success of its business.

Even if Appili's owned and licensed patent applications issue as patents, they may not issue in a form that will provide the Company with any meaningful protection, prevent competitors from competing with the Company or otherwise provide the Company with any competitive advantage. Appili's competitors may be able to circumvent its owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and the Company's owned and licensed patents may be challenged in the courts or patent offices in Canada, the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated, or held unenforceable, which could limit Appili's ability to stop or prevent the Company from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of its technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, the Company's owned and licensed patent portfolio may not provide it with sufficient rights to exclude others from commercializing products similar or identical to Appili's.

The Company may become involved in lawsuits to protect or enforce its patents, which could be expensive, time consuming and whether successful or unsuccessful, limit the commercial value of the Company's product or have a material adverse effect on the Company's business

Competitors may infringe any of Appili's current or future patents. To counter infringement or unauthorized use, the Company may be required to file expensive and time-consuming infringement claims. Also, the court may decide in an infringement proceeding that a specific patent held by the Company is not valid or enforceable or may refuse to stop the other party from using the Company's intellectual technology at issue on the grounds that its patents do not cover the intellectual property being disputed. An adverse result in any litigation proceeding could put one or more of the Company's patents at risk of being invalidated or interpreted narrowly. Additionally, due to the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of Appili's confidential information could be compromised by disclosure during this type of litigation. In addition, the Company's licensor may have rights to file and prosecute such claims and it is reliant on them.

The Company's commercial successes depends upon its ability and the ability of its partners and other collaborators to develop, manufacture, market and sell its product candidates and use its proprietary technologies without infringing the proprietary rights of third parties. Third parties may assert infringement claims against the Company based on existing patents or patents that may be granted in the future. The Company may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to its products and technology, including interference proceedings before the U.S. Patent and Trademark Office or other similar regulatory authorities. If the third party is successful and the Company is found to infringe on their intellectual property rights, the Company could be forced to negotiate the rights to the third party's intellectual property in order to continue to develop and market the Company's products and technology. There is no guarantee that the Company will be able to obtain any required license on commercially reasonable terms or at all. Even if the Company was able to obtain a license, it could be non-exclusive, thereby giving its competitors access to the same technologies licensed to the Company. If the Company is not able to obtain a license for the rights to their technology, the Company could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, the Company could be found liable for additional monetary damages. A finding of infringement could prevent the Company from commercializing its product candidates or force the Company to cease some of its business operations, which could materially harm the Company's business. Claims that the Company has misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on its business.

Litigation or other legal proceedings relating to intellectual property claims may cause the Company to incur significant expenses and could distract the Company's employees from their normal responsibilities, even if it is resolved in the Company's favor. Also, any public announcements of the results of hearings, motions or other interim proceedings or developments could be perceived to be negative by securities analysts or investors, leading to a potential adverse effect on the price of the Common Shares. These types of litigation or proceedings could substantially increase the Company's operating losses and reduce the resources available for product development activities. The Company may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of the Company's competitors may be able to sustain the costs of such litigation or proceedings more effectively than it can because of their greater financial resources. Uncertainties resulting from the initiation

and continuation of patent litigation or other proceedings could have a material adverse effect on the Company's ability to compete in the marketplace.

The Company may be subject to claims that its employees have wrongfully used or disclosed alleged trade secrets of their former employers

The Company makes efforts to ensure that its employees do not use the proprietary information or know-how of others in their work for the Company, however the Company may be subject to claims that it or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. This would most likely result in the Company having to enter litigation to defend against these claims. If the Company fails in defending any such claims, in addition to paying monetary damages, it may lose valuable intellectual property rights and/or personnel. Even if the Company is successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

If the Company is unable to protect the confidentiality of its trade secrets, the Company's business, competitive position, and reputation as a preferred business/licensing partner would be harmed

The Company relies on trade secrets, including unpatented know-how, technology, and other proprietary information, to maintain its competitive position, in addition to filing patents for some of its technology and products. Appili seeks to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as the Company's employees, corporate collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisors and other third parties. The Company also enters into confidentiality and invention or patent assignment agreements with its employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose the Company's proprietary information, including its trade secrets, and the Company may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, courts in certain jurisdictions are less willing or unwilling to protect trade secrets. If any of the Company's trade secrets were to be lawfully obtained or independently developed by a competitor, it would have no right to prevent them from using that technology or information to compete with the Company. If any of the Company's trade secrets were to be disclosed to or independently developed by a competitor, its competitive position would be harmed.

The Company must protect and manage confidential PII and sPII data, including reporting from marketed product adverse event reporting and clinical trials. Accidental release of information could harm the Company

As the Company's programs advance in development, the Company expects to generate or otherwise obtain clinical data that may include PII and sPII. These data are required for successful development and commercialization of pharmaceutical products, such as clinical trial data to support regulatory submissions and pharmacovigilance data to monitor for potential adverse events following product launch. The Company recognizes the sensitivity of this data and will apply protections to minimize the risk of PII or sPII release, including strict data blinding protocols and secure information technology infrastructure. However, despite these measures, it is possible that PII or sPII could be released and may expose the Company to substantial reputational risk and legal liabilities. Regardless of merit or eventual outcome, liability claims may result in decreased demand for any product candidates or products that it may develop, injury to Appili's reputation and significant negative media attention, withdrawal of clinical trial participants, significant costs to defend the related litigation, substantial monetary awards to trial participants or patients, loss of revenue and the inability to commercialize any products that the Company may develop.

