

Appili Therapeutics Inc

Annual General Meeting

September 2021

TSX: APLI / OTCQX: APLIF



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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 an 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 24, 2020. 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.

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 ANTIMICROBIAL COMPANY DRIVING LONG-TERM VALUE



**SOLID AND DIVERSIFIED PIPELINE
ADDRESSING URGENT GLOBAL UNMET NEEDS**



**MULTIPLE DEVELOPMENT INCENTIVES AND
REVENUE STREAMS**







**STRONG GROWTH STRATEGY AND
FINANCIAL FOUNDATION**



PROVEN LEADERSHIP TEAM

DIVERSIFIED PIPELINE DRIVING NEAR- AND LONG-TERM VALUE

Program	Discovery	Preclinical	Phase I	Phase II	Phase III	Regulatory Submission	Partners
Favipiravir Oral Antiviral Tablet	Complete		Ongoing		2021	 FUJIFILM  	
ATI-2307 Novel Antifungal	Complete		2022				
ATI-1701 Tularemia Vaccine (Biodefense)	Complete	Ongoing	2022	Animal Rule Pivotal animal studies pre-Phase I Phase II/III in humans not required			
ATI-1503 Novel Gram- Antibiotic	Ongoing	2021					
Out-Licensed Program							
ATI-1501 Metronidazole Suspension	Complete		505(b)(2) Phase II/III trials not required		2021		

