



Appili Therapeutics Inc.



TSX: APLI / OTCPink: APLIF

CORPORATE DECK



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This presentation contains forward-looking statements or forward-looking information under applicable Canadian securities legislation (collectively herein referred to as “forward-looking statements”) that may not be based on historical fact, and can often be identified by words such as “believe,” “may,” “plan,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “expect,” “predict,” “project,” “potential,” “continue,” “ongoing” or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words and similar expressions. Forward-looking statements are necessarily based on estimates and assumptions made by the Company in light of its experience and perception of historical trends, current conditions and expected future developments, as well as the factors the Company believes are appropriate. Forward-looking statements in this presentation may include, but are not limited to, statements relating to: (i) the Company’s strategy, including product pipeline and upcoming milestones; (ii) potential sources of funding; (iii) the Company’s expected outcomes from its ongoing and future research and research collaborations; (iv) the Company’s exploration of opportunities to maximize shareholder value as part of the ordinary course of its business through collaborations, strategic partnerships and other transactions with third parties; (v) the Company’s plans for the research and development of certain product candidates; (vi) the Company’s ability to identify licensable products or research suitable for licensing and commercialization; (vii) the Company’s plans for generating revenue; and (viii) the Company’s plans for future clinical trials.

Forward-looking statements are expectations only and are subject to known and risks and uncertainties, including, among others: risks relating to limited operating history and early stage of development, risks relating to identifying, developing and commercializing product candidates, regulatory risks, risks related to market competition, risks related to the Company’s dependence on third parties, clinical trial risks, third party manufacturing and supplier risks, risks related to the ownership and protection of intellectual property, litigation and product liability risks, risks related to employee matters and managing growth, general risks related to ownership of the Company’s securities and the other risk factors discussed in Appili’s annual information form dated June 29, 2022. These factors should be considered carefully, and readers are cautioned not to place undue reliance on such forward-looking statements. In making the forward-looking statements included in this presentation, the Company has made various material assumptions, including, without limitation, those related to: (i) obtaining positive results of clinical trials; (ii) obtaining regulatory approvals; (iii) general business and economic conditions; (iv) the Company’s ability to successfully out-license or sell its current products and in-license and develop new products; (v) the availability of financing on reasonable terms; (vi) the Company’s ability to attract and retain skilled staff; (vii) market competition; (viii) the products and technology offered by the Company’s competitors; and (ix) the Company’s ability to protect patents and proprietary rights; (x) priority review voucher (PRV) eligibility of certain of the Company’s programs; and (xi) the ability of the Company to successfully partner with the U.S. Department of Defense to advance ATI-1701 and access the requisite funding to do so. Should one or more risks or uncertainties, or a risk that is not currently known to the Company materialize, or should assumptions underlying those forward-looking statements prove incorrect, actual results may vary materially from those described herein.

The Company does not assume any obligation to update any forward-looking statements, except as required by applicable securities laws.

NOVEL ANTI-INFECTIVES COMPANY DRIVING LONG-TERM VALUE



Commercial-stage anti-infectives / biodefense pipeline, anticipating milestones & royalties in 2024



~ \$100M invested (~\$38M Non-Dilutive)



Two programs potentially eligible for Priority Review Vouchers from FDA

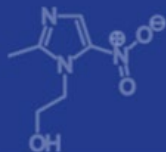


Proven leadership team

PIPELINE SNAPSHOT

LIKMEZ™, novel oral taste-masked suspension of metronidazole to treat serious anaerobic and protozoal infections

- FDA approved, commercialized late 2023
- Formulation provides convenient alternative to patients with difficulty swallowing tablets
- Formulation patented in US through 2039 with EU / LATAM claims following



ATI-1701, potential first-in-class live-attenuated vaccine for tularemia, a serious biothreat

- Awarded \$14.0M funding from USAFA
- Funding used to conduct development and regulatory activities through IND (2025)
- Composition and preparation methods patented through 2039



ATI-1801, novel topical antiparasitic product to treat disfiguring skin infections around the world

- Positive Phase 3 clinical data. Approaching FDA to identify package required for submission
- Identified CDMO and are working on tech transfer