Risks Related to Regulatory Approval of the Company's Product Candidates and Other Legal Compliance Matters

If the Company, one of its contractors, or license partners are not able to comply with regulations and guidelines governing pharmaceutical product development (including, but not limited to GMP, Good Clinical Practices, GLP, quality assurance/quality control, and guidelines set forth by the International Conference for Harmonization), it could impact the overall development and/or commercialization activities, the timing of development or result in a supply disruption of commercial product that would negatively impact the business

The development and manufacturing of pharmaceutical products is strictly governed by a series of standardized regulations and guidelines to ensure data and product quality including, but not limited to GMP, GLP, and additional guidelines set forth by the International Conference for Harmonization. These guidelines are mandatory standards for most regulatory agencies and designed to ensure the highest quality of research and manufacturing for pharmaceutical products. The Appili team has experience in the development and commercialization of pharmaceutical products under these regulations. The Company has put in place infrastructure to ensure compliance with relevant guidelines, including standard operation procedures and third-party audits. Despite these precautions, it is possible that activities conducted internally or by a third party may be non-compliant with industry standard regulations, with significant negative impact on the Company.

During product development, non-compliance with standard guidelines and regulations may invalidate drug product and/or data such that they are not appropriate to support regulatory filings. The Company may be required to repeat development activities as a result, incurring additional development risk and costs. Repeating specific development activities could also delay overall development and commercialization timelines, negatively impacting a product's revenue potential. Adverse effects on timing and costs could lead to discontinuation of product development. In the event that non-compliance with standard guidelines adversely impacts clinical trial activities and trial participants, the Company could also be exposed to substantial reputational risk and legal liabilities. Regardless of merit or eventual outcome, liability claims may result in decreased demand for any product candidates or products that it may develop, injury to the Appili's reputation and significant negative media attention, significant costs to defend the related litigation, substantial monetary awards to trial participants, loss of revenue and the inability to commercialize any products that the Company may develop.

For commercial products, non-compliance with standard guidelines and regulations may prevent the Company from releasing product to the market or require the Company to withdraw product from the market. In either case, the Company would incur manufacturing costs for product without the potential to generate revenues. In addition, delays in delivery of product to the market could adversely impact long-term product utilization and drive substitution to competitor products. In the case where product released to the market is retroactively found to be non-compliant with existing guidelines, the Company could also incur significant costs related to the returns, refunds, and destructions of non-compliant product. Additionally, the Company could be exposed to substantial reputational risk and legal liabilities with potential negative consequences outlined above.

In any situation of guideline non-compliance, the Company will be required to undertake a comprehensive investigation and engage in activities to remedy and prevent future deviations. These activities could impose significant costs on the Company and draw resources away from other Company objectives.

If the Company or one of the license partners contravenes regulated pricing or reimbursement and/or promotion guidelines, the legal costs, penalties, and corporate/reputational risk would impact the Company's business

The Company intends to seek out partnership opportunities with third parties to maximize product penetration and revenues in global markets. Any prospective partner under consideration by the Company will be subjected to thorough due diligence including assessment of commercialization capabilities and track record in the pharmaceutical industry. The Company intends to seek out partners with a history of successful product launches and compliance with regional reimbursement and promotional guidelines. The Company will also include in any licensing agreements provisions that provide Appili mechanisms to influence partner behaviour up to and including claw back provisions. However, a partner may deliberately or accidentally engage in activities that contravene regional pricing and promotion regulations. Partner behaviour may adversely impact revenues for licensed regions and also may expose

the Company to reputational risk and legal liabilities within the licensed region and globally. Although the Company would seek reparations and if necessary, sever partnerships with licensees, the Company may not be able to obtain adequate remedies for such breaches. Litigation or other legal proceedings relating to licensing partners may cause the Company to incur significant expenses and could distract the Company's employees from their normal responsibilities, even if it is resolved in the Company's favor. Also, any public announcements of the results of hearings, motions or other interim proceedings or developments could be perceived to be negative by securities analysts or investors, leading to a potential adverse effect on the price of the Common Shares. These types of litigation or proceedings could substantially increase the Company's operating losses and reduce the resources available for product development activities. The Company may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of the third parties may be able to sustain the costs of such litigation or proceedings more effectively than it can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of litigation or other proceedings could have a material adverse effect on the Company's ability to compete in the marketplace. Finally, even if successful, disruption of commercialization of the Company's products in the licensed region will adversely impact revenues and future adoption of the product in the region.

The Company anticipates increased limitations on reimbursement, rebates, and other payments within the healthcare industry due to healthcare reform, potentially impacting third-party coverage and the circumstances under which healthcare providers will prescribe or administer the Company's products, if approved.

The Company anticipate that ongoing healthcare reforms, particularly the Inflation Reduction Act ("IRA"), may negatively impact Appili's product sales and pricing strategies. The IRA allows the U.S. Department of Health and Human Services ("HHS") to negotiate prices for certain high-expenditure drugs covered under Medicare Part B and Part D, with negotiated prices starting in 2026. Additionally, the IRA imposes penalties on manufacturers that increase Medicare drug prices above the inflation rate. These provisions could reduce reimbursement rates and exert additional pricing pressures, adversely affecting our revenue generation and market positioning. Although the full impact of these legislative changes is uncertain, they could materially affect how healthcare providers prescribe and administer the Company's products, if approved.

