



**MANAGEMENT'S DISCUSSION AND ANALYSIS**

*For the Interim Period Ended June 30, 2023*

## APPILI THERAPEUTICS INC.

The following Management's Discussion and Analysis ("MD&A") of Appili Therapeutics Inc. ("Appili", the "Company", "we", "us" or "our") is prepared as of August 11, 2023, provides information concerning the Company's financial condition and results of operations. This MD&A should be read in conjunction with our audited annual consolidated financial statements for the fiscal years ended March 31, 2023, and 2022 and our unaudited condensed consolidated financial statements for the three months ended June 30, 2023 and 2022, including the related notes thereto. The preparation of financial information included in the MD&A has been prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board, unless otherwise noted. Unless stated otherwise, all references to "\$" are to Canadian dollars ("CAD").

### FORWARD-LOOKING STATEMENTS

This MD&A 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 based on 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 MD&A include, but are not limited to, statements relating to:

- our ability to maintain the listing of the Company's Class A common shares (the "Common Shares") on the Toronto Stock Exchange (the "TSX");
- our strategy;
- our ability to continue as a going concern;
- 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 US Department of Defense ("USDOD") and US Air Force Academy ("USAF") at all and in a timely manner;
- our intention to secure certain regulatory designations, such as Fast-Track status, for our development programs;
- 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 MD&A, 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 company's

ability 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; and (xiii) our ability to continue to partner with the USDOD and USAFA with respect to the funding of ATI-1701.

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;
- the Company's ability to meet certain debt obligation covenants;
- 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 USAFA for its ATI-1701 program;
- ability to attract and retain key personnel;
- the company's existing credit facility with Long Zone Holdings ("LZH");
- implementation and development delays;
- product deficiencies;
- volatility of share price; and
- the other risks discussed under the heading "*Risk Factors*" in the Company's annual information form dated June 22, 2023.

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 MD&A 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.

## **MARKET DATA**

Certain market and industry data (including study results) used in this MD&A were obtained from market research, publicly available information and industry publications. Appili believes that these sources are generally reliable, but the accuracy and completeness of this information is not guaranteed. Appili has not independently verified this information and does not make any representation or warranty as to the accuracy of this information.

## **BUSINESS OVERVIEW**

Appili is a pharmaceutical company focused on the acquisition and development of novel treatments 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 product development portfolio currently includes three programs, described below: ATI-1701, ATI-1801 and ATI-1501.

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 or biologic license application. PRVs are transferrable and the secondary market for PRVs is well established with over 30 transactions reported publicly and recent transactions typically around or exceeding US\$100 million.

#### *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 *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 depends 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 governments around the world. There is currently no approved vaccine for the prevention of tularemia in the United States or other major global markets.

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 (Conlan 2010, Shen 2010). Vaccine manufacturing activities have been initiated and animal work commenced in 2019. A non-human primate study showed that vaccination with a ATI-1701 provided >88% survival protection when animals were challenged with a lethal dose of *F. tularensis* at either 28 or 90 days after vaccination. The Company recently 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. 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 Therapeutics is helping to sponsor the 10<sup>th</sup> International Conference on Tularemia and will be presenting data at this conference in September 2023.

The primary focus for commercializing ATI-1701 is the United States market, where approval from the FDA is necessary. However, rare and severe diseases like tularemia present unique challenges during clinical development. These challenges include limited patient availability for clinical trials, unreasonable risks associated with experimental infection studies, and the impracticality of conducting field efficacy studies.

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 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 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 seeking approval for 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 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.

Appili's activities related to ATI-1701 have been and continue to be funded through its current resources and USDOD funding. On May 5th, 2023, Appili signed an initial cooperative agreement with USAFA (the "**USAFA Cooperative Agreement**") for the previously announced funding of the ATI-1701 program. This cooperative agreement represents the first stage of funding from the USDOD award. The initial funding amounts to US\$7.3 million and will be used to initiate early-stage development and regulatory activities for ATI-1701. As progress is made, Appili plans to engage USAFA for additional funding tranches to continue development through Investigation New Drug ("**IND**") submission.

Under the terms of its agreement with USAFA, Appili will be reimbursed for direct costs and labour associated with budgeted program activities, plus will recover a portion of its overhead costs. During the quarter ended June 30, 2023, Appili submitted invoices for such costs and anticipates receiving payment for these invoices in the coming weeks. Additional invoices have been submitted since June 30, 2023 and payments are expected for these invoices in due course.