- **Two assets are potentially eligible for priority review vouchers**
- **Strong collaborations with industry partners and federal government agencies**
- **Pursuing non-dilutive funding opportunities**

PRIORITY REVIEW VOUCHER (PRV)

36+	<i>PRV Sales Since Program Inception</i>
\$123M	<i>Average PRV Sale Price (range from \$67.5 to \$350M)</i>

- **ATI-1701*** and **ATI-1801** may be eligible for PRVs
- PRVs allow holder to accelerate FDA review of any NDA
- **Granted by FDA to reward R&D in target areas**
 - *Rare pediatric disease*
 - *Tropical disease*
 - *Medical countermeasures*
- **PRVs are transferrable with a robust secondary market**

*Subject to extension of medical countermeasure legislation

2022+ Disclosed Transactions		
Seller	Buyer	Price
 BIOMARIN [®]	Undisclosed	\$110M
 bridgebio	Undisclosed	\$110M
 MARINUS	 novo nordisk [®]	\$110M
 Mallinckrodt	 NOVARTIS	\$100M
 bluebirdbio [™]	 argenx [✓]	\$102M
 bluebirdbio [™]	Undisclosed	\$95M
 Pharming [®]	 NOVARTIS	\$21M*
 SAREPTA THERAPEUTICS	Undisclosed	\$102M
 Krystal	Undisclosed	\$100M



ATI-1701

Tularemia Vaccine

ATI-1701: BIODEFENSE VACCINE WITH ~14M IN DOD FUNDING



Opportunity

- *Francisella tularensis* is a top priority biothreat
- 1,000X more infectious than anthrax - highly lethal
- No FDA approved vaccine available

Solution

- ATI-1701 is a novel, live-attenuated tularemia vaccine candidate

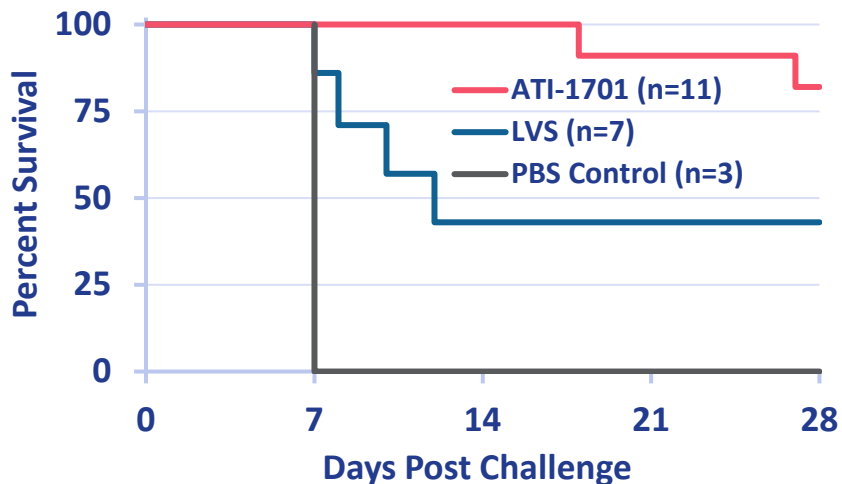
Unique Development Path with Funding

- DoD providing ~\$14M in non-dilutive funding
- FDA's Animal Rule approval pathway
- PRV and Fast-Track designation applications planned