If the Company is not able to obtain, or if there are delays in obtaining, required regulatory approvals, the Company may not be able to fully realize the expected value of product candidates, and long-term profitability of the asset may be materially impaired

The Company's product candidates, including ATI-1701, ATI-1801, and ATI-1501, and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, record keeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA, Health Canada and by comparable authorities in other countries. Failure to obtain regulatory approval for a product candidate will prevent Appili and its partners from commercializing the product candidate. The Company has not received regulatory approval to market any of its product candidates in any jurisdiction. The Company has only limited experience in filing and supporting the applications necessary to gain regulatory approvals and expects to rely on third party contract research organizations to assist it in this process. Securing FDA or Health Canada approval requires the submission of extensive preclinical and clinical data and supporting information to the FDA or Health Canada for each therapeutic indication to establish the product candidate's safety and efficacy. Securing FDA or Health Canada approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the FDA or Health Canada. Appili's product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude the Company from obtaining regulatory approval or prevent or limit commercial use.

The process of obtaining regulatory approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in regulatory approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA or Health Canada has substantial discretion in the approval process and may refuse to accept any application or may decide that the Company;s data is insufficient for approval and require additional preclinical, clinical, or other studies.

In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent regulatory approval of a product candidate. Any regulatory approval the Company ultimately obtains may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If the Company experiences delays in obtaining approval or if it fails to obtain approval of its product candidates, the commercial prospects for the Company's product candidates may be harmed and its ability to generate revenues will be materially impaired.

Failure to obtain regulatory approval in international jurisdictions would prevent the Company;s product candidates from being marketed abroad. Risk of a rejection, incomplete response, or poor approved label by a regulatory authority outside of the United States may adversely impact the United States market opportunity and limit the value of the asset to the Company

The Company intends to enter into agreements with third parties for the marketing of its products outside Canada and the United States. In order to market and sell the Company's products in the European Union and many other jurisdictions, Appili or its third parties must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA or Health Canada approval. The regulatory approval process outside the United States generally includes all the risks associated with obtaining FDA or Health Canada approval. In addition, in many countries outside the United States or Canada, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. The Company may not obtain approvals from regulatory authorities outside the United States or Canada on a timely basis, if at all. Approval by the FDA or Health Canada does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States or Canada does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. The Company may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize its products in any market.

Any product candidate for which the Company obtains marketing approval could be subject to restrictions or withdrawal from the market and the Company may be subject to penalties if it fails to comply with regulatory requirements or if it experiences unanticipated problems with its products, if any of them are approved

Any product candidate for which Appili acquires marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising, and promotional activities for such product, will be subject to continual requirements of, and review by, the FDA and other regulatory authorities. These requirements include, among others, submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and record keeping. Even if regulatory approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved label. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if the Company does not market its products for their approved indications, Appili may be subject to enforcement action for off-label marketing.

In addition, later discovery of previously unknown problems with the Company's products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including the restrictions on such products, manufacturers or manufacturing processes; the restrictions on the marketing of a product; the restrictions on product distribution; requirements to conduct post-marketing clinical trials; withdrawal of the products from the market; refusal to approve pending applications or supplements to approved applications that it submits; recall of products; fines, restitution or disgorgement of profits or revenue; suspension or withdrawal of regulatory approvals; refusal to permit the import or export of Appili's products; product seizure; or injunctions or the imposition of civil or criminal penalties.

The Company's direct and indirect relationships with healthcare customers, government, Payers, and reimbursement/contract decision makers, will be subject to applicable anti-bribery anti-corruption and other healthcare laws and regulations, which could expose the Company to criminal sanctions, civil penalties, program exclusion, debarment, contractual damages, reputational harm and diminished profits and future earnings

Healthcare providers, physicians and third-party Payers play a primary role in the recommendation and prescription of any product candidates for which the Company obtains marketing approval. Appili's future arrangements with third party Payers and customers may expose the Company to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which it markets, sells, and distributes its products for which it obtains marketing approval. Restrictions under applicable United States federal and state healthcare laws and regulations that may impact the Company's activities, include the following:

- the federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs;
- civil penalties could be imposed against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- criminal and civil liability could be imposed for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- manufacturers of drugs, devices, biologics, and medical supplies are generally required to report information related to physician payments and other transfers of value and physician ownership and investment interests; and
- analogous laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party Payers, including private insurers, and some laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures.

Costs will be substantial to ensure that the Company's business arrangements with third parties will comply with applicable healthcare laws and regulations in each jurisdiction when the Company products will eventually be offered. It is possible that governmental authorities will conclude that the Company's business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If the Company's operations are found to be in violation of any of these laws or any other governmental regulations that may apply to it, it may be subject to significant civil, criminal, and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid in the United States, and the curtailment or restructuring of the Company's operations. If any of the physicians or other providers or entities with whom the Company's expects to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Market access, legislative and pricing policy changes may increase the difficulty and cost for the Company to obtain optimal marketing approval to commercialize its product candidates and affect the prices it may obtain

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of the Company's product candidates, restrict or regulate post-approval activities and affect its ability to profitably sell any product candidates for which it obtains marketing approval.

In the United States, the *Medicare Prescription Drug, Improvement, and Modernization Act of 2003* ("**Medicare Modernization Act**") changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician administered drugs. In addition, this legislation provided authority for

limiting the number of drugs that will be covered in any therapeutic class in certain cases. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and reimbursement that is provided for any approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private Payers often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private Payers.