USAFA serves as the prime contractor to the Defense Threat Reduction Agency ("**DTRA**") for this program, a USDOD agency. The USAFA Cooperative Agreement establishes Appili as the top-tier performer responsible for managing development activities through the IND stage. The anticipated total program funding is expected to be approximately US\$14 million, depending on US federal budget funding activities. The initial tranche of US\$7.3 million is authorized by the award. These funds, along with other planned funding tranches, are expected to advance the ATI-1701 program toward an IND submission to the FDA in 2024. Appili will oversee a comprehensive development program for ATI-1701, which includes nonclinical studies, manufacturing, and regulatory activities to support the IND submission.

It is important to note that the milestones mentioned are based on management's current expectations regarding the development and advancement of ATI-1701. However, they are 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 Materiel 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 world (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. 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 < 0.001).

Subject to completing a successful tech transfer to the Company's contract manufacturing organization, Appili plans to request a meeting with the FDA later this year to discuss the previously generated Phase 3 data and agree on the necessary registration package to support a New Drug Application ("**NDA**") submission, which the Company expects will include available nonclinical, manufacturing, and clinical data generated to date. 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.

In September 2022, Appili submitted a funding proposal to NIH entitled, "A Randomized, Double-blind, Pivotal Phase 3 Study of ATI-1801 (Paromomycin Topical Cream) vs. oral Miltefosine for the Treatment of Cutaneous Leishmaniasis in Panama for Paromomycin Topical Cream." This submission was made in response to the funding opportunity announcement number RFA-FD-23-001: Clinical Studies of Orphan Products Addressing Unmet Needs of Rare Diseases (R01) grant application. The objective of this R01 grant application is to provide support for clinical trials of orphan drug products, encompassing all phases of product evaluation, including efficacy and/or safety assessments. The aim is to address unmet needs in rare diseases or conditions, leading to new indications or changes in labeling. By funding collaborative, efficient, and innovative clinical trials, the FDA aims to enhance the number of approved treatments for rare diseases and make a significant positive impact on rare disease drug development. As of June 2023, Appili is awaiting a R01 grant decision from the FDA.

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".

#### *ATI- 1501*

ATI-1501 is a taste-masked liquid oral suspension formulation of the antibiotic metronidazole. 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 have to 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 Pharmaceuticals LLC ("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. In addition, Saptalis is responsible for overseeing the regulatory review, manufacturing, and preparation for the filing of an NDA with the FDA, as well as the anticipated commercialization of ATI-1501 in the United States, which are the next major development milestones for ATI-1501. 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 November 2020, Saptalis requested and obtained several Type C meetings with the FDA to discuss potential adjustments to the formulation. The FDA accepted the changes in the formulation on condition of characterization in an additional bioequivalence study, which per the terms of the licence agreement were partially funded by the Company. The bioequivalence study was completed-followed by an NDA submission in December 2022. In February 2023, the Company announced that the FDA accepted the ATI-1501 NDA. The FDA established a Prescription Drug User Fee ("PDUFA") action date of September 23, 2023. Appili received US\$250,000 in milestone payments from Saptalis in 2023.

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.

In May 2023, United States Patent and Trademark Office ("USPTO") 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 milestones set out above are based on management's current expectations with respect to the development and advancement of ATI-1501 and are subject to certain underlying assumptions 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".

## **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 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.

## **RECENT DEVELOPMENTS**

### **Overall Performance**

The Company has no commercial product revenues. Accordingly, its ability to ensure continuing operations is dependent on obtaining the necessary financing to complete the development of the Company's product development portfolio, which includes three active programs (ATI-1701, ATI-1801, and ATI-1501).

The Company had the following recent key developments and achievements since April 2023:

- On June 29, 2023, the Company announced that it had entered into an unsecured \$300,000 bridge loan (the "**Bridge Loan**") from Bloom Burton & Co. ("**Bloom Burton**") Inc. Pursuant to the terms of the agreement, the 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. The Bridge Loan was funded in two equal tranches.
- On May 24, 2023, the Company announced Issuance of Patent for ATI-1501 Liquid Oral Reformulation of Metronidazole. This patent covers the composition and preparation methods for ATI-1501 through 2039.
- On May 5, 2023, the Company announced that it had entered into the USAFA Cooperative Agreement with respect to the development of ATI-1701.
- On April 3, 2023, the Company announced the appointment of Dr. Gary Nabors, Ph.D., as Chief Development Officer. Dr. Nabors will lead the advancement of programs through development, regulatory submission and key commercialization milestones.