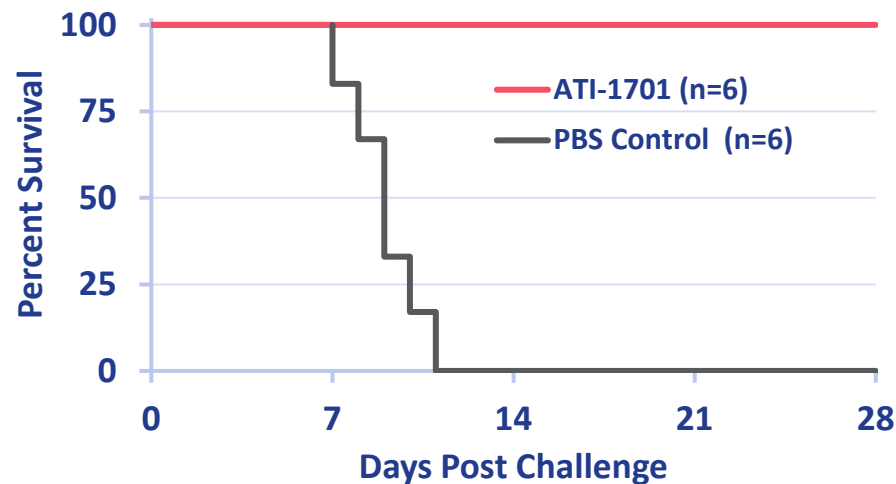
DEMONSTRATED EFFICACY IN NON-CLINICAL STUDIES

ATI-1701 protective against lethal aerosolized *F. tularensis* challenge and superior to LVS in cynomolgus macaques

28 Days Post Vaccination



90 Days Post Vaccination



Note: Administered a very high challenge dose of aerosolized pathogenic *F. tularensis* to demonstrate the robust efficacy of ATI-1701

ATI-1701 is also effective in rats for 365 days post-vaccination

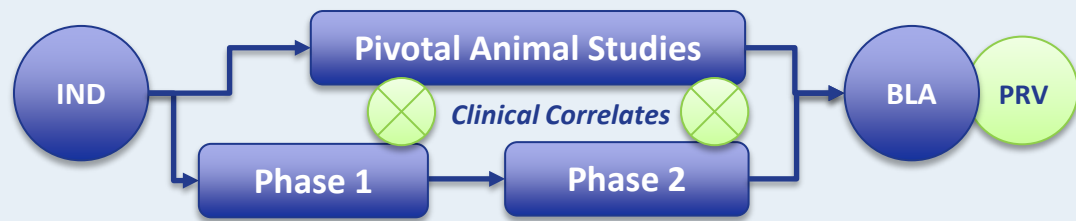
DEVELOPMENT PATH AND FUNDING

USAFA (DTRA) funding of ~ \$14M reaffirms DoD commitment to ATI-1701 through IND



- **US Air Force Academy** (*Prime Contractor*) and **Appili** (*Top Tier Contractor*) are driving ATI-1701 development through IND
- IND late 2024 / Phase 1 start in late 2025 / early 2026

Initiate clinical and animal studies to support FDA Animal Rule submission



- Pivotal animal studies replace clinical efficacy studies
- Clinical correlates link studies
- Seeking non-dilutive funding

MARKET OPPORTUNITY FOR BIODEFENSE VACCINE

Substantial stockpiling opportunities expected before approval

Potential Military Use (NATO +)

- Tularemia weaponized since mid 1900s; Iran, North Korea and Russia may stockpile
- Claims that the Soviet Union deployed *F. tularensis* in Stalingrad in WWII; similar conditions exist in Ukraine today
- 500K+ Israeli, South Korean soldiers at risk
- Potential deployment to hot zones; 1.4M+ US soldiers deployed to Middle East in OIF / OEF



Civilian Stockpiling (US)

- Strategic National Stockpile (SNS) to secure medical counter measures for US civilians
- Managed by CDC, US Dept. of Health & Health and Human Services (HHS)



Stockpiling Benchmarks

- **SIGA (2018):** Up to \$629M for 1.7M courses of smallpox antiviral TPOXX®
- **Bavarian Nordic (2017):** Up to \$539M for bulk smallpox vaccine Imvamune®
- **Emergent (2016):** Up to \$1.6B for 52M units of anthrax vaccine NuThrax®
- **Emergent (2011):** Up to \$1.25B for 44.75M units of anthrax vaccine Biothrax®
- **SIGA (2011):** Up to \$472M for 2M courses of smallpox antiviral ST-246 (now TPOXX®)

HHS can procure biodefense agents prior to FDA approval

All financial data in USD



ATI-1801

Topical Treatment for Cutaneous Leishmaniasis

CUTANEOUS LEISHMANIASIS (CL) HAS SIGNIFICANT UNMET NEED

Opportunity: *CL is a common and disfiguring disease without appropriate treatment options*