In March 2010, President Obama signed into law the *Health Care Reform Law, a* law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Effective October 1, 2010, the Health Care Reform Law revised the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the new law imposes a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may affect the Company's business practices with health care practitioners. The Company will not know the full effects of the Health Care Reform Law until applicable federal and state agencies issue regulations or guidance under the law. Although it is too early to determine the effect of the Health Care Reform Law, this law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase the Company's regulatory burdens and operating costs.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Health Care Reform Law. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the Health Care Reform Law. The Company expects that the current Presidential Administration and U.S. Congress will likely continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the Health Care Reform Law. The Company cannot be sure whether legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of the Company's product candidates, if any, may be.

With the enactment of the *Biologics Price Competition and Innovation Act of 2009* ("**BPCIA**"), as part of the Health Care Reform Law, an abbreviated pathway for the approval of biosimilar and interchangeable biological products was created. The new abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a bio similar as "interchangeable" based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product cannot be submitted to the FDA until four years, or approved by the FDA until 12 years, after the original brand product identified as the reference product was approved under a BLA. The BPCIA is complex and is only beginning to be interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning is subject to uncertainty. While it is uncertain when any such processes may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for the Company's biological products.

Appili believes that if any of its product candidates were to be approved as biological products under a BLA, such approved products should qualify for the four-year and 12-year periods of exclusivity. However, there is a risk that the United States Congress could amend the BPCIA to significantly shorten these exclusivity periods, or that the FDA will not consider the Company's product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the Company's reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

Inability of the Company to secure and advance the portfolio through development and regulatory hurdles to successful commercialization, may impact ability to partner the Company's portfolio

The Company will rely on third party partnerships to maximize the commercial potential of its product candidates in global markets. Success in securing commercial partners depends on multiple factors including the Company's reputation and its ability to advance a product through regulatory approval to market in a timely manner. Portfolio optimization and product launch strategies require years of advance notice and planning. Uncertainty around product

development timelines, regulatory approval, and product availability may reduce the attractiveness of the Company's product candidates to partners and impact the Company's ability to secure accretive third-party partnerships.

If the Company experiences delays in obtaining third party partnerships for its product candidates, the commercial prospects for the Company's product candidates will be impacted.

Risks Related to Employee Matters and Managing Growth

The Company is highly dependent upon certain key executives and other key personnel and their loss could adversely affect its ability to achieve its business objective

The Company is highly dependent on its executive officers. Although Appili has formal employment agreements with each of its executive officers, these agreements do not prevent them from terminating their employment with the Company at any time. The loss of the services of any of these persons could potentially harm the Company's research, development and commercialization objectives and financial condition.

Appili's success is also dependent on the Company's ability to recruit, retain and motivate qualified scientific, clinical, manufacturing and commercialization personnel. The Company may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel, as well as the location of the head office in Halifax, NS. The Company also experiences competition for the hiring of scientific and clinical personnel from universities and research institutions. The Company also depends on scientific and clinical collaborators and advisors, all of whom have outside commitments that may limit their availability.

The Company may to expand its development, regulatory, manufacturing, and commercial market capabilities, and if so , the Company may encounter difficulties in managing its growth, which could disrupt the Company's operations

As the Company executes on its business strategy and acquires additional product candidates, the Company may experience significant growth in the number of its employees and the scope of its operations, particularly in the areas of drug development, regulatory affairs, manufacturing and sales and marketing. If so, the Company would need to identify, hire, and integrate personnel who have not worked together previously.

This growth may also result in significant additional responsibilities on management, who may need to spend a disproportionate amount of its attention away from the business operations and spend a substantial amount of time to managing these growth activities. Managing this growth would also require the Company to continue to implement and improve its managerial, operational, and financial systems, expand its facilities and continue to recruit and train additional qualified personnel. Due to its limited financial resources, the Company may not be able to effectively manage the expansion of its operations or recruit and train additional qualified personnel. If the Company is unable to effectively manage this growth, the expenses may increase greater than anticipated and the Company may not be able to effectively implement its business strategy.

The Company's ability to secure new assets and progress pipeline products to commercialization will be key to attracting new talent for growth

Appili has been successful attracting, retaining, and motivating qualified management, clinical and scientific personnel. However, if the Company does not secure new assets and progress its product candidates through its pipeline, the Company could experience difficulties attracting and retaining qualified employees as competition for qualified personnel in the biotechnology and pharmaceutical field is intense. As well, the Company will likely need to hire additional personnel as Appili expands its clinical development activities and develops commercial capabilities, including a potential sales infrastructure to support commercialization efforts if the Company so chooses to market its products independently. Appili may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for individuals with similar skill sets. The inability to recruit or loss of the services of any executive or key employee may impede the progress of the Company's research, development, and commercialization objectives.

LEGAL PROCEEDINGS AND REGULATORY ACTIONS

We are not aware of any legal proceedings involving the Company or to which any of its property is subject during the Appili's most recently completed financial year, nor are any such proceedings known by us to be contemplated.

During the financial year ended March 31, 2024, there were no: (a) penalties or sanctions imposed against the Company by a court relating to securities legislation or by a securities regulatory authority; (b) other penalties or sanctions imposed by a court or regulatory body against the Company that would likely be considered important to a reasonable investor in making an investment decision; or (c) settlement agreements the Company entered into before a court relating to securities legislation or with a securities regulatory authority.