## SELECTED FINANCIAL INFORMATION

	<b>Three Months ended June 30, 2023 (\$)</b>	<b>Three Months ended June 30, 2022 (\$)</b>
Net loss and comprehensive loss for the period	(1,548,559)	(2,324,760)
Basic and diluted loss per share	(0.01)	(0.03)

	<b>As at June 30, 2023</b>	<b>As at March 31, 2023</b>
Cash and short-term investments	520,589	2,465,882
Total assets	2,170,690	3,132,375
Long-term liabilities	7,687,442	7,665,345

## RESULTS FOR THE THREE MONTHS ENDED JUNE 30, 2023 (“Q1 2024”), COMPARED TO THE THREE MONTHS ENDED JUNE 30, 2022 (“Q1 2023”)

	<b>Three months ended June 30, 2023 \$</b>	<b>Three months ended June 30, 2022 \$</b>
<b>Income</b>		
Interest income	8,327	4,841
	<u>8,327</u>	<u>4,841</u>
<b>Expenses</b>		
R&D	1,231,787	1,007,100
General and administrative (“G&A”)	932,711	1,077,164
Business development (“BD”)	66,568	(20,442)
Financing costs	381,286	173,057
Government assistance	(922,576)	(55,226)
Exchange (gain)/loss	(145,390)	137,386
	<u>1,544,386</u>	<u>2,319,039</u>
<b>Loss before Income taxes</b>	(1,536,059)	(2,314,198)
Income tax expense	12,500	10,562
<b>Net loss and comprehensive loss for the period</b>	<u>(1,548,559)</u>	<u>(2,324,760)</u>



## Income

### i. Interest income

Interest income increased by \$3,486 to \$8,327 during Q1 2024 as compared to \$4,841 in Q1 2023, due to higher interest rates in Q1 2024.

## Operating expenses

Overall operating expenses decreased by \$774,653 to \$1,544,386 during Q1 2024 compared to \$2,319,039 in Q1 2023 as a result of a decrease of \$144,453 in G&A costs due to lower employment costs, an increase of \$867,350 in government assistance due to reimbursement stemming from the contract with USAFA to support the ATI-1701 program and an increase of \$282,776 in foreign exchange gains resulting from revaluation of the LZH secured loans. This was offset by an increase of \$224,687 in R&D costs mainly due to ATI-1701 program costs, an increase of \$87,010 in BD costs primarily due to consulting fees from related party and an increase of \$208,229 in financing costs, due to accretion of interest and cash interest paid on LZH secured loans. Explanations of the nature of costs incurred, along with explanations for those changes in costs are discussed below.

### i. R&D expenses

The Company's R&D expenses have related primarily to costs incurred in performing research and development activities that include non-clinical, clinical manufacturing, regulatory and clinical trial expenses of its product candidates. The R&D expenses for the period relate to costs incurred for the development of the two product candidates, including ATI-1701 and ATI-1501, general R&D and close-out-costs for Favipiravir clinical study, discontinuation costs associated with ATI-2307 and ATI-1501 research project.

R&D expenses consist of the following:

	<u>Three months ended</u> <u>June 30, 2023</u> <u>(\$)</u>	<u>Three months ended</u> <u>June 30, 2022</u> <u>(\$)</u>
Favipiravir expenses	2,869	226,063
ATI-2307 expenses	47,740	241,995
ATI-1701 expenses	432,396	118,921
ATI-1503 expenses	-	19,119
ATI-1501 expenses	21,544	-
General R&D expenses	48,787	34,490
Amortization of property and equipment	1,454	312
Salaries and benefits	639,950	336,391
Stock-based compensation	37,047	29,809
<b>Total</b>	<b><u>1,231,787</u></b>	<b><u>1,007,100</u></b>

The increase in R&D expenses of \$224,687 from \$1,007,100 in Q1 2023 to \$1,231,787 in Q1 2024 is mainly attributable to a \$313,475 increase in ATI-1701, an increase of \$303,559 in salaries and benefits, an increase of \$21,544 in ATI-1501 program expenses, an increase of \$14,297 in general R&D expenses, an increase of \$7,238 in stock based compensation, and an immaterial increase in amortization of property and equipment. These increases were offset by a \$223,194 decrease in the Favipiravir clinical trials and a \$194,255 decrease in ATI-2307 and a \$19,119 decrease in the ATI-1503 program expenses due to discontinuation of these programs.

### *Favipiravir*

The decrease in Favipiravir expenses is due to the completion of the clinical trial in November 2021. During the quarter the company received the final close-out-costs associated with the trial.