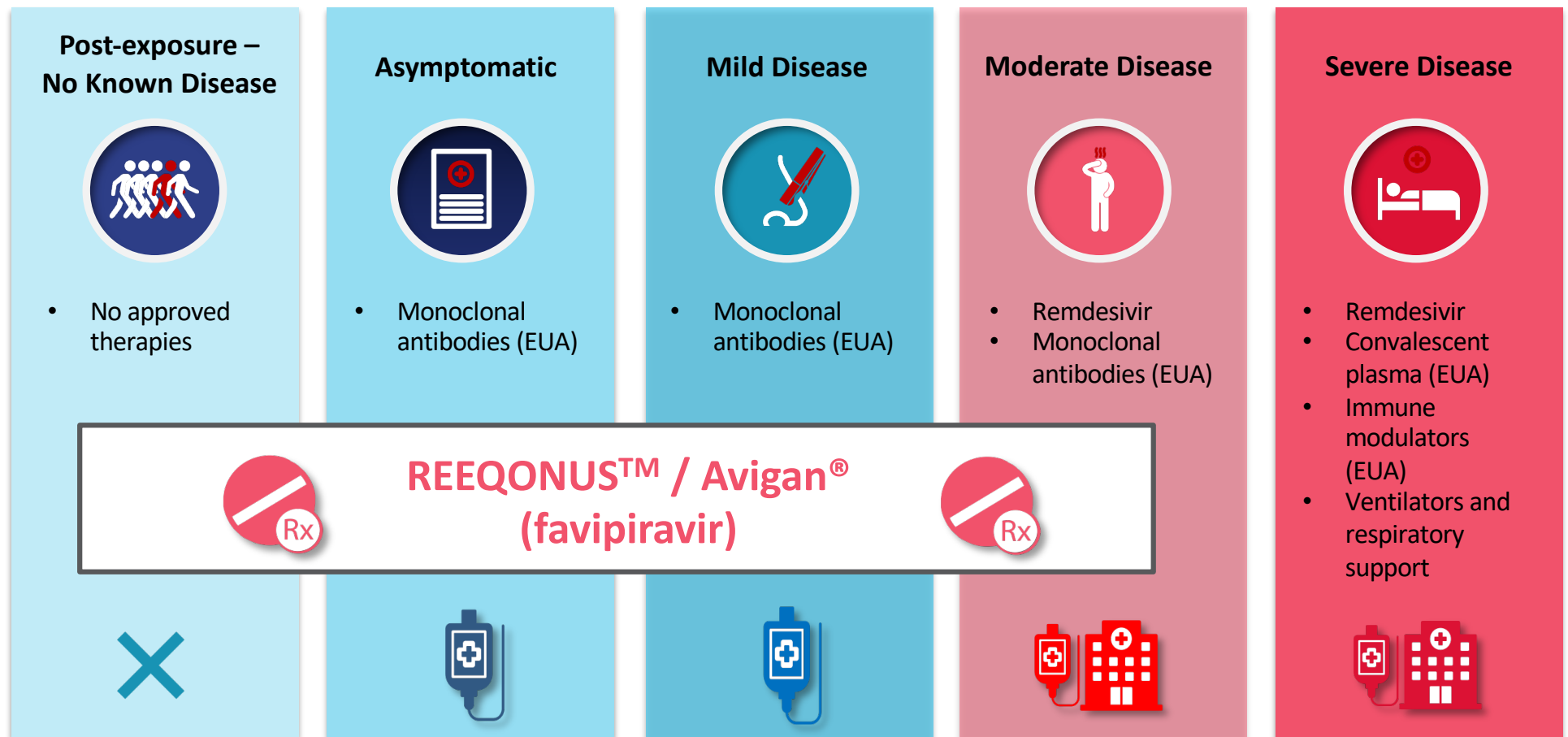
 Complete
  In Progress
  Planned



Favipiravir

Antiviral for Treatment and Prevention of COVID-19

COVID-19 TREATMENT GAP: ORAL ANTIVIRAL NEEDED



EUA=emergency use authorization.

REEQONUS™ / AVIGAN®: PHASE 3 ORAL ANTIVIRAL FOR COVID-19



REEQONUS™ / Avigan® (favipiravir)

- Novel, broad-spectrum oral antiviral
- Approved in Russia and India for COVID-19
- Well-understood mechanism targeting essential viral polymerase
- Promising trial data for mild to moderate COVID-19
- Extensive clinical experience, safety database > 3,000 subjects
- Oral tablet suitable for use at home and outside the hospital
- Shelf stable and compatible with existing distribution channels

Global coalition advancing favipiravir for COVID-19

- Appili working with global partners FUJIFILM, Dr. Reddy's, Global Response Aid
- Team built to support rapid development, and sustainable long-term supply
- Clinical program underway to definitively assess safety and efficacy
- Engaging with governments on access / supply

APPILI
THERAPEUTICS

Dr.Reddy's



GLOBAL
RESPONSE
AID

FUJIFILM

APPILI
THERAPEUTICS

REEQONUS™ / AVIGAN® CLINICAL TRIALS

Appili program designed to support global registrations and leverage advantages of oral dose format with focus on early treatment and prevention in the community



THE VALUE OF ORAL ANTIVIRALS



Benefits of oral antivirals

- Opportunity to rapidly intervene prior to or early after infection when viral loads are highest
- Potential to limit spread of disease, duration and progression to severe illness, hospitalizations
- Significant public health and economic benefits enabling reopening of the economy
- Durable need even after vaccine is available, protecting and treating high-risk groups including the elderly

Prior experience with Roche's Tamiflu® underscores value of oral antiviral, even when vaccine is available

2009 H1N1 Influenza Pandemic

Over \$3B

*Global Tamiflu® Sales
2009*


8.7M / \$905M

*Estimated US Outpatient Rx / Sales
Excluding Stockpile
2009*

Seasonal Influenza

Over \$500M

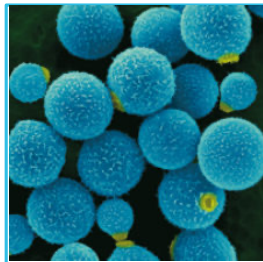
*Annual US Tamiflu® Sales
2014-2015*

The background of the slide features a close-up, shallow depth-of-field photograph of an intravenous (IV) drip chamber. The chamber is a clear plastic device with a white plastic body and a blue roller wheel. It is suspended and contains a clear liquid. A clear plastic tube leads from the bottom of the chamber, and a small, clear droplet is visible just above the needle tip. The background is blurred, showing hints of a clinical setting with warm lighting on the left and cooler blue tones on the right. A solid blue horizontal band is superimposed over the lower half of the image, serving as a background for the text.

ATI-2307

Novel Clinical Stage Antifungal

CRYPTOCOCCUS AND CANDIDA: URGENT, GLOBAL UNMET NEEDS



Cryptococcus

Opportunistic, invasive infection causing meningitis; underserved and growing orphan segment



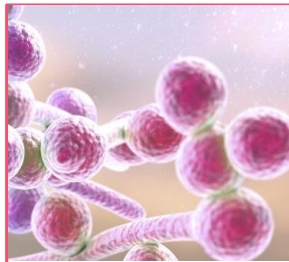
Heavy global disease burden with high mortality

- Neglected, decades old public health crisis
- Unacceptable loss of life, political will to fix



Suboptimal outcomes with toxic standard of care

- Severe infections treated with toxic agents
 - In-hospital mortality >10%
 - Average hospital stay 15 days
 - Costs estimated >\$70K/case



Candida

Among the most common fungal pathogens; resistance is threatening existing antifungal arsenal

- CDC estimates **over 34K drug-resistant cases** in US annually
- Last resort agent amphotericin B is highly toxic