INTEREST OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS

Other than as described elsewhere in this AIF, none of (i) the directors or executive officers of the Company, (ii) a person or company that beneficially owns, or controls or directs, directly or indirectly, more than 10% of any class or series of outstanding voting securities of the Company, or (iii) any associate or affiliate of the persons or companies referred to in (i) and (ii), has or has had any material interest, direct or indirect, in any transaction within the three most recently completed financial years of the Company or during the current financial year that has materially affected or is reasonably expected to materially affect the Company.

TRANSFER AGENT AND REGISTRAR

The registrar and transfer agent for the Common Shares is Computershare Investor Services Inc. at its offices located at 1500 Robert-Bourassa Boulevard, 7th Floor, Montreal, Quebec.

MATERIAL CONTRACTS

Except for contracts entered into in the ordinary course of business, the only contracts entered into by Appili since the beginning of the last financial year, or before the beginning of the last financial year that are still in effect, which may be regarded as material, are as follows:

1. The license agreement with Saptalis dated November 27, 2019, for the exclusive license of Appili's intellectual property for ATI-1501 in the United States and its territories, as amended on February 4, 2023.

2. License Agreement with the NRC for the worldwide rights to NRC's intellectual property related to the ClpB and CapB Mutants of *F. tularensis.*

3. License Agreement with USAMMDA for the worldwide rights to topical antiparasitic product ATI-1801.

4. The warrant indenture dated October 14, 2021, between the Company and Computershare Trust Company of Canada with respect to the warrant issued in connection with the October 2021 Offering.

5. The warrant indenture dated May 26, 2022, between the Company and Computershare Trust Company of Canada with respect to the warrants issued in connection with the May 2022 Offering.

6. The Amended LZH Loan Agreement.

7. Amended and Reinstated LZH distribution and license agreement dated March 17, 2023

8. USAFA Cooperative Agreement dated May 4, 2023

9. Definitive Arrangement Agreement dated April 1, 2024 between the Company and Aditxt Inc.

All of the material contracts of the Company are available on the SEDAR+ website at www.sedar.ca.

INTERESTS OF EXPERTS

The Company's auditors PricewaterhouseCoopers LLP, who have prepared the Auditor's Report to Shareholders dated June 25, 2024. PricewaterhouseCoopers LLP has confirmed that it is independent from the Company in accordance with the Chartered Professional Accountants of Nova Scotia Code of Professional Conduct in Nova Scotia, Canada.

ADDITIONAL INFORMATION

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 plans, where applicable, is contained in the Company's information circular dated August 22, 2023, and will also be included in the Company's information circular for its next annual meeting of securityholders that involves the election of directors. Additional financial information relating to the Company is contained in the Company's comparative financial statements and associated management's discussion and analysis for its most recently completed fiscal year ended March 31, 2024.

All of these documents as well as additional information relating to the Company are (or will be) available on SEDAR+ at www.sedarplus.ca.

GLOSSARY OF TERMS

As used in this AIF, the following terms have the respective meaning as specified below:

"**AIF**" has the meaning given to such term under the heading entitled *"Forward-Looking and Other Statements"*.

"**AiPharma**" has the meaning given to such term under the heading entitled "*Business of the Company – Three-Year History – Fiscal 2022 (April 2021 to March 2022*)".

"**Amended LZH Loan Agreement**" has the meaning given to such term under the heading entitled "*Business of the Company – Three-Year History – Fiscal 2023 (April 2022 to March 2023*)".

"**Animal Rule**" has the meaning given to such term under the heading entitled *"Business of the Company - Our Development Programs - ATI-1701"*.

"**API**" has the meaning given to such term under the heading entitled *"Risk Factors - Risks Related to the Manufacturing of the Company's Product Candidates"*.

"**Aradigm**" has the meaning given to such term under the heading entitled *"Executive Officers and Directors Biographies"*.

"**Articles**" has the meaning given to such term under the heading entitled *"The Corporate Structure - Name, Address and Incorporation"*.

"**Audit Committee**" has the meaning given to such term under the heading entitled *"Audit Committee – Composition of the Audit Committee"*.

"**BARDA**" has the meaning given to such term under the heading entitled "Business of the Company-Market Opportunity- ATI-1701".

"**Bavarian Nordic**" has the meaning given to such term under the heading entitled *"Business of the Company - Market Opportunity - ATI-1701"*.

"**BBDC**" has the meaning given to such term under the heading "*Business of the Company – Overview of the Company – Our Business Strategy*".

"**BBSI**" has the meaning given to such term under the heading "*Executive Officers and Directors – Conflicts of Interest*".

"**BLA**" has the meaning given to such term under the heading entitled *"Business of the Company - Regulatory Environment - United States Government Regulation"*.

"**Bloom Burton & Co.**" means Bloom Burton & Co. Inc., a company existing under the laws of the Province of Ontario.

"**Board**" has the meaning given to such term under the heading entitled *"The Corporate Structure – Name, Address and Incorporation"*.

"**BPCIA**" has the meaning given to such term under the heading entitled *"Risk Factors - Risks Related to Regulatory Approval of the Company's Product Candidates and Other Legal Compliance Matters"*.

"**CBCA**" has the meaning given to such term under the heading entitled *"The Corporate Structure - Name Address and Incorporation"*.

"**CDC**" has the meaning given to such term under the heading entitled *"Business of the Company - Overview of the Company - ATI-1701"*.

"**CDO**" means Chief Development Officer.

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

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

"**cGMP**" has the meaning given to such term under the heading entitled *"Business of the Company - Regulatory Environment - United States Government Regulation"*.

"**CMO**" means Chief Medical Officer.