### *ATI-2307*

The decrease in ATI-2307 program expenses is due to discontinuation of the development of this program as part of its strategic review and reprioritization.

### *ATI-1701*

The increase in ATI-1701 program expenses is due to increased consultant expenses, to support the planned activity under USAFA agreement, in Q1 2024 in comparison to Q1 2023. These are primarily being reimbursed by USAFA as part of the Cooperative Agreement and recorded as government assistance.

### *ATI-1501*

The increase in ATI-1501 program expenses is due to increased consultancy fees relating to commercialization activity in Q1 2024.

### *General R&D Expenses*

The increase in expenses related to general R&D expenses is due to increased R&D travel and conferences costs. This is offset by decrease in related party consulting fees and reduced R&D rent in Q1 2024 in comparison to Q1 2023.

### *Salaries and Benefits and Stock-based compensation*

The increase in salaries and benefits and stock-based compensation in Q1 2024 are mainly due to additional staff recruited to support the ATI-1701 research program.

## **ii. G&A expenses**

The Company's G&A expenses include salaries and benefits of the senior executive team and the finance and administrative staff, stock-based compensation expenses, professional fees including legal, auditing and tax, costs associated with the public listing on the TSX, regulatory, investor relations and public relations costs, travel expenses, office rent, operating and information technology costs, director compensation, and directors' and officers' insurance premiums.

G&A expenses consist of the following:

	<u>Three months ended</u> <u>June 30, 2023</u> <u>(\$)</u>	<u>Three months ended</u> <u>June 30, 2022</u> <u>(\$)</u>
G&A expenses, excluding salaries	738,184	724,795
Salaries and benefits	82,243	146,612
Stock-based compensation	110,297	183,699
Amortization of property and equipment	1,987	22,058
<b>Total</b>	<b><u>932,711</u></b>	<b><u>1,077,164</u></b>

G&A expenses decreased by \$144,453 from \$1,077,164 in Q1 2023 to \$932,711 in Q1 2024, a decrease of \$64,369 in salaries and benefits, a decrease of \$73,402 in stock-based compensation, and a \$20,071 decrease in amortization of property and equipment. These decreases are offset by an increase of \$13,389 in G&A expenses excluding salaries,

### *Stock-based compensation*

The decrease in stock-based compensation in Q1 2024 by \$73,402 in comparison to Q1 2023, is due to staff changes in Q1 2024.

### *G&A expenses, excluding salaries*

G&A expenses, excluding salaries, for Q1 2024 increased by \$13,389 in comparison to Q1 2023, is mainly due to an increase in legal fees, business advisory costs, insurance, accounting services, audit fees, regulatory fees, information technology costs and travel related charges. These increases were offset by a decrease in related party salary costs, public relation costs, and investor relation fees.

### *Salaries and Benefits*

Salaries and benefits decreased by \$64,369 in Q1 2024 in comparison to Q1 2023, mainly due to staff changes.

### **iii. BD expenses**

BD expenses consist of new program acquisition research costs and business development office rent. BD expenses increased by \$87,010 in Q1 2024 as compared to Q1 2023, due to increased stock-based compensation costs associated with staff changes.

### **iv. Financing costs**

Financing costs relate to the valuation of zero interest bearing government loans.

Under IFRS, the zero-interest bearing government loans from the Atlantic Canada Opportunities Agency (“**ACOA**”) must be initially valued at fair value and the difference between the fair value of the loans and the contribution received must be treated as government assistance. These loans are then accreted to their original value over time. For the loan repayable on a percentage of future gross revenue from ATI-1501, management is required to revise the estimated cash flows whenever new information related to ATI-1501 and its potential market, including time of entry, market size, etc., is made available. Management recalculates the carrying amount by computing the present value of the estimated future cash flows at the original effective interest rate and any adjustments are recognized in the statements of loss and comprehensive loss as accreted interest after initial recognition.

The increase of financing costs by \$208,229 in Q1 2024 as compared to Q1 2023, is due mainly to the accretion LZH secured loans and ACOA loans, as well as the increase in cash interest paid to LZH due to additional secured loan obtained from LZH in March 2023 and higher interest rate.

### **v. Government assistance**

Government assistance consists of investment tax credits, conditionally repayable government loans, repayable government loans, government grants and reimbursement of costs from government agreements.

Government assistance increased by \$867,350 in Q1 2024 as compared to Q1 2023, mainly due to the cost reimbursement from the USAFA Cooperative Agreement to support the development of ATI-1701 in Q1 2024.