- Multiple segments of urgent unmet need, including:
 - Refractory and resistant *Candida* UTI
 - Emergent, highly resistant *C. auris* infections

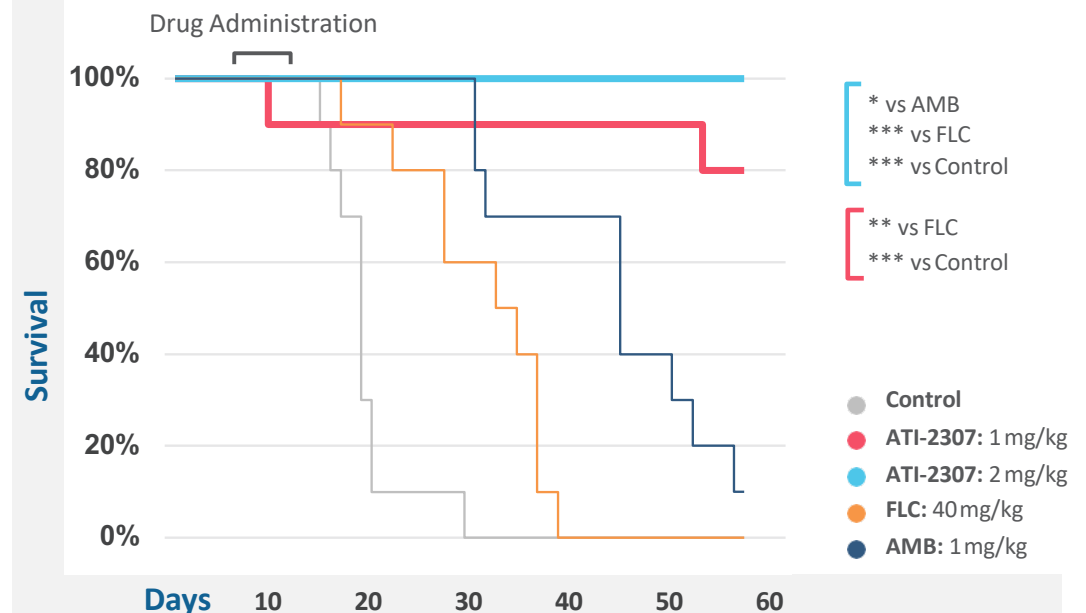
ATI-2307: NOVEL ANTIFUNGAL WITH DIFFERENTIATED MECHANISM OF ACTION

New treatment option for physicians to overcome difficult to treat and resistant fungal infections like *Cryptococcus* and *Candida*

- A novel antifungal with broad spectrum activity against a wide array of fungi, including *Candida*, *Aspergillus* and *Cryptococcus*
- 100% survival in lethal lung infection model
- Evaluated in 3 Phase 1 studies; safe and well tolerated at anticipated Phase 2 dose levels

Survival Data
AMB = Amphotericin B
FLC = Fluconazole
* / ** / *** = p < 0.05 / 0.01 / 0.001 by log-rank test

Intrapulmonary Cryptococcus Infection Model



Mitsuyama J (2008) Antimicrob Agent Chemother 52: 1318-1324 Kaeriyama M (2013) ICAAC Poster M-771

Appili Data on File

ATI 2307: MULTIPLE ATTRACTIVE MARKET OPPORTUNITIES + PRV ELIGIBLE

US Orphan *Cryptococcal Meningitis* Market



Over 5,000 Rx

Estimated based on
amphotericin B Rx/year
for indication

IQVIA
+ Appili Analyses



\$350M US market

potential at \$70K per Rx

\$60K - \$90K per Rx premium
pricing supported by payer
research*

RESEARCH AMERICA
MARKET RESEARCH • CONSUMER INSIGHT

US Refractory / Resistant *Candida* Markets

- Drug-Resistant *Candida*
 - **34.8K Cases / 1.7K Deaths** (CDC estimates for 2017)

- *Candida auris*
 - 90% resistant to at least ONE antifungal
 - 30% resistant to at least TWO antifungals