"**Collaboration Agreement**" has the meaning given to such term under the heading entitled "*Business of the Company – Three-Year History – Fiscal 2021 (April 2020 to March 2021)*".

"**Common Shares**" has the meaning given to such term under the heading "*Forward-Looking and Other Statements*".

"**Company**" has the meaning given to such term under the heading "*Meaning of Certain References*".

"**Complete Response Letter**" has the meaning given to such term under the heading entitled *"Business of the Company - Regulatory Environment – Meaning of Certain References"*.

"**COO**" means Chief Operating Officer.

"**COVID-19**" has the meaning given to such term under the heading entitled *"Forward-Looking and Other Statements"*.

"**CRO**" has the meaning given to such term under the heading entitled *"Business of the Company – Management and Employees "*.

"**CTA**" has the meaning given to such term under the heading entitled *"Business of the Company - Regulatory Environment - Canada Drug Products and Biologics Regulation"*.

"**DCMA**" has the meaning given to such term under the heading entitled "*Risk Factors – Regulatory Matters*".

"**DRL**" has the meaning given to such term under the heading entitled "*Business of the Company – Three-Year History – Fiscal 2021 (April 2020 to March 2021)*".

"**DTRA**" has the meaning given to such term under the heading entitled "*Business of the Company – Our Development Programs – ATI-1701*".

"**DVC**" has the meaning given to such term under the heading entitled *"Business of the Company - Competitive Conditions - ATI-1701"*.

"**DVC-LVS**" has the meaning given to such term under the heading entitled *"Business of the Company - Competitive Conditions - ATI-1701"*.

"**EMA**" has the meaning given to such term under the heading entitled *"Business of the Company"*.

"**Emergent Biosolutions**" has the meaning given to such term under the heading entitled *"Business of the Company - Market Opportunity - ATI-1701"*.

"***F. tularensis***" has the meaning given to such term under the heading entitled *"Business of the Company - Overview of the Company - ATI-1701"*.

"**FAR**" has the meaning given to such term under the heading entitled "*Risk Factors – Regulatory Matters"*.

*"**FDA**" has the meaning given to such term under the heading entitled "Business of the Company – Overview of the Company".*

"**FDCA**" has the meaning given to such term under the heading entitled *"Business of the Company - Our Development Programs - ATI-1501"*.

"**FFTC**" has the meaning given to such term under the heading entitled "*Business of the Company-Three Year History-Fiscal 2022 (April 2021 to March 2022)*".

"**First Tranche Loan**" has the meaning given to such term under the heading entitled "*Business of the Company – Three-Year History – Fiscal 2023 (April 2022 to March 2023)*".

"**forward-looking statements**" has the meaning given to such term under the heading entitled *"Forward-Looking and Other Statements"*.

"**GCP**" has the meaning given to such term under the heading entitled *"Business of the Company - Regulatory Environment - United States Government Regulation"*.

"**GLP**" means good laboratory practices.

"**GMP**" has the meaning given to such term under the heading entitled *"Business of the Company – Competitive Conditions – ATI-1701"*.

"**GRA**" has the meaning given to such term under the heading entitled "*Business of the Company – Three-Year History – Fiscal 2021 (April 2020 to March 2021)*".

"**IND**" has the meaning given to such term under the heading entitled *"Business of the Company - Our Development Programs - ATI-1801"*.

"**Interim Order**" has the meaning given to such term under the heading entitled "*Business of the Company – Three-Year History – Fiscal 2021 (April 2020 to March 2021)*".

"**IRB**" has the meaning given to such term under the heading entitled *"Business of the Company - Regulatory Environment - United States Government Regulation"*.

"**June 2020 Broker Warrants**" has the meaning given to such term under the heading entitled *"Business of the Company - Three-Year History - Fiscal 2021 (April 2020 to March 2021)".*

"**June 2020 Offering**" has the meaning given to such term under the heading entitled *"Business of the Company - Three-Year History - Fiscal 2021 (April 2020 to March 2021)".*

"**June 2020 Units**" has the meaning given to such term under the heading entitled *"Business of the Company - Three-Year History - Fiscal 2021 (April 2020 to March 2021)".*

"**June 2020 Warrant**" has the meaning given to such term under the heading entitled *"Business of the Company - Three-Year History - Fiscal 2021 (April 2020 to March 2021)".*

"**Lind**" has the meaning given to such term under the heading entitled "*Business of the Company – Three-Year History – Fiscal 2022 (April 2021 to March 2022)*".

"**Lind Funding Agreement**" has the meaning given to such term under the heading entitled "*Business of the Company -– Three-Year History -– Fiscal 2022 (April 2021 to March 2022*)".

"**LZH**" has the meaning given to such term under the heading entitled "*Forward-Looking and Other Statements*".

"**LZH Loan**" has the meaning given to such term under the heading entitled "*Business of the Company – Three-Year History -– Fiscal 2023 (April 2022 to March 2023)".*

"**March 2023 Warrants**" has the meaning given to such term under the heading entitled "*Business of the Company – Three-Year History – Fiscal 2023 (April 2022 to March 2023*)".

"**May 2022 Broker Warrants**" has the meaning given to such term under the heading entitled "*Business of the Company – Three-Year History – Fiscal 2023 (April 2022 to March 2023*)".

"**May 2022 Offering**" has the meaning given to such term under the heading entitled "*Business of the Company – Three-Year History – Fiscal 2023 (April 2022 to March 2023*)".