## **Income tax expense**

Income tax expense is due on taxable income recognized in the US subsidiary.

### **vi. Net loss and comprehensive loss**

The net loss and comprehensive loss was \$1,548,559 for Q1 2024, a decrease of \$776,201 compared to the net loss and comprehensive loss of \$2,324,760 for Q1 2023.

## **CASH FLOWS**

As at June 30, 2023, the Company had cash of \$520,589 and negative working capital of \$1,336,924 compared to a cash balance of \$2,465,882 and positive working capital of \$140,631, as at March 31, 2023.

To date, operations have been financed through the issuance of equity securities, debt, interest income on funds available for investment, government loans and assistance and tax credits.

### *Operating activities*

During the three months ended June 30, 2023, \$2,023,842 was used in operating activities, including a reported net loss of \$(1,548,559) prior to being adjusted for add-backs of \$381,474 (non-cash finance costs), \$147,346 (stock-based compensation), \$(142,196) (unrealized foreign exchange translation (LZH)), \$3,442 (amortization of property equipment), \$(690) (unrealized gain from changes in foreign currency) and a net decrease of \$(864,659) in cash as a result of changes in working capital.

### *Financing activities*

During the three months ended June 30, 2023, the Company received \$150,000 as long-term debt, which was offset by repayment of long-term debt of \$23,225 and \$19,199 for the payment of accreted interest involving cash.

### *Investing activities*

During the three months ended June 30, 2023, the Company purchased lab equipment and computer amounting to \$29,717.

## LIQUIDITY AND CAPITAL RESOURCES

The Company prepares and updates the cash flow forecasts on a regular basis to manage the Company's liquidity, ensuring that the Company has sufficient cash to meet operational needs.

The Company aims to maintain adequate cash and cash resources to support planned activities which include: supportive activities for pre-IND and IND-enabling activity costs for ATI-1701 including regulatory, manufacturing and non-clinical activities; other early-stage R&D activities on other exploratory programs; business development costs incurred relating to assessing and evaluating new drug product candidates that fit within the Company's strategic focus; administration costs, and intellectual property maintenance and expansion.

It is common for early-stage biotechnology companies to require additional funding to further develop product candidates until successful commercialization of at least one product candidate. Appili's product candidates are still in the development stage of the product cycle and therefore are not generating revenue to fund operations. The Company continuously monitors its liquidity position, the status of its development programs, including those of its partners, cash forecasts for completing various stages of development, the potential to license or co-develop each product candidate, and continues to actively pursue alternatives to raise capital, including the sale of its equity securities, debt and non-dilutive funding.

At June 30, 2023, the Company had approximately \$1.8 million of existing and identified potential sources of cash including:

- cash of \$0.5 million; and
- amounts receivable and investment tax credits receivable of \$1.3 million.

The Company was previously granted a three-year Peer Review Medical Research Program award for up to USD\$3.2 million to fund the Company's ATI-1503 program, of which the Company had only drawn down approximately USD\$0.894 million as of June 30, 2022, which was the last period the Company could draw down funds from this grant.

Under the terms of the USAFA Cooperative Agreement, Appili will be reimbursed for direct costs and labour associated with budgeted program activities, plus will recover a portion of its overhead costs. During the quarter ended June 30, 2023, Appili submitted two invoices for such costs totaling \$914,576 and anticipates receiving payment for these invoices in the coming weeks.

USAFA serves as the prime contractor to DTRA for this program as USDOD Agency. The USAFA Cooperative Agreement establishes Appili as the top-tier performer responsible for managing development activities through the IND stage. The anticipated total program funding is expected to be approximately US\$14 million, depending on US federal budget funding activities. The initial tranche of US\$7.3 million is authorized by the contract. These funds, along with other planned funding tranches, are expected to advance the ATI-1701 program toward an IND submission to the FDA in 2024. Appili will oversee a comprehensive development program for ATI-1701, which includes nonclinical studies, manufacturing, and regulatory activities to support the IND submission.

### Going Concern

While the Company has potential sources of cash of approximately \$1.8 million as at June 30, 2023, 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 the capital sufficient to meet any or all of the Company 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, in the termination or delay of clinical trials for our products, in curtailment of the product development programs designed. Such adjustments or delays could be material. In addition, failure to secure additional financing as required to fund current working capital requirements 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 the reimbursement by USAFA of previously submitted expenses pursuant to the USAFA Cooperative Agreement in the near term 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.

