

# In the Global Fight Against Infection

February 2021

TSX: APLI / OTCQX: APLIF



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

# APPILI THERAPEUTICS: TACKLING TODAY'S GLOBAL ID CHALLENGES



## ID Portfolio Company

Built to identify and advance promising infectious disease (ID) programs



## Founded by Investment Bank

Backed by leading investment advisory firm



bloom burton & co



## Diversified Pipeline

Diversified pipeline of 5 programs with multiple near-term milestones



## Skilled Leadership Team

Leadership team skilled in advancing programs with upside potential



## Business Development

Active in-licensing / partnering to expand clinical programs and accelerate commercialization

## DIVERSIFIED PIPELINE DRIVING NEAR- AND LONG-TERM VALUE

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


























 Complete
  In Progress
  Planned



# Favipiravir

Antiviral for Treatment and Prevention of COVID-19

# THE COVID-19 TREATMENT SPECTRUM

	No Therapy	Vaccine (Not Approved)	Avigan® (favipiravir)	Other R&D Antivirals (Not Approved)	Monoclonal Antibodies (EUA)	Convalescent plasma (EUA)	Remdesivir (Approved)	Dexamethasone (Not Approved)	Ventilators & Respiratory Support
 Pre Exposure No Disease									
 Post Exposure Unknown Disease									
 Asymptomatic									
 Mild Disease									
 Moderate Disease									
 Severe Disease									

Approved Treatments at this stage

# FAVIPIRAVIR OVERVIEW



## 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





# AVIGAN® (FAVIPIRAVIR) ORAL ANTIVIRAL CLINICAL PROGRAM

Program	Discovery	Preclinical	Phase I	Phase II	Phase III	Regulatory Submission	Partners
<b>Avigan® (favipiravir)</b> Oral Antiviral Tablet	Complete		Ongoing		2021		 <b>Dr.Reddy's</b>  <b>FUJIFILM</b>  GLOBAL RESPONSE AID  Sinai Health
<b>PRESECO</b> Early Treatment Community Ph III US + LATAM / N > 800				2020 / 2021			
<b>PEPCO</b> Post-Exposure Prophylaxis Community Ph III US + Canada / N > 1,100				2020 / 2021			
<b>CONTROL</b> Long-Term Care Outbreak Control Ph II Canada / N > 700			2020 / 2021				

Focused on early-stage community infections in high-risk patients

 Complete
  In Progress
  Planned



## UPDATE ON APPILI TRIALS



### Now enrolling in two out of three planned trials including pivotal treatment Phase 3 PRESECO

- Overall program focused on early administration to limit spread and severity of COVID-19 in at-risk groups
- Trials include Phase 2 in Ontario long-term care and two Phase 3 early treatment and prophylaxis studies
- Phase 2 enrolling in Canada, treatment Phase 3 now enrolling, and prophylaxis Phase 3 under review
- Integrated with global partners to support global regulatory approvals including Canada and US



### Robust trials focused on early intervention for patient groups at highest risk for severe COVID-19

#### Phase 3

Early Treatment  
COVID-19 Trial  
**PRESECO**

Status: **Enrolling**  
Interim Look: **Q1 2021**  
Top-Line: **Q2 2021**

#### Phase 2

COVID-19 Outbreak Control  
in Ontario Long-Term Care  
**CONTROL**

Status: **Enrolling**  
Top-Line: **Q4 2021**

#### Phase 3

COVID-19 Post-Exposure  
Prophylaxis Trial  
**PEPCO**

Status: **Under Review**  
Top-Line: **Q3 2021**

Confidential



# GLOBAL CONSORTIUM TO DEVELOP ORAL ANTIVIRAL FAVIPIRAVIR



## Global coalition advancing favipiravir for COVID-19

- Appili working with global partners to develop leading COVID-19 antiviral candidate favipiravir
- Consortium includes innovator FUJIFILM, Dr. Reddy's Laboratories, and Global Response Aid
- Team built to support rapid development, regulatory submissions, and sustainable long-term supply
- Clinical program underway to definitively assess favipiravir's role in COVID-19 care