318% case increase
2018 vs 2015-2017

+ Ex-US Markets

ANTIFUNGAL BENCHMARKS AND VALUATIONS

Recent Approval: Cresemba®



- Developed by Basilea
- Azole Derivative
- FDA Approval in 2015

US License

Total Value: Over \$400M

+ double-digit royalties



Signed in 2010, amended in 2014, 2015

EU + APAC License

Total Value: Over \$700M

+ mid-teen royalties



Signed and amended in 2017

Valuations & Funds Raised*

Phase 2



\$90M+ Series C
2017-2020



\$120M Raised
2016 & 2019

Phase 3



\$151.6M
NASDAQ: SCYX, Aug 31, 2021



\$113.4M
NASDAQ: CDTX, Aug 31, 2021

+ Ex-US/Japan Partnership
Total value: Over \$568M
+ double-digit royalties



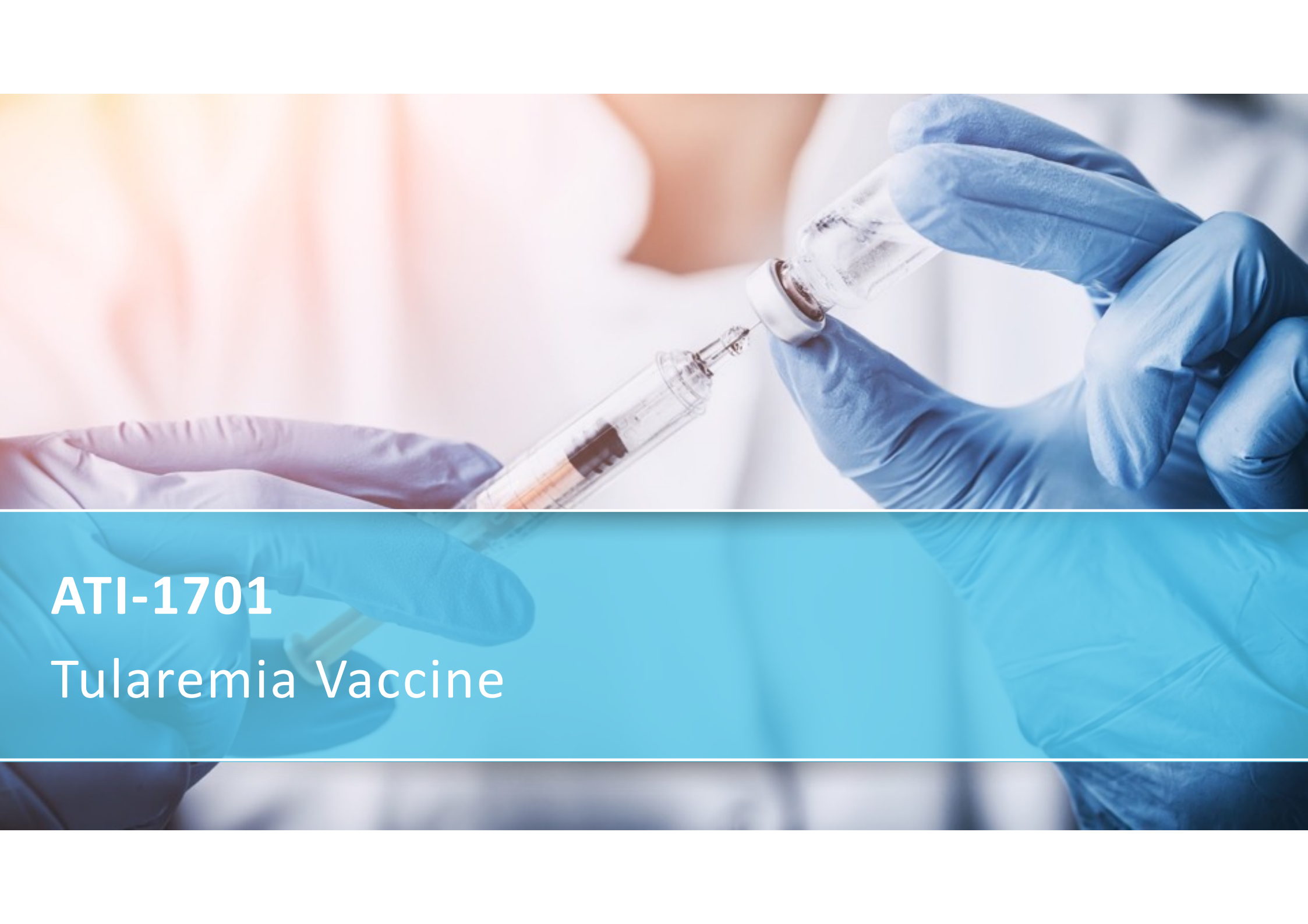
Announced Sept 2019

CRESEMBA® FDA Label (2015)
Basilea 2016 Annual Report
GlobalData (2019) Basilea– Astellas Deal Report
GlobalData (2019) Basilea-Pfizer Deal Report

Astellas PR Feb 24 2010
Basilea PR Dec 01 2017
F2G PR Jun 20 2016
Amplifyx PR Aug 02 2017