## RELATED PARTY TRANSACTIONS

The Company's Chair of the Board of Directors (formerly Chief Executive Officer) is a partner of Bloom Burton, which is a principal shareholder of the Company. For the three months ended June 30, 2023, the Company was charged \$nil (June 30, 2022 - \$88,913) for services performed by the former Chief Executive Officer. As at June 30, 2023, \$212,572 (June 30, 2022 - \$nil) is included in accounts payable and accrued liabilities owing to the former Chief Executive Officer in accordance with his employment contract, which was terminated on November 12, 2022 due to his change in role.

During the three months ended June 30, 2023, the Company was charged \$66,568 (June 30, 2022 - \$nil) for consulting services in relation to business development activities by Bloom Burton Securities Inc., an affiliate of Bloom Burton. For the three months ended June 30, 2022, the Company issued 1,189,579 compensation warrants valued at \$46,666 and paid \$315,000 in cash commission to Bloom Burton Securities Inc. No Compensation warrants were issued for the three months ended June 30, 2023.

On June 28, 2023, the Company obtained a Bridge Loan from Bloom Burton in the aggregate amount of \$300,000. The Bridge Loan was funded in two equal tranches. As at June 30, 2023, \$150,000 (June 30, 2022 - \$nil) is outstanding and the fair value of the loan was determined to be \$100,689 and is included in current portion of long-term debt.

## CONTRACTUAL OBLIGATIONS

- On November 21, 2019, the Company signed an asset purchase agreement (the "**Asset Purchase Agreement**") with FFTC receiving exclusive worldwide rights, excluding Japan, to acquire and develop a novel broad-spectrum antifungal drug candidate, ATI-2307.

On December 27, 2022, the Company notified FFTC that it was returning ownership of ATI-2307 to FFTC for no additional consideration. No further payments are expected to be made to FFTC pursuant to the Asset Purchase Agreement.

- On March 28, 2022, the Company executed a loan agreement (the "**Original Loan Agreement**") with LZH providing secured gross proceeds of US\$3,600,000 (CAD\$4,500,000) ("**First Tranche Loan**"). Under the terms of the Original Loan Agreement, LZH obtained a secured loan of US\$3.6 million. The loan is secured by a general security over all the assets of the Company, including intellectual property.

On March 17, 2023, the Company entered into an amended and restated secured loan agreement with LZH, amending and restating the Original Loan Agreement (the “**Amended Loan Agreement**”). Pursuant to the terms of the Amended Loan Agreement, LZH provided an additional loan of \$2,500,000 (“**Second Tranche Loan**”), which supplements the First Tranche Loan (collectively with Second Tranche Loan, the “**Loans**”). The Loans mature on March 15, 2025, bearing the following terms:

- The interest rate on the First Tranche Loan was amended to be higher of 11% or the US prime lending rate plus 3.25%;
- Second Tranche Loan, higher of 11% or the Canadian prime lending rate plus 4.3%;
- The Loans include a prepayment feature at the option of the Company, which bears penalty interest of 5%; and
- The Loans include a default interest feature whereby the Company will owe 5% in additional interest if an event of default occurs.
- The Loans require the Company to maintain a minimum cash balance at all times.

Interest is compounded quarterly and paid in arrears. In addition, a 4% per year fixed maintenance fee is payable on the Loans to LZH.

- On March 28, 2022, the Company entered into a licencing agreement which entitled LZH an exclusive licence to commercialize the Company’s future approved products in the in Latin America, Canada, and Israel, excluding ATI-1501 in Latin America, which was recently licenced to existing partner Saptalis. The Company will receive a supply price for products sold by LZH or its sublicensees, as well as royalties on net sales.
- On May 5, 2023, the Company entered into the USAFA Cooperative Agreement with respect to the development of ATI-1701.
- On June 28, 2023, the Company obtained the Bridge Loan from Bloom Burton, a related party (see note 7) in the aggregate amount \$300,000. The Bridge Loan bears interest at 1% per annum for the first month increasing to 2% thereafter and matures on the earlier of September 28, 2024, or the date on which the Company receives aggregate reimbursements from USAFA of not less than \$2,500,000. The Bridge Loan was funded in two equal tranches, with the first tranche advanced on June 29, 2023, and the second tranche advanced on July 10, 2023. The Bridge Loan is intended to be used by the Company for working capital purposes in the event that reimbursements from USAFA are delayed.

There is no other material change in the contractual obligations of the Company since the beginning of the 2024 fiscal year. Details on the contractual obligations of the Company can be found in the financial statements and related notes in the audited annual consolidated financial statements for the year ended March 31, 2023.