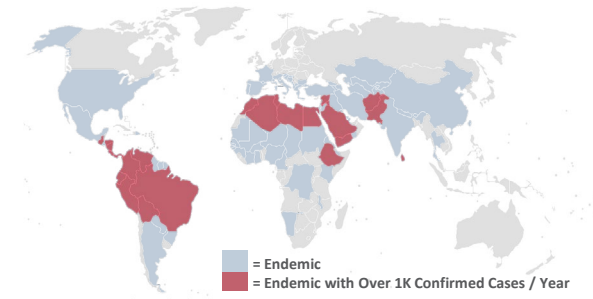
- Leishmaniasis is an obligate intracellular parasite that is transmitted to humans by sandfly bites
- Skin lesions (ulcers/papules) are the typical clinical manifestation of CL infections
- Infection leads to scarring and stigmatization



- Most common in Latin America, Middle East, North Africa but increasing in US / EU
- WHO estimates 700K to 1.2M cases / yr
- Current therapies (antimonials and miltefosine) are invasive, toxic, and/or require hospitalization limiting access



Cutaneous Leishmaniasis Global Footprint

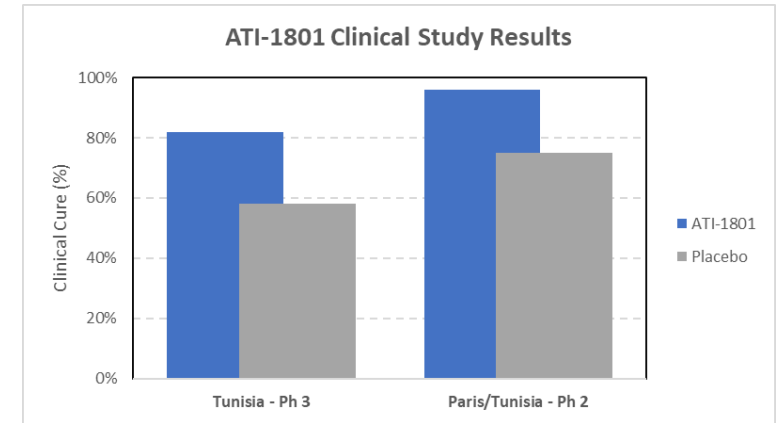


Safe, effective, and convenient (at home) therapy is urgently needed

ATI-1801: NOVEL TOPICAL TREATMENT FOR CL

Solution

- Easy-to-use topical cream formulation of paromomycin
- Repurposed drug (approved for intestinal amebiasis in 1960s)
- Potent activity against New World and Old-World species of leishmaniasis
- Low clinical risk – positive results in several Phase 2 and 3 studies
- USAMMDA developed ATI-1801 through Phase 3 in uncomplicated CL



PATHWAYS TO MONETIZE ATI-1801

FDA approval path could lead to PRV and then open up Prequalification Path



CDMO Tech Transfer initiates the next steps



• Regulatory Approval

- Bridging study likely required to link to prior efficacy studies
- Applied for grants to fund clinical study requirements, seeking other non-dilutive sources for other submission requirements

• Apply for PRV with NDA submission



• Prequalification of Medicines Program

- Established to provide high quality medications for low-income countries
- 646 drugs are prequalified, 85% of those are anti-infectives / antivirals
- WHO's prequalified medicinal products are purchased in bulk by int'l procurement agencies for low-income countries
- WHO spent >\$170M for drug contracts in 2021, with contracts averaging from \$4.5 to 8.4M

• Planning to engage with WHO

LIKMEZ™

Taste-Masked Liquid Metronidazole

LIKMEZ™ , Metronidazole Oral Suspension 500mg/5mL approved by FDA in September 2023.

