Appili Therapeutics Inc

January 2022

TSX: APLI / OTCQX: APLIF

APPILI THERAPEUTICS

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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
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		2022				
Favipiravir Oral Antiviral Tablet	Complete			Ongoing			Dr.Reddy's FUJIFILM GLOBAL RESPONSE AID
Out-Licensed Program							
ATI-1501 Metronidazole Suspension	Complete			505(b)(2) Phase II/III trials not required	2022		SAPTALIS

Complete In Progress Planned

APPILI THERAPEUTICS

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

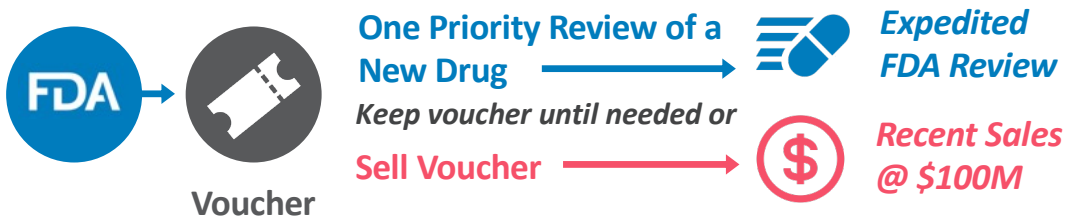
Additional Revenue Streams

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 (PRV)

- Vouchers 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 with a robust secondary market



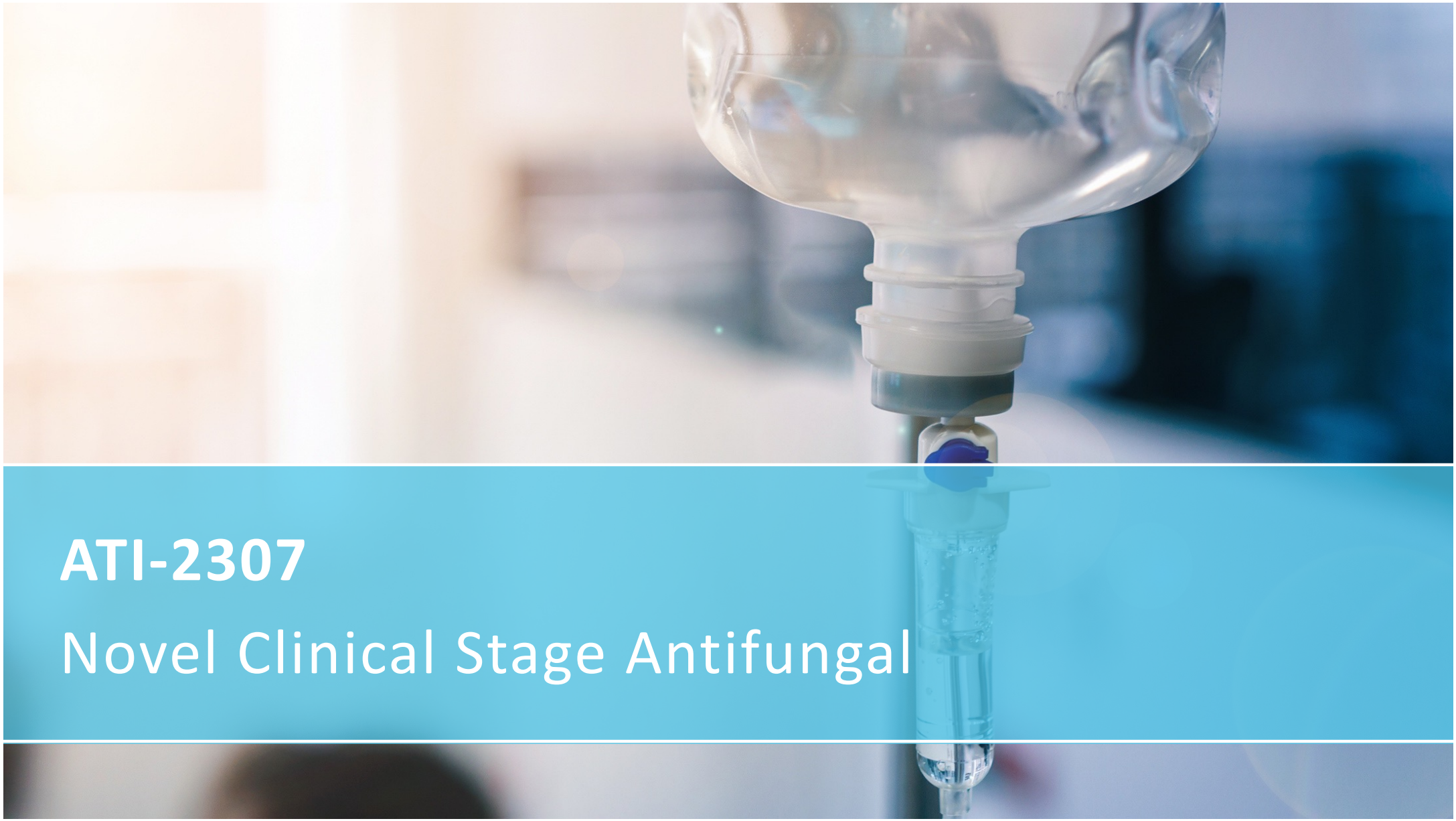
20+	***PRV Sales Since Program Inception***
$100M+	***Average PRV Sale Price in 2020-2021 (USD)***