Cidara / Mundipharma Joint PR Sep 03 2019
Bloomberg (2021) queries: SCYX, CDTX, close of market

*for companies where valuation data available and primarily driven by clinical stage antifungal asset(s)
Values in USD



ATI-1701

Tularemia Vaccine

ATI-1701: BIODEFENSE VACCINE PROGRAM

Problem

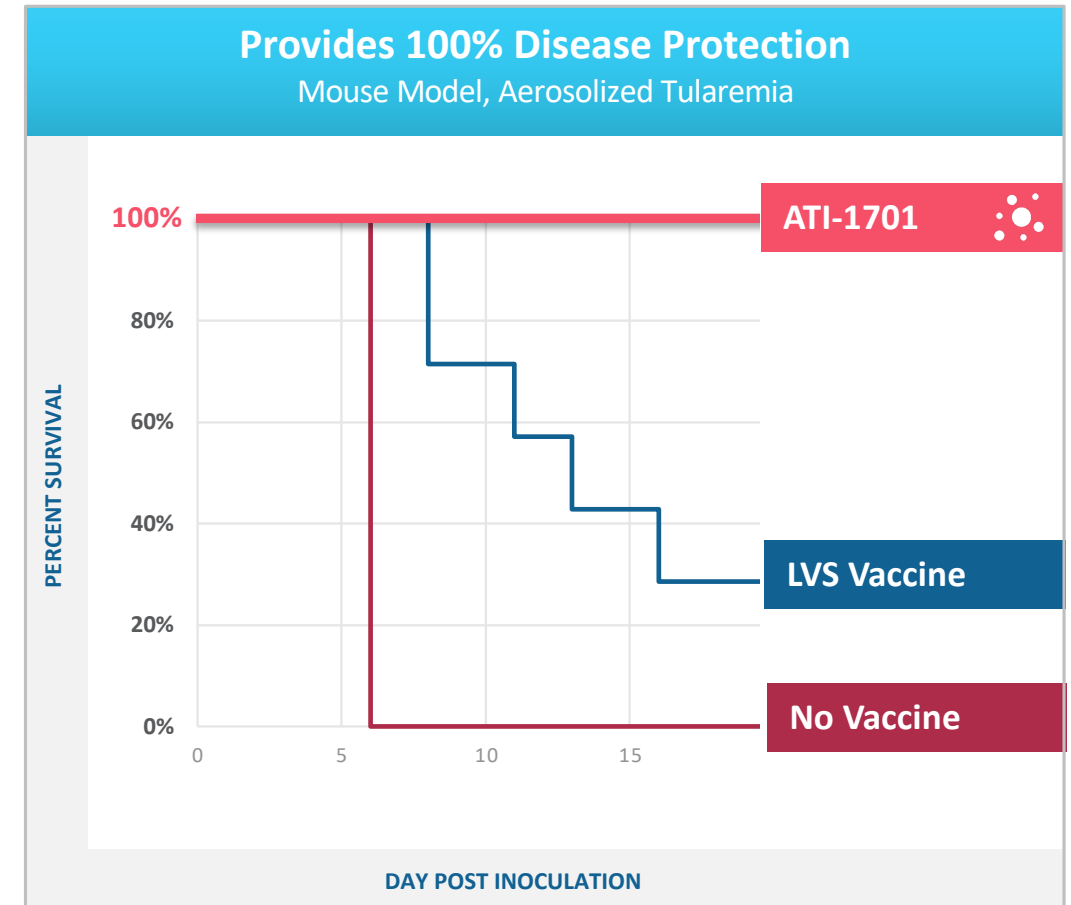
- *Francisella tularensis* is 1,000X more infectious than anthrax and easily dispersed
- No FDA approved vaccine available
- Medical Counter Measure (MCM) needed for military, civilians

Solution

- ATI-1701 is a novel, live-attenuated tularemia vaccine candidate
- Superior to LVS in nonclinical study conferring 100% survival

Unique Development Path

- Alternative development per FDA's Animal Rule
- Priority Review + Fast Track designation
- US DOD DTRA supported with ~\$6M USD to May 2021
- Additional \$6.3M USD in DTRA funding announced October 2020