"**Medicare Modernization Act**" has the meaning given to such term under the heading entitled *"Risk Factors - Risks Related to Regulatory Approval of the Company's Product Candidates and Other Legal Compliance Matters"*.

"**NDA**" has the meaning given to such term under the heading entitled "*Business of the Company – Overview of the Company – ATI-1801".*

"**NDS**" has the meaning given to such term under the heading entitled *"Business of the Company - Regulatory Environment - Canada Drug Products and Biologics Regulation"*.

"**NGO**" has the meaning given to such term under the heading entitled "*Business of the Company – Our Development Programs – ATI-1801*".

"**NI 52-110**" has the meaning given to such term under the heading entitled *"Audit Committee – Composition of the Audit Committee"*.

"**NIH**" has the meaning given to such term under the heading entitled *"Business of the Company - Our Development Programs - ATI-1701".*

"**NOC**" has the meaning given to such term under the heading entitled *"Business of the Company - Regulatory Environment - Canada Drug Products and Biologics Regulation"*.

"**NOC/c**" has the meaning given to such term under the heading entitled *"Business of the Company - Regulatory Environment - Submission of an NDS to Health Canada"*.

"**NOD**" has the meaning given to such term under the heading entitled *"Business of the Company – Regulatory Environment – Canada Drug Products and Biologics Regulation"*.

"**NOI Filing**" has the meaning given to such term under the heading entitled "*Executive Officers and Directors – Corporate Cease Trade Orders, Bankruptcies, Penalties and Sanctions*".

"**NOL**" has the meaning given to such term under the heading entitled *"Business of the Company – Three Year History – Fiscal 2021 (April 2020 to March 2021)"*.

"**NON**" has the meaning given to such term under the heading entitled *"Business of the Company - Regulatory Environment - Canada Drug Products and Biologics Regulation"*.

"**Non-Voting Shares**" has the meaning given to such term under the heading entitled *"The Corporate Structure-Name Address and Incorporation"*.

"**NRC**" has the meaning given to such term under the heading entitled *"Business of the Company - Our Development Programs - ATI-1701"*.

"**October 2021 Broker Warrants**" has the meaning given to such term under the heading entitled *"Business of the Company - Three-Year History – Fiscal 2022 (April 2021 to March 2022)*".

"**October 2021 Offering**" has the meaning given to such term under the heading entitled *"Business of the Company - Three-Year History – Fiscal 2022 (April 2021 to March 2022)*".

"**October 2021 Units**" has the meaning given to such term under the heading entitled *"Business of the Company - Three-Year History – Fiscal 2022 (April 2021 to March 2022)*".

"**October 2021 Warrant**" has the meaning given to such term under the heading entitled *"Business of the Company - Three-Year History – Fiscal 2022 (April 2021 to March 2022)*".

"**ODD**" has the meaning given to such term under the heading entitled *"Business of the Company – Our Development Programs - ATI-1801"*.

"**OFCCP**" has the meaning given to such term under the heading entitled "*Risk Factors – Regulatory Matters*".

"**Ology**" has the meaning given to such term under the heading entitled *"Business of the Company - Three-Year History – Fiscal 2021 (April 2020 to March 2021)*".

"**Original LZH Loan Agreement**" has the meaning given to such term under the heading entitled "*Business of the Company – Three-Year History – Fiscal 2023 (April 2022 to March 2023)*".

"**Payers**" has the meaning given to such term under the heading entitled *"Risk Factors – Risks Related to the Company and our Business"*.

"**PCT**" has the meaning given to such term under the heading entitled *"Business of the Company – Intellectual Property Rights – ATI-1501"*.

"**PDUFA**" has the meaning given to such term under the heading entitled "*Business of the Company – Three-Year History – Fiscal 2023 (April 2022 to March 2023)*".

"**PII**" has the meaning given to such term under the heading entitled *"Risk Factors - Risks Related to the Company's Intellectual Property, Personally Identifiable Information and Sensitive Personally Identifiable Information"*.

"**Preferred Shares**" has the meaning given to such term under the heading entitled *"The Corporate Structure – Name, Address and Incorporation"*.

"**PRV**" has the meaning given to such term under the heading entitled *"Forward-Looking and Other Statements"*.

"**R&D**" has the meaning given to such term under the heading entitled *"Forward-Looking and Other Statements"*.

"**REB**" has the meaning given to such term under the heading entitled *"Business of the Company - Regulatory Environment - Canada Drug Products and Biologics Regulation"*.

"**Saptalis**" has the meaning given to such term under the heading entitled *"Business of the Company – Overview of the Company – ATI-1501"*.

"**Second Tranche Loan**" has the meaning given to such term under the heading entitled "*Business of the Company – Three-Year History – Fiscal 2023 (April 2022 to March 2023)*".

"**SEDAR**" means the System for Electronic Document Analysis and Retrieval.

"**Share Split**" has the meaning given to such term under the heading "*The Corporate Structure – Name, Address, and Incorporation*.

"**SIGA Technologies**" has the meaning given to such term under the heading entitled *"Business of the Company - Market Opportunity - ATI-1701"*.

"**Spartan**" has the meaning given to such term under the heading entitled "*Executive Officers and Directors – Biographies"*.

"**sPII**" has the meaning given to such term under the heading entitled *"Risk Factors - Risks Related to the Company's Intellectual Property, Personally Identifiable Information and Sensitive Personally Identifiable Information"*.

"**TSX**" means the Toronto Stock Exchange.

"**U.S.**", "**US**" or "**United States**" means the United States of America.