- LIKMEZ is a novel oral taste-masked suspension of metronidazole to treat serious anaerobic and protozoal infections.
- LIKMEZ is the **first FDA approved oral liquid form available**; the current tablet form of metronidazole is the only other approved oral form on the U.S. market

Opportunity

- Metronidazole is heavily prescribed in US with **10M+ oral scripts**
- Pediatric and elderly patients with difficulty swallowing tablets must crush and resuspend to take their dose. Process exacerbates metronidazole's bitter taste which promotes non-compliance and switching to alternative products



Solution



- **LIKMEZ™** , only liquid oral suspension of metronidazole approved in the U.S
- Solves significant issue for patients who cannot tolerate the current tablet formulation

Out-licensing deal brings income streams to Appili

- License agreement with Saptalis for US rights (Dec 19) and EU/Latin American rights (Feb 22)
- **U.S. patent coverage** protects the composition and preparation methods **through 2039**
- Expecting **milestone and royalty payments** based on Saptalis' **commercialization plans (2024+)**



UPCOMING MILESTONES

Program	Partners	Discovery	Preclinical	Phase I	Phase II	Phase III	Regulatory Submission / Approval
ATI-1701 Tularemia Vaccine (Biodefense)		Complete	Ongoing	2024	2026	Animal Rule Pivotal animal studies replace pivotal human studies	2028 / 2029 Potential PRV & Stockpiling
ATI-1801 Topical Paromomycin	Search ongoing	Complete			Ongoing	2027 / 2028 Potential PRV & NGO Contracts	
Out-Licensed Program							
LIKMEZ™ Metronidazole Oral Suspension		Complete			505(b)(2) Phase II/III trials not required	Complete	Milestones & Royalties – early 2024

▶ Complete
 ▶ In Progress
 ▶ Planned

Note: Anticipated timing, costs and funding are best estimates based on assumptions relating to regulatory requirements and funding agency acceptance



- **USAFA Award** expected to enable us to advance **ATI-1701 to IND**
- **Requesting FDA meeting** to discuss **ATI-1801** previously generated **Phase 3 data** and agree on the necessary registration package to **support NDA**
- Expect to receive **milestone and royalty payments** for **LIKMEZ™** based on Saptalis' **commercialization plans**



ATI-1501 Market Opportunity

- Over 10M oral Metronidazole scripts in the U.S.
- **LIKMEZ™** first FDA approved liquid oral form available

DIVERSIFIED PIPELINE DRIVING NEAR- AND LONG-TERM VALUE

Program	Partners	Discovery	Preclinical	Phase I	Phase II	Phase III	Regulatory Submission / Approval
ATI-1701 Tularemia Vaccine (Biodefense)		Complete	Ongoing	2024	2026	Animal Rule Pivotal animal studies replace pivotal human studies	2028 / 2029 Potential PRV & Stockpiling
ATI-1801 Topical Paromomycin	Search ongoing	Complete			Ongoing	2027 / 2028	Potential PRV & NGO Contracts
Out-Licensed Program							
LIKMEZ™ Metronidazole Oral Suspension		Complete			505(b)(2) Phase II/III trials not required	Complete	Milestones & Royalties – early 2024

 Complete
  In Progress
  Planned

Note: Anticipated timing, costs and funding are best estimates based on assumptions relating to regulatory requirements and funding agency acceptance

SKILLED MANAGEMENT TEAM TO DELIVER PORTFOLIO VALUE



DON CILLA, PHARMD, MBA

PRESIDENT AND CHIEF EXECUTIVE OFFICER

30+ years drug development experience, including clinical, clinical pharmacology and program leadership positions for many marketed compounds



KENNETH HOWLING

ACTING CHIEF FINANCIAL OFFICER

25+ years of financial management and public company experience in Pharma



GARY NABORS, PHD

CHIEF DEVELOPEMENT OFFICER

25+ years experience leading vaccine and antibody product development for infectious disease indications



CARL GELHAUS, PHD

DIRECTOR, NON-CLINICAL RESEARCH

20+ years infectious disease and animal model experience; founding member of the tularemia international society



ARTHUR BARAN, MBA, PMP

DIRECTOR, NEW PRODUCT DEVELOPMENT

20+ years CMC and global product operations leadership experience in the pharmaceutical industry