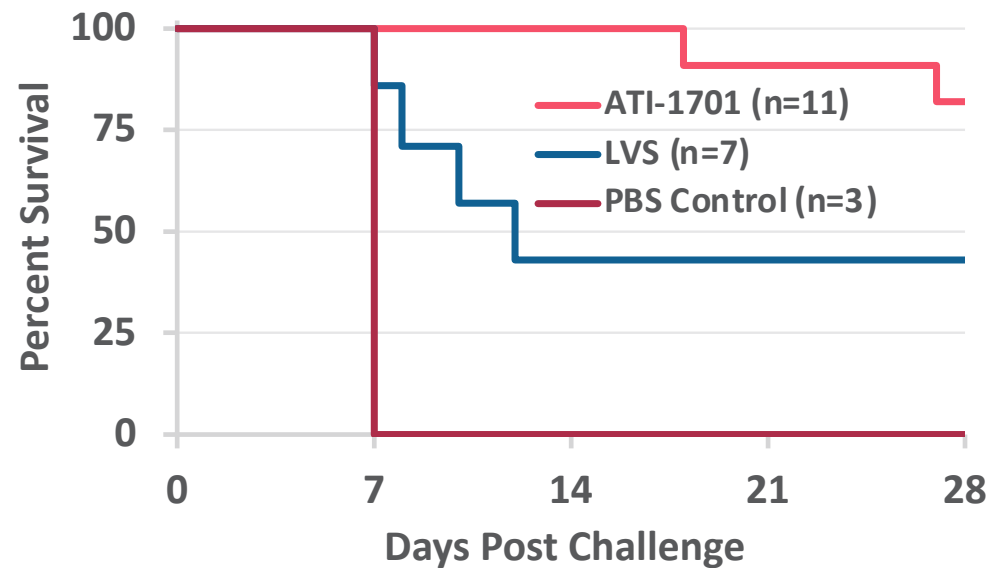


ONGOING NON-HUMAN PRIMATE STUDY

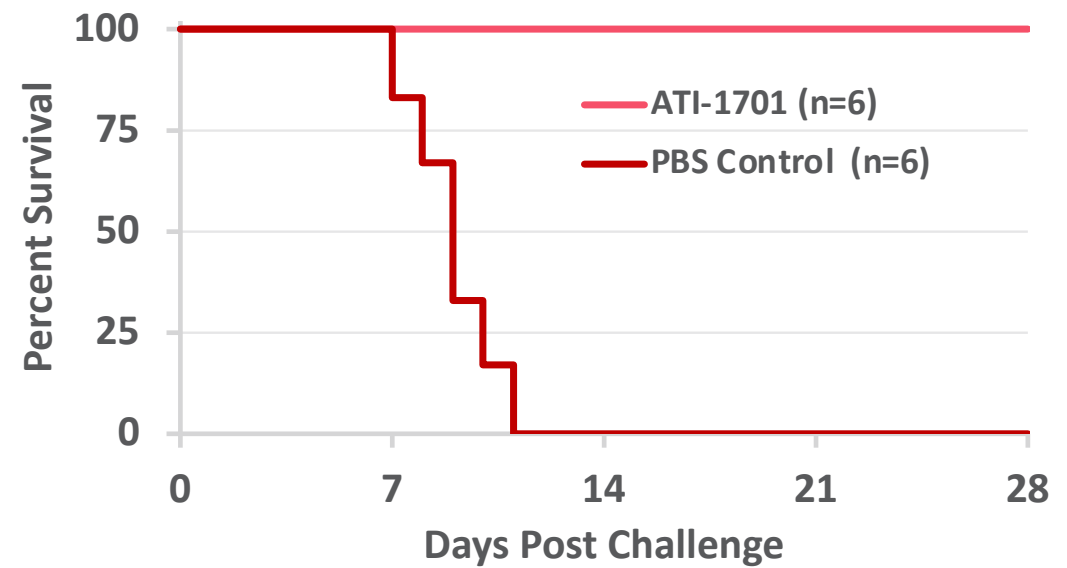


Survival Data

28 Days Post Vaccination



90 Days Post Vaccination



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

MARKET OPPORTUNITY

Civilian Stockpiling (US)

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



Potential Military Use (US +)

- Tularemia weaponized since mid 1900s; Iran, North Korea and Russia may stockpile
- 500K+ Israeli, South Korean soldiers at risk
- Potential deployment to hot zones; 1.4M+ US soldiers deployed to Middle East in OIF / OEF



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 has authority to procure biodefense agents prior to FDA approval

+ PRV eligible (\$100M+)



MULTIPLE DEVELOPMENT INCENTIVES AND REVENUE STREAMS

MULTIPLE INCENTIVES FOR INFECTIOUS DISEASE ASSETS

R&D Funding

Multiple US and global funding sources to support preclinical and clinical development



National Institutes of Health



CARB-X



AMR action fund

+ recently announced \$3B US government funding for pandemic antivirals

Regulatory Reforms

Led by US FDA, new regulatory pathways to accelerate and promote anti-infective R&D