## **OFF-BALANCE SHEET ARRANGEMENTS**

The Company was not party to any off-balance sheet arrangements as of June 30, 2023.

## **OUTSTANDING SECURITIES**

As of August 11, 2023, the Company issued and has 121,266,120 Common Shares, 7,842,000 stock options and 58,247,879 warrants issued and outstanding.

## **RISKS AND UNCERTAINTIES**

The Company is a clinical-stage company that operates in an industry that is dependent on a number of factors that include the capacity to raise additional capital on reasonable terms, obtain positive results of clinical trials without serious adverse or inappropriate side effects, and obtain market acceptance of its product by physicians, patients, healthcare payers and others in the medical community for commercial success, etc. An investment in the Common Shares is subject to a number of risks and uncertainties. In addition to the risks set out herein, an investor should carefully consider the risks described under the heading “*Risk Factors*” in the Company’s annual information form dated June 22, 2023, filed in respect of the fiscal year ended March

31, 2023. If any of such described risks occur, or if others occur, the Company's business, operating results and financial condition could be seriously harmed, and investors may lose a significant proportion of their investment. There are important risks which management believes could impact the Company's business.

## **DISCLOSURE CONTROLS AND PROCEDURES AND INTERNAL CONTROLS OVER FINANCIAL REPORTING**

### Disclosure Controls and Procedures

Disclosure controls and procedures ("DC&P") are intended to provide reasonable assurance that material information is gathered and reported to senior management to permit timely decisions regarding public disclosure and internal controls over financial reporting ("ICFR") are intended to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with Canadian generally accepted accounting principles.

The Company maintains DC&P designed to ensure that information required to be disclosed in reports filed under applicable securities laws, is recorded, processed, summarized and reported within the appropriate time periods and that such information is accumulated and communicated to the Company's management, including the CEO and CFO, to allow for timely decisions regarding required disclosure.

The CEO and the CFO of the Company are responsible for establishing and maintaining the Company's disclosure controls and procedures, including adherence to the Disclosure Policy adopted by the Company. The CEO and CFO have evaluated whether there were changes to the disclosure controls and procedures during the period ended June 30, 2023, that have materially affected, or are reasonably likely to materially affect, the disclosure controls and procedures. No such changes were identified through their evaluation.

In designing and evaluating the DC&P, the Company recognizes that any disclosure controls and procedures, no matter how well conceived or operated, can only provide reasonable, not absolute, assurance that the objectives of the control system are met, and management is required to exercise its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

### Internal Control over Financial Reporting

The Company's management, including the CEO and the CFO, are responsible for establishing and maintaining adequate ICFR. The control framework used by the CEO and CFO of the Company to design the Company's ICFR is the Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission.

The CEO and CFO have evaluated whether there were changes to ICFR during the period ended June 30, 2023, that have materially affected, or are reasonably likely to materially affect, ICFR. No such changes were identified through their evaluation. There have been no significant changes in the Company's internal controls during the period ended June 30, 2023, that have materially affected, or are reasonably likely to materially affect, ICFR.

The Company's ICFR may not prevent or detect all misstatements because of inherent limitations. Additionally, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because changes in conditions or deterioration in the degree of compliance with the Company's policies and procedures.

## **BASIS OF PRESENTATION OF FINANCIAL STATEMENTS AND SIGNIFICANT ACCOUNTING POLICIES**

The consolidated financial statements have been prepared in accordance with the IFRS as issued by the International Accounting Standards Board. The accounting policies, methods of computation and presentation applied in the consolidated financial statements are consistent with those of previous financial years. The Company's significant accounting policies are detailed in the notes to the audited consolidated financial statements for March 31, 2023.



## CRITICAL ACCOUNTING ESTIMATES AND JUDGEMENTS

Estimates and assumptions are continually evaluated and are based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances. The determination of estimates requires the exercise of judgement based on various assumptions and other factors such as historical experience and current and expected economic conditions. Actual results could differ from those estimates. Critical judgements in applying the Company's accounting policies are detailed in note 3 of the Company's annual audited consolidated financial statements for the year ended March 31, 2023. The unaudited interim condensed consolidated financial statements have been prepared using the same policies and methods as the annual audited consolidated financial statements of the Company for the fiscal year ended March 31, 2023.