APPILI MANAGEMENT TEAM HAS SUBSTANTIAL EXPERIENCE



DON CILLA, PHARMD, MBA
PRESIDENT AND CHIEF EXECUTIVE OFFICER



KENNETH HOWLING
ACTING CHIEF FINANCIAL OFFICER



GARY NABORS, PHD
CHIEF DEVELOPMENT OFFICER



CARL GELHAUS, PHD
DIRECTOR, NON-CLINICAL RESEARCH



ARTHUR BARAN, MBA, PMP
DIRECTOR, NEW PRODUCT DEVELOPMENT

- Over 140 years of cumulative pharma experience
- Worked in 22 other biotech / pharma companies, 6 were in top 12
- Worked on > 100 programs; incl small molecules, biologics, and vaccines
- Involved in 16 NDA/BLA filings and 4 FDA Advisory Committees
- Contributed to development of 43 marketed drugs
- Managing/raising capital, including > \$2.5B from equity markets and > \$1B from non-dilutive sources

Access to Key Consultants

- Regulatory
(Leona Saunders)
- Clinical/Medical
(Scott White)
- Biologics GMP
(Greg Liposky)
- Biologic Assays
(Laureen Little)
- Non-Clinical
(Robert House)
- Vaccine Regulatory
(Wellington Sun)
- Clinical P'cology
(Jeff Lazar)

BOARD OF DIRECTORS



LT COL ARMAND BALBONI, MD, PHD, JD

CHAIR

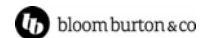
Extensive drug development experience in civilian, academic, and military organizations



BRIAN BLOOM

MEMBER

Chairman and CEO of Bloom Burton & Co, 20+ years of capital market experience



THERESA MATKOVITS, PHD

LEAD INDEPENDENT DIRECTOR

20+ years of experience as a leader in global drug development, with extensive expertise in infectious disease



PRAKASH GOWD, MBA, PHARM, CDIR

MEMBER

25+ years biopharma experience, including corporate development, fundraising, and marketing across multiple business models and therapeutic areas



JUERGEN FROELICH, MD

MEMBER

30+ years of biotech experience including all phases of drug development and regulatory interactions



DON CILLA, PHARMD, MBA

MEMBER

30+ years drug development experience, including clinical, clinical pharmacology and program leadership positions for many marketed compounds



FINANCIAL OVERVIEW AND CAPITAL STRUCTURE

FINANCING (As of June 30, 2023)

Capital Raised:

- **\$102.9M** raised in total
 - **\$58.0M** in equity
 - **\$ 7.0M** in debt (Long Zone Holdings)
 - **\$37.9M** in government assistance

Cash & cash resources

- Cash & Short-term Investments: **\$0.5M**

CAPITAL STRUCTURE (As of June 30, 2023)

121.3M Common shares outstanding
58.2M Warrants
7.8M Options
187.3M Fully diluted

STOCK INFORMATION (As of March 31, 2024)

TSX: APLI

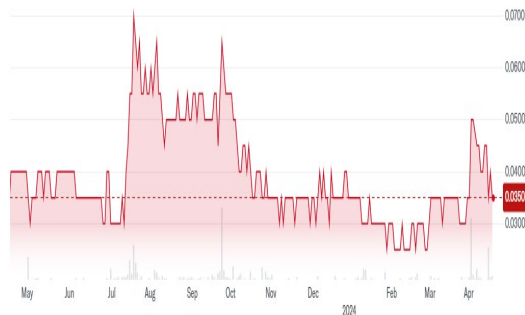
Listed June 25, 2019

\$0.025 - \$0.08

52 week low-high

\$4.3M

Market Cap @\$0.035/share



SIGNIFICANT OWNERSHIP (As of June 30, 2023)

Bloom Burton & Co. 11.8%

NOVEL ANTI-INFECTIVES COMPANY DRIVING LONG-TERM VALUE



Commercial-stage anti-infectives / biodefense pipeline, anticipating milestones & royalties in 2024



~ \$100M invested (~\$38M Non-Dilutive)



Two programs potentially eligible for Priority Review Vouchers from FDA



Proven leadership team

CONTACT

For more information contact:

Don Cilla, PharmD, MBA, President and CEO



+1 902.442.4655 ext #1

dcilla@appilitherapeutics.com

www.appilitherapeutics.com