For eligible products:

- Special designations for accelerated review
- Streamlined Phase 2/3 development pathways
- Extended regulatory exclusivity (+ 5 years)
- Priority review vouchers on approval

Similar programs under consideration ex-US

Additional Revenue Streams

Anti-infectives can generate revenues via multiple mechanisms – potential to supplement commercial sales

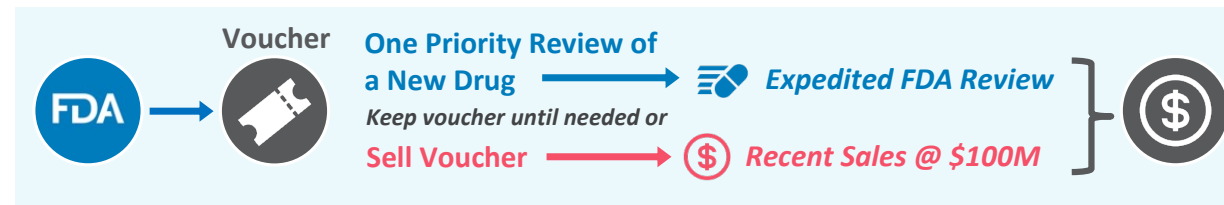
- Government stockpiling of priority medicines including US contracts for \$200M to \$1B+
- Pilot subscription models guaranteeing revenues post approval launched in EU
- Priority review voucher sales (\$100M+)
- Additional reforms under review by US Congress - PASTEUR Act

PRIORITY REVIEW VOUCHER

Multiple Appili programs including ATI-2307 and ATI-1701 may be eligible for a priority review voucher

What is a priority review voucher (PRV)?

- Allow holder to accelerate FDA review of any NDA
- Granted by FDA to reward R&D in target areas
 - Rare pediatric disease
 - Tropical disease
 - Biodefense
- PRVs are **transferrable**, sale prices around \$100M



Date	Sell	Purchaser	Value (USD)
H2 2014	BioMarin	Sanofi / Regeneron	\$67.5M
H2 2014	Knight Therapeutics	Gilead	\$125M
H1 2015	Asklepion / Retrophin	Sanofi	\$245M
H2 2015	United Therapeutics	AbbVie	\$350M
H2 2016	PaxVax	Gilead	\$290M
2017	5 separate transactions		\$125M - \$150M
2018	3 separate transactions		\$80M - \$110M
2019	3 separate transactions		\$95M - \$105M
2020	5 separate transactions		\$95M - \$111M
H1 2021	Rhythm Pharmaceuticals	Alexion	\$100M
H2 2021	Liminal BioSciences	-	\$105M

At least two additional transactions with no financials disclosed, both involving Novo Nordisk as buyer

BUSINESS DEVELOPMENT: BUILDING AND ADVANCING ID PIPELINE



Company built to find and advance ID programs



Robust in-licensing strategy to identify overlooked assets

- Agnostic to any particular platform or technology
- Pharma, academia, government agencies
- Constantly analyzing programs to identify those that can address compelling unmet needs



Establishing relationships with pharma for future commercialization

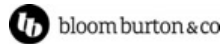
SKILLED MANAGEMENT TEAM



ARMAND BALBONI

CHIEF EXECUTIVE OFFICER

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



MYRIAM TRIEST

SR. DIRECTOR, MANUFACTURING AND PHARMACEUTICAL DEVELOPMENT

20+ years as a drug development professional and PhD chemist; discovery to Phase 3



YOAV GOLAN, MD

CHIEF MEDICAL OFFICER

30+ years as an infectious disease physician; published research on *C. difficile* infections and invasive candidiasis



STÉPHANE PAQUETTE

SENIOR DIRECTOR, CORPORATE DEVELOPMENT

10+ years infectious disease and industry R&D experience; PhD in virology & immunology



KIMBERLY STEPHENS

CHIEF FINANCIAL OFFICER

CPA, CA 20+ years of financial management and public company experience



JASON MCEWAN

DIRECTOR, REGULATORY AFFAIRS

15+ years of regulatory consulting for Canada and the US; part of team receiving the Deputy Minister Award for his work during a major global healthcare crisis.



DON CILLA, PHARMD, MBA

CHIEF DEVELOPMENT OFFICER

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



BOARD OF DIRECTORS



IAN MORTIMER

CHAIR

President and Chief Financial Officer of Xenon Pharmaceuticals Inc, 20+ years of experience in the biotechnology sector



BRIAN BLOOM

MEMBER

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



JUERGEN FROEHLICH, MD

MEMBER

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



THERESA MATKOVITS, PhD

MEMBER

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



ROCHELLE STENZLER

MEMBER

25+ years of experience as a board director and senior operating executive in healthcare and other industries.