## Coalition Advantages

- ✓ **Proprietary Data:** Access to FUJIFILM data and IP accelerate development and block competitor entry
- ✓ **Robust Trial Infrastructure:** Coordinated global program with multiple near-term trial readouts
- ✓ **Global Manufacturing Scale and Reach:** Leading global manufacturing and distribution partners to maximize supply and revenue following approvals

# 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 photograph of an intravenous (IV) drip chamber. The chamber is a clear plastic device with a white cap and a blue filter. It is connected to a clear plastic IV bag at the top and a clear plastic tube at the bottom. The tube has a blue filter and a clear plastic drip chamber. The background is blurred, showing a hospital setting with a window and some medical equipment. A semi-transparent blue horizontal band is overlaid across the middle of the image, containing the text.

**ATI-2307**

Novel Clinical Stage Antifungal

# URGENT UNMET NEEDS IN *CRYPTOCOCCUS* AND *CANDIDA*

## *Cryptococcus*

- Opportunistic, invasive infection causing meningitis
  - Heavy disease burden globally with high mortality
  - Suboptimal outcomes with toxic standard of care
- Global**
- Neglected, decades old public health crisis
  - Unacceptable loss of life, political will to fix
- US+**
- Severe infections treated with toxic agents
    - In-hospital mortality over 10%
    - Average hospital stay 15 days
    - Costs estimated over \$70K / case
  - Underserved and growing orphan segment

## *Candida*

- Among the most common fungal pathogens
- Resistance threatening existing antifungal arsenal
- CDC estimate **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

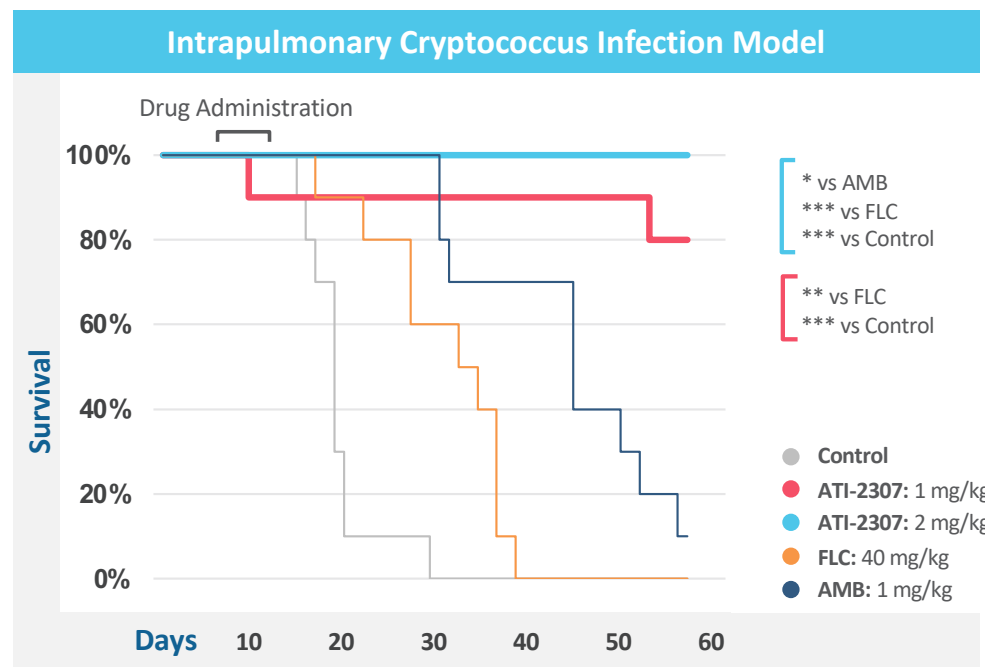
**The New York Times** April 6, 2019 *A Mysterious Infection, Spanning the Globe in a Climate of Secrecy*

The rise of *Candida auris* embodies a serious and growing public health threat: drug-resistant germs.