## FINANCIAL INSTRUMENTS

Financial instruments are defined as a contractual right or obligation to receive or deliver cash on another financial asset. The following table sets out the approximate fair values of financial instruments as at the statement of financial position date with relevant comparatives:

	June 30, 2023		March 31, 2023	
	Carrying Value	Fair Value	Carrying Value	Fair Value
	\$	\$	\$	\$
Cash	520,589	520,589	2,465,882	2,465,882
Amounts Receivable	967,661	967,661	69,006	69,006
Accounts Payable and accrued liabilities	3,197,520	3,197,520	2,823,001	2,823,001
Long-term debt	7,687,442	7,687,442	7,665,345	7,665,345

Assets and liabilities, such as commodity taxes, that are not contractual and arise as a result of statutory requirements imposed by governments, do not meet the definition of financial assets or financial liabilities and are, therefore, excluded from amounts receivable and accounts payable and accrued liabilities in this table.

Fair value of items, which are short-term in nature, have been deemed to approximate their carrying value. The above noted fair values, presented for information only, reflect conditions that existed only at June 30, 2023, and do not necessarily reflect future value or amounts, which the Company might receive if it were to sell some or all of its assets to a willing buyer in a free and open market.

### *Risk management*

The Company, through its financial assets and liabilities, has exposure to the following risks from its use of financial instruments: credit risk; market risk; and liquidity risk. Management is responsible for setting acceptable levels of risk and reviewing risk management activities as necessary.

### *Credit risk*

Credit risk is the risk of a financial loss to the Company if a counterparty to a financial instrument fails to meet its contractual obligation. The Company is exposed to credit risk on its cash and short-term investment balances. The Company's cash management policies include ensuring that the cash is deposited in Canadian chartered banks.

### *Market risk*

Market risk is the risk the fair value or future cash flows of a financial instrument will fluctuate because of changes in market

prices, including interest rate risk and foreign currency risk.

#### *Interest rate price risk*

The Company has limited exposure to interest rate risk on its lending and borrowing activities. The Company has interest-free debt that is either repayable over 84 months or 120 months or becomes repayable when revenue is earned. The Company also has a secured loan of US\$3,600,000 based on a minimum interest rate of 11% or the US Prime Lending rate plus 3.25% per year, compounded quarterly and paid in arrears, repayable over 24 months and a secured loan of \$2,500,000 based on minimum interest rate of 11% or the Canadian Prime Lending rate plus 4.3% per year, compounded quarterly and paid in arrears, repayable over 24 months.

#### *Foreign currency risk*

Foreign currency risk occurs as a result of foreign exchange rate fluctuations between the time a transaction is recorded and the time it is settled.

The Company has exposure to foreign exchange on the First Tranche Loan of \$3,600,000 denominated in US dollars. The Company performed a sensitivity analysis on the foreign exchange rate. If the foreign exchange rate as at June 30, 2023 was 5% higher or lower, First Tranche Loan would be \$227,425 higher or \$227,425 lower, respectively.

The Company does not enter into derivative financial instruments to reduce exposure to foreign currency risk.

#### *Liquidity risk*

Liquidity risk is the risk the Company will encounter difficulties in meeting its financial liability obligations as they come due. The Company has a planning and budgeting process in place to help determine the funds required to support the Company's normal operating requirements on an ongoing basis.

The Company controls liquidity risk through management of working capital, cash flows and the availability and sourcing of financing. As described in note 1 of the unaudited interim condensed consolidated financial statements as at June 30, 2023, the Company's ability to accomplish all of its future strategic plans is dependent on obtaining additional financing or executing other strategic options; however, there is no assurance that the Company will achieve these objectives.

The following table outlines the contractual repayments for long-term debt, which includes loans with a set repayment schedule, as well as loans that are repayable based on a percentage of revenues, for the Company's financial liabilities. The long-term debt is comprised of the contributions received described in note 6 of the unaudited interim condensed consolidated financial statements as at June 30, 2023:

	<b>Total</b>	<b>Year 1</b>	<b>Years 2 to 3</b>	<b>Years 4 to 5</b>	<b>After 5 Years</b>
	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>
Accounts payable and accrued liabilities	3,197,520	3,197,520	-	-	-
Long-term debt	8,172,230	352,073	4,924,467	348,086	2,547,604
	<u>11,369,750</u>	<u>3,549,593</u>	<u>4,924,467</u>	<u>348,086</u>	<u>2,547,604</u>

## **ADDITIONAL INFORMATION**

Additional information relating to the Company, including the Company's annual information dated June 22, 2023., filed in respect of the fiscal year ended March 31, 2023, is available under the Company's profile on SEDAR+ at [www.sedarplus.ca](http://www.sedarplus.ca).