ARMAND BALBONI

MEMBER

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



FINANCIAL OVERVIEW AND CAPITAL STRUCTURE

FINANCING (As of August 31, 2021)

Capital Raised:

- **\$72.4M** raised in total
 - **\$47.1M** in equity
 - **\$25.3M** in government assistance

Cash & cash resources (June 30, 2021)

- **Cash & Short-term Investments:** **\$9.3M**
- **Government grants (1-2 years):** **\$3.9M USD**

CAPITAL STRUCTURE (As of August 31, 2021)

62.8M Common shares outstanding

14.3M Warrants

6.8M Options

83.9M Fully diluted

STOCK INFORMATION (As of August 31, 2021)

TSX: APLI Graduated to TSX September 16, 2020
\$0.63 - \$1.60 52 week low-high
\$49.6M Market Cap

SIGNIFICANT OWNERSHIP

Bloom Burton & Co.
K2 Principal Fund L.P.
Innovacorp

CONTACT

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 abalboni@appilitherapeutics.com

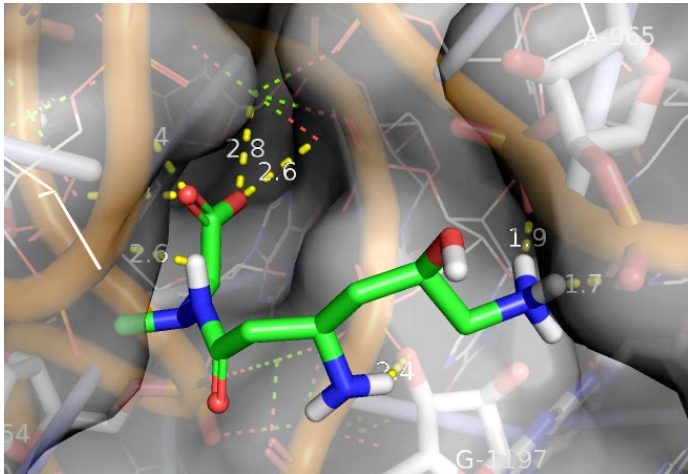
 www.appilitherapeutics.com

A close-up photograph of a male scientist with dark hair and a mustache, wearing a white lab coat and purple nitrile gloves. He is holding a white pipette in his right hand and a small vial in his left hand, looking intently at the camera. The background is a blurred laboratory setting with various equipment and bottles.

ATI-1503

Novel Class of Gram-Negative Antibiotics

NOVEL CLASS GRAM-NEGATIVE ANTIBIOTIC PROGRAM



ATI-1503 Program

- Developing novel class of antibiotics to address antibiotic resistance
- Novel mechanism, active vs *Enterobacteriaceae*, *Pseudomonas*, *Acinetobacter*
- Promising safety, PK, but original compound not potent enough
- Building on AstraZeneca program to improve potency

Recent Developments

- Novel structural biology approaches driving analogue design
- Efficacy gains now >10-fold compared to parent compound negamycin
- Demonstrated *in vivo* proof of concept vs *Klebsiella* and *Escherichia*
- Additional *in vivo* characterization underway focused on safety, PK/PD

Strong Partner Engagement and Funding

- Two Peer Reviewed Medical Research Program (PRMRP) awards: **\$4.2M USD**
- Funding from National Research Council of Canada: **\$759K CDN**
- Preclinical testing with partners at USAMRIID and NIAID



A close-up photograph of an elderly woman with wrinkled skin, wearing a dark purple sweater. She is holding a small, clear glass bottle with a gold-colored cap and pouring a light brown liquid into a white plastic spoon. The background is a plain, light-colored wall.

ATI-1501

Taste-Masked Liquid Metronidazole

TASTE-MASKED LIQUID METRONIDAZOLE

Opportunity

- Metronidazole is a front-line anti-infective that is heavily prescribed in US with 10M+ oral Rx but no approved liquid oral forms
- Pediatrics and elderly with difficulty swallowing tablets must crush and resuspend
- Process exacerbates metronidazole's bitter taste = non-compliance, switching

Solution

- ATI-1501 is a proprietary, taste-masked liquid metronidazole formulation, evaluated in clinic
 - Demonstrated bioequivalence to solid metronidazole tablets
 - Revealed strong and clear palatability improvements vs crushed tablets

Outlicensing Deal

- Announced license agreement with Saptalis Pharmaceuticals for US rights in December 2019
- NDA filing expected in 2021