# ATI-2307: A NOVEL CLINICAL STAGE ANTIFUNGAL

- 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



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

# MULTIPLE ATTRACTIVE MARKET OPPORTUNITIES

## US Orphan Cryptococcal Meningitis Market

**Over 5,000 Rx**

Estimated amphotericin B Rx / year for CM and cryptococcosis

 **IQVIA™** + Appili Analyses

**\$60K-\$90K per Rx**

Premium pricing supported by payer research\*

 **RESEARCH AMERICA**  
MARKET RESEARCH • CONSUMER INSIGHT

**Over \$350M market opportunity**

Annual US market potential at \$70K per Rx

## + US Refractory / Resistant *Candida* Markets



2019 AR  
Threats Report

**Drug-Resistant *Candida***

**34.8K Cases / 1.7K Deaths**

Estimates for 2017

***Candida auris***

**90%** resistant to at least ONE antifungal

**30%** resistant to at least TWO antifungals

**318%**

Case increase 2018 v 2015-2017

## + Ex-US Markets

IQVIA (2019) Amphotericin B Utilization by Indication 2016-2018, CDM  
Research America (2019) P&T ID Survey Q2 2019  
CDC (2019) AR Threats Report

\*dependent on positive clinical data

 **APPILI**  
THERAPEUTICS

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# 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 Raise**  
2016 & 2019

### Phase 3



**\$145.1M**  
NASDAQ: SCYX, Feb 1, 2021



**\$113.8M**  
NASDAQ: CDTX, Feb 1, 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

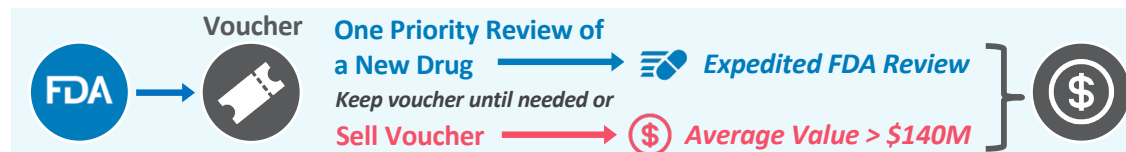
Astellas PR Feb 24 2010  
Basilea PR Dec 01 2017  
F2G PR Jun 20 2016  
Amplix PR Aug 02 2017

Cidara / Mundipharma Joint PR Sep 03 2019  
Bloomberg (2020) queries: SCYX, CDTX, close of market

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

# PRIORITY REVIEW VOUCHER ELIGIBLE

If approved by the FDA for cryptococcal meningitis, candidate would 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**, average price >\$140M

Date	Sell	Purchaser	Value (USD)
H2 2014	BioMarin	Sanofi / Regeneron	\$67.5M
H2 2014	Knight Therapeutics	Gilead	\$125M
H1 2015	Asklepios / Retrophin	Sanofi	\$245M
H2 2015	United Therapeutics	AbbVie	\$350M
H2 2016	PaxVax	Gilead	\$290M
2017	5 separate transactions		\$125M - \$150M
H1 2018	Spark Therapeutics	Jazz Therapeutics	\$110M
H1 2018	Ultragenyx / Kyowa Hakko Kirin	Gilead	\$80.6M
H2 2018	SIGA Technologies	Eli Lilly	\$80M
H1 2019	GW Pharmaceuticals	Biohaven	\$105M
H2 2019	SOBI	AstraZeneca	\$95M
H2 2019	Bavarian Nordic	-	\$95M
H1 2020	Sarepta Therapeutics	Vifor Pharma	\$111M
H2 2020	Lumos Pharma	Merck	\$100M

At least two additional transactions with no financials disclosed, both involving Novo Nordisk as buyer  
Primary reference GAO-20-251, with supporting data from press releases or financial disclosures

Kyowa Hakko Kirin Q2 2018  
Consolidated Financial Summary  
SIGA Technologies Form 8-K, date November 1, 2018  
GW Pharmaceuticals, PR March 18, 2019  
Biohaven Pharmaceuticals, PR March 18, 2019

BioMarin Pharmaceutical PR Jul 30 2014  
Knight Therapeutics PR Nov 19 2014  
Retrophin PR May 27 2015  
United Therapeutics Corporation PR Aug 19 2015  
AstraZeneca PR Aug 22 2019

Sarepta Therapeutics PR Feb 21 2017  
ViiV Healthcare PR Jun 2017  
BioMarin Pharmaceutical PR Nov 27 2017  
Ultragenyx Pharmaceutical PR Dec 18 2017  
Bavarian Nordic PR Dec 17 2019