2021 Disclosed Transactions	
Seller	**Price (USD)**
Rhythm Pharmaceuticals	$100M
Liminal Biosciences	$105M
Albireo Pharma	$105M
Mirium Pharmaceuticals	$110M

Appili programs ATI-2307 and ATI-1701 may both be eligible for priority review vouchers

Primary reference GAO-20-251, with supporting data from press releases or financial disclosures

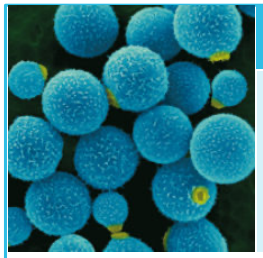
At least two additional transactions with no financials disclosed, both involving Novo Nordisk as buyer



ATI-2307

Novel Clinical Stage Antifungal

CRYPTOCOCCUS AND CANDIDA: URGENT, GLOBAL UNMET NEEDS



Cryptococcus

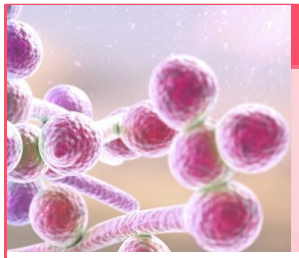
Opportunistic, invasive infection causing meningitis; underserved and growing orphan segment

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

CDC (2018) https://www.cdc.gov/fungal/diseases/cryptococcosis-neoformans/statistics.html
CDC (2019) AR Threats Report
CDC (2020) https://www.cdc.gov/fungal/candida-auris/tracking-c-auris.html
CDC (2019) https://www.cdc.gov/fungal/diseases/candidiasis/invasive/statistics.html

Rajasingham R (2017) Lancet Infect Dis 17: 873-881
IQVIA (2019) Amphotericin B Utilization by Indication 2016-2018,
CDM Research America (2019) P&T ID Survey Q2 2019
Pyrgos V (2013) PLoS ONE e56268