"**USAFA**" has the meaning given to such term under the heading entitled "*Forward-Looking and Other Statements*".

"**USAFA Cooperative Agreement**" has the meaning given to such term under the heading entitled "*Business of the Company – Overview of the Company – Recent Developments*".

"**USAMMDA**" has the meaning given to such term under the heading entitled "*Business of the Company – Our Development Programs – ATI-1801*".

"**USAMRIID**" has the meaning given to such term under the heading entitled *"Business of the Company – Competitive Conditions – ATI-1701"*.

"**USAMRIID-LVS**" has the meaning given to such term under the heading entitled *"Business of the Company - Competitive Conditions - ATI-1701"*.

"**WHO**" has the meaning given to such term under the heading entitled "*Business of the Company – Market Opportunity – ATI-1801*".

APPENDIX A
AUDIT COMMITTEE CHARTER

I. MANDATE

The Audit Committee (the "**Committee**") is appointed by the Board of Directors (the "**Board**") of Appili Therapeutics Inc. (the "**Corporation**") to assist the Board in fulfilling its oversight responsibilities relating to financial accounting and reporting process and internal controls for the Corporation. The external auditors will report directly to the Committee and the Committee shall have direct communication channels with the external auditors of the Corporation. The Committee's mandate and responsibilities are to:

- recommend to the Board the external auditors to be nominated and the compensation of such auditors;
- oversee and monitor the work and performance of the Corporation's external auditors, including meeting with the external auditors and reviewing and recommending all renewals or replacements of the external auditors and their remuneration;
- pre-approve all non-audit services to be provided to the Corporation by the external auditors;
- review the financial statements and management's discussion and analysis (MD&A) and annual and interim financial results press releases of the Corporation;
- oversee the integrity of internal controls and financial reporting procedures of the Corporation and ensure implementation of such controls and procedures; and
- provide oversight to any related party transactions entered into by the Corporation.

II. AUTHORITY OF THE AUDIT COMMITTEE

The Committee shall have the authority to:

- engage independent counsel and other advisors as it determines necessary to carry out its duties;
- set and pay the compensation for advisors employed by the Committee; and
- communicate directly with the external auditors.

III. COMPOSITION AND MEETINGS

The Committee and its membership shall meet all applicable legal, regulatory, and listing requirements, including those of all applicable securities regulatory authorities.

The Committee shall be composed of three directors as shall be designated by the Board from time to time. The members of the Committee shall appoint from among themselves a member who shall serve as Chair. A minimum of two members of the Committee present either in person or by telephone shall constitute a quorum.

The Committee members will be elected annually at the first meeting of the Board following the annual general meeting of shareholders.

Each member of the Committee shall be "financially literate" and a majority of the members of the Committee shall be "independent" (as each such term is defined in Multilateral Instrument 52-110 *Audit Committees*). At least one member of the Committee shall have accounting or related financial expertise.

The Committee shall meet at least quarterly, as circumstances dictate or as may be required by applicable legal or listing requirements.

Any member of the Committee may participate in the meeting of the Committee by means of conference telephone or other communication equipment, and the member participating in a meeting pursuant to this paragraph shall be deemed, for purposes hereof, to be present in person at the meeting.

IV. RESPONSIBILITIES

The Committee shall review the annual audited financial statements to satisfy itself that they are presented in accordance with International Financial Reporting Standards (IFRS) and report thereon to the Board and recommend to the Board whether or not same should be approved, prior to their being filed with the appropriate regulatory authorities. The Committee shall also review the interim financial statements.

The Committee shall oversee the integrity of internal controls and financial reporting procedures of the Corporation and ensure implementation of such controls and procedures. The Committee shall review any internal control reports prepared by management and the evaluation of such report by the external auditors, together with management's response.

The Committee shall be satisfied that adequate procedures are in place for the review of the Corporation's public disclosure of financial information extracted or derived from the Corporation's financial statements, management's discussion and analysis and annual and interim earnings press releases before the Corporation publicly discloses this information.

The Committee shall review management's discussion and analysis relating to annual and interim financial statements and any other public disclosure documents, including interim earnings press releases, before the Corporation publicly discloses this information.

The Committee shall meet no less frequently than annually with the external auditors to review accounting practices, internal controls and such other matters as the Committee deems appropriate (including the establishment of the independence of the external auditor). The Committee shall be directly responsible for overseeing the work of the external auditor.

The Committee shall resolve any disagreements between the management and the external auditors.

The Committee shall establish procedures for:

- the receipt, retention and treatment of complaints received by the Corporation regarding accounting, internal accounting controls or auditing matters; and
- the confidential, anonymous submission by employees of the Corporation of concerns regarding questionable accounting or auditing matters.

The Committee shall annually make recommendations to the Board regarding the selection, appointment, and fees of the independent auditors.

The Committee shall provide oversight to any related party transactions entered into by the Corporation.

In the event that the Corporation wishes to retain the services of the Corporation's external auditors for tax compliance or tax advice or any non-audit services, the Committee must first pre-approve any such non-audit services (however, the Committee may delegate such approval to one independent committee member if desired, subject to compliance with applicable laws). The Committee shall maintain a record of non-audit services approved by the Committee for each fiscal year and provide a report to the Board on an annual basis.

The Committee shall review and approve the Corporation's hiring policies regarding partners, employees and former partners and employees of the present and former auditors of the Corporation.

The Committee shall perform any other activities consistent with this Charter and governing law, as the Committee or the Board deems necessary or appropriate.