Spark Therapeutics PR April 30 2018  
Teva Form 6-K, dated November 2, 2017  
Vifor Pharma Annual Report 2019  
Ultragenyx Pharmaceutical PR Aug 02 2018  
Medicines Development for Global Health PR Aug 9 2019

GAO-20-251  
Lumos PR Jul 27 2020





**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

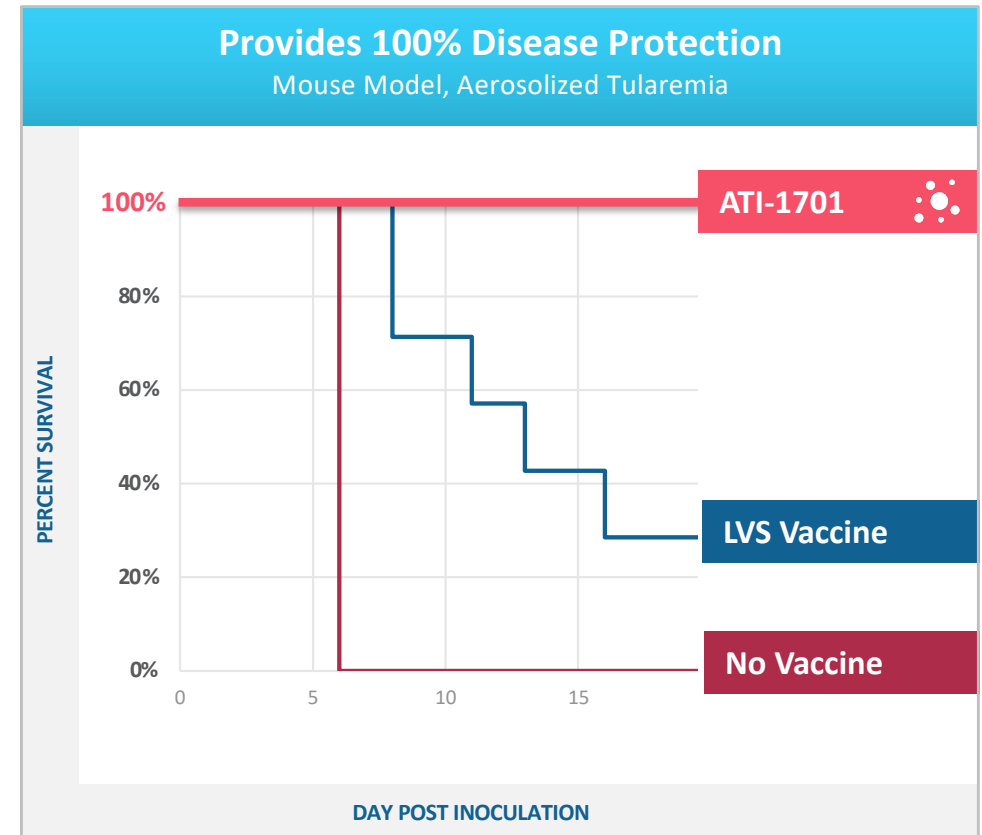
- ATI-1701 is a novel, live-attenuated tularemia vaccine candidate
- Superior to LVS in nonclinical study conferring 100% survival

## 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

## Program Milestones

- Validation work by DTRA – **Key primate data readout in 2020**
- Correlates of protection work ongoing