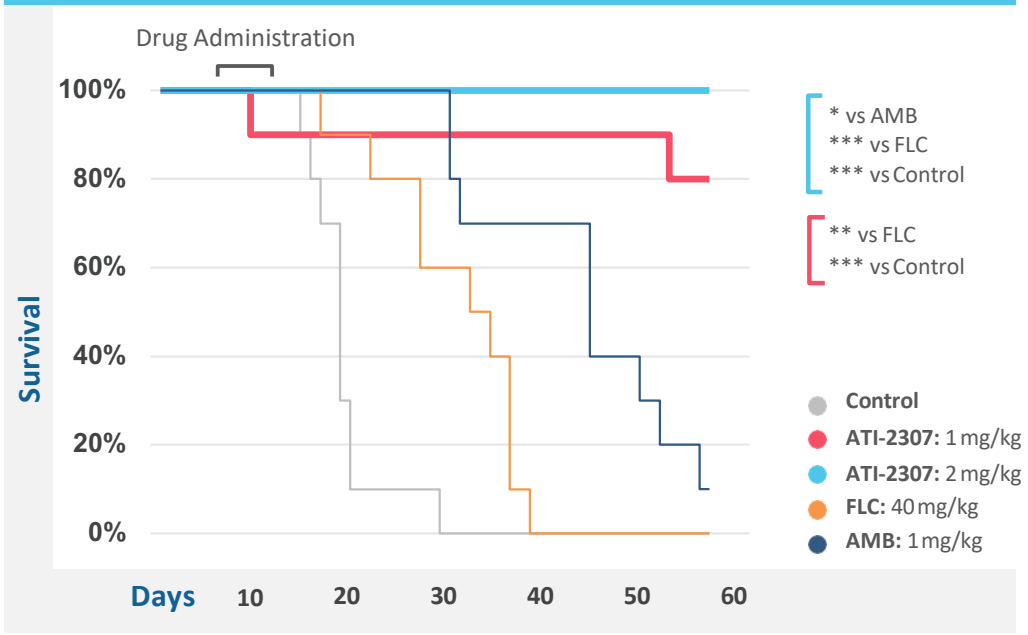
Pappas PG (2016) Clin Inf Dis 62: e1-e50

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

Intrapulmonary Cryptococcus Infection Model



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

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

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

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ANTIFUNGAL BENCHMARKS AND VALUATIONS

Recent Approval: Cresemba®

CRESEMBA® (ISAVUCONAZOLE)

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

US License

Total Value: Over $400M

+ double-digit royalties

astellas

Signed in 2010, amended in 2014, 2015

EU + APAC License

Total Value: Over $700M

+ mid-teen royalties

Pfizer

Signed and amended in 2017

Valuations & Funds Raised*

Phase 2	amplyx **$90M+ Series C** 2017-2020	F2G Advancing Antifungal R&D **$120M Raised** 2016 & 2019
Phase 3	CIDARA THERAPEUTICS **$108.7M** NASDAQ: CDTX, Oct 15, 2021 + Ex-US/Japan Partnership Total value: Over $568M + double-digit royalties mundipharma Announced Sept 2019	
Launch	SCYNEXIS **$129.3M** NASDAQ: SCYX, Oct 15, 2021	

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

Astellas PR Feb 24 2010
Baseila PR Dec 01 2017
F2G PR Jun 20 2016
Amplyx PR Aug 02 2017

Cidara / Mundipharma Joint PR Sep 03 2019
https://ir.scynexis.com/quote
Google Finance, query 'CDTX'