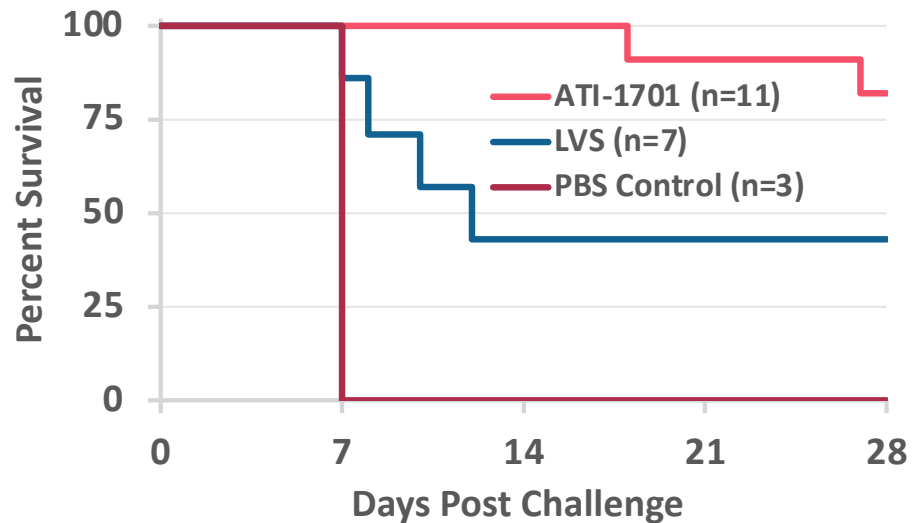


# ONGOING NON-HUMAN PRIMATE STUDY

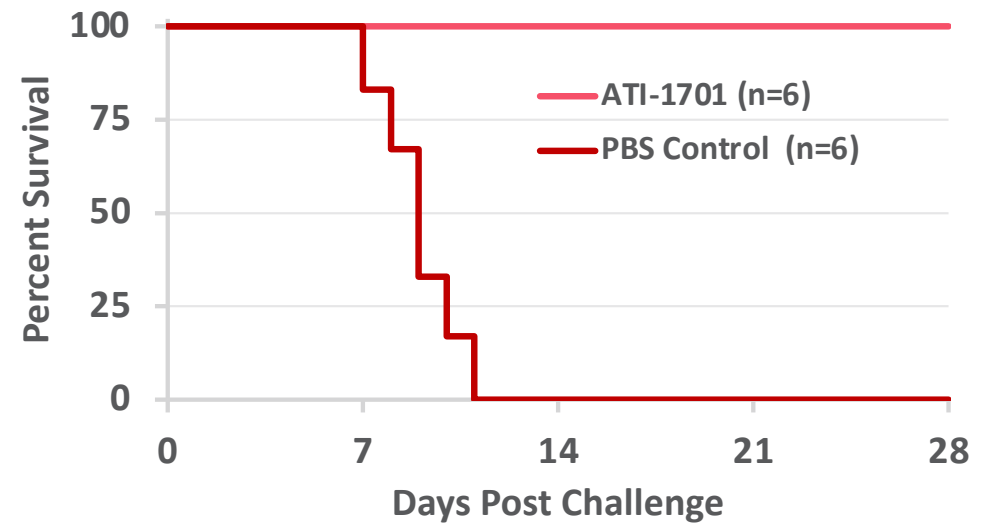


## Survival Data

### 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+)***

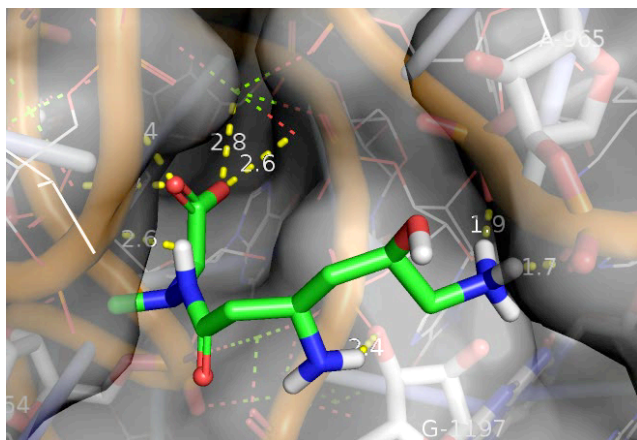
A close-up photograph of a male scientist with dark hair and a mustache, wearing a white lab coat and purple nitrile gloves. He is holding a white pipette in his right hand and a small glass vial in his left hand, looking intently at the vial. The background is a blurred laboratory setting with various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

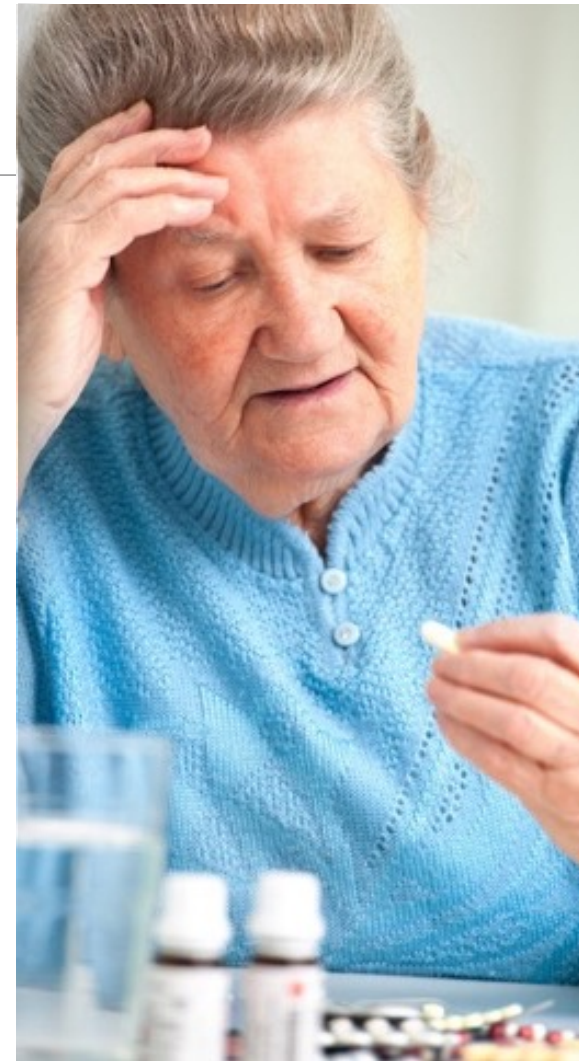
- Metronidazole is a front-line anti-infective that is heavily prescribed in US with 10M+ oral Rx but no approved liquid oral forms
- Pediatrics and elderly with difficulty swallowing tablets must crush and resuspend
- Process exacerbates metronidazole's bitter taste = non-compliance, switching

## 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



## 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*

15+ 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 18+ 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 of program management experience in the drug development industry





# BOARD OF DIRECTORS



**IAN MORTIMER**

CHAIR

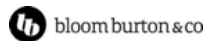
President and Chief Financial Officer of Xenon Pharmaceuticals Inc, 20+ years of experience in the biotechnology sector



**BRIAN BLOOM**

MEMBER

Chairman and CEO of Bloom Burton & Co, 18+ 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 February 1, 2020)

### Capital Raised:

- **\$68M** raised in total
  - **\$42.7M** in equity
  - **\$25.3M** in government assistance

### Cash & cash resources (September 30, 2020)

- **Cash & Short-term Investments: \$22.9M**
- **Government grants over 2.5 years: \$2.6M USD**

## CAPITAL STRUCTURE (As of February 1, 2020)

**62.4M** Common shares outstanding

**14.9M** Warrants

**4.5M** Options

**81.8M** Fully diluted

## STOCK INFORMATION (As of February 1, 2020)

**TSX: APLI**      Graduated to TSX September 16, 2020  
**\$0.50 - \$1.89**      52 week low-high  
**\$66.7M**      Market Cap

## SIGNIFICANT OWNERSHIP

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



## NEWS FLOW AND MILESTONES

Milestone	Program	Expected Date	Completed
Prospectus Financing	Corporate	Q1-2020	✓
Regulatory clearance for COVID-19 Clinical Trial(s)	Favipiravir	Q2 2020	✓
Graduation to the TSX	Corporate	Q3-2020	✓
First enrollment for COVID-19 Clinical Trial(s)	Favipiravir	Q4-2020	✓
Partnership for a New Asset / Indication	Corporate	Q4-2020	✓
Bolstering Industry Focused Board	Corporate	Q1-2021	✓
Interim Data readout (PRESECO Trial)	Favipiravir	Q1-2021	
Full data readout(s)	Favipiravir	Q2-2021	
NDA Submission	Favipiravir	H2-2021	
<i>Cryptococcus</i> Proof of Concept Nonclinical Results	Antifungal (ATI-2307)	H2-2021	
Phase 2 Clinical Study Start	Antifungal (ATI-2307)	H1-2022	

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## CONTACT

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