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

APPILI THERAPEUTICS

ATI-1701

Tularemia Vaccine

ATI-1701: BIODEFENSE VACCINE PROGRAM

Problem

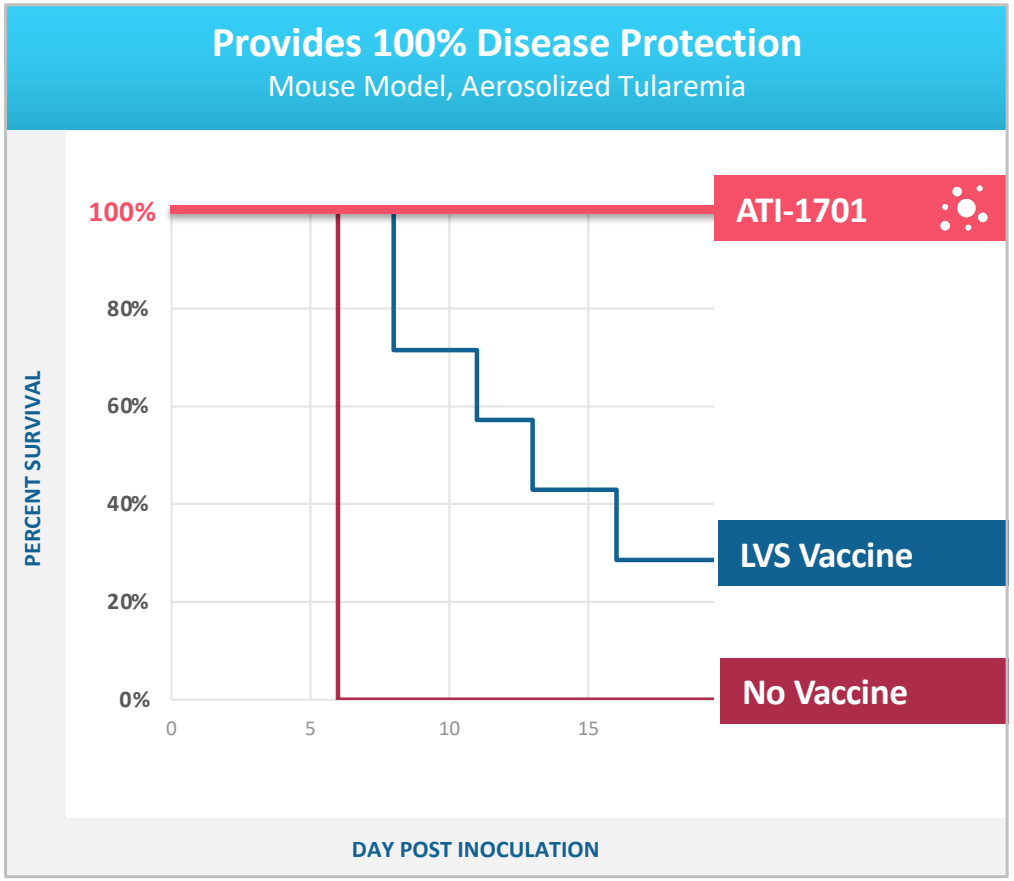
- *Francisella tularensis* is 1,000X more infectious than anthrax and easily dispersed
- No FDA approved vaccine available
- Medical Counter Measure (MCM) needed for military, civilians

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

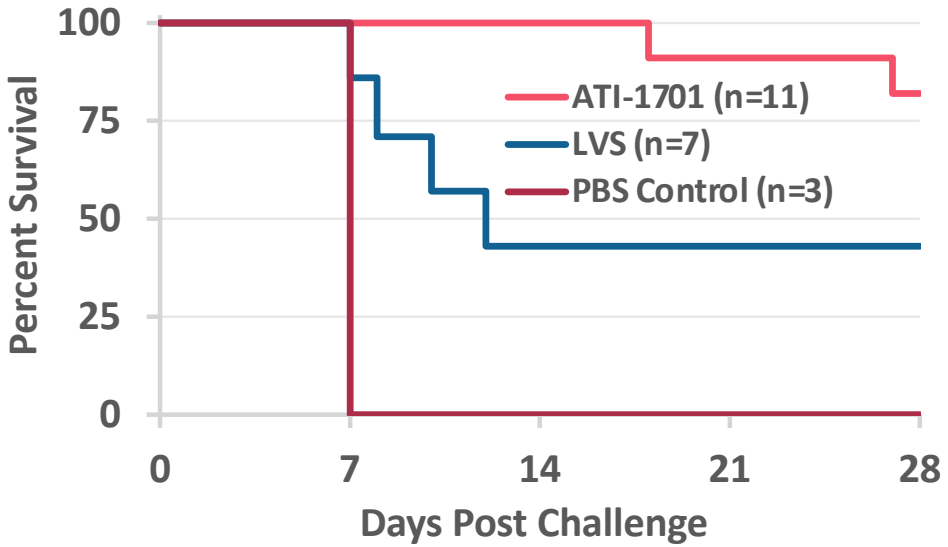


Tularemia Background: WHO (2007) Guidelines on Tularemia; PHAC PSDS (2011) Anthrax; PHAC PSDS (2011) Tularemia; Army Technology (2015); Mulligan MJ (2017) Vaccine 35: 4730-4737
ATI-1701 Data: Data On File, intranasal challenge with 75 CFU of *F. tularensis* SCHU S4; additional preclinical data: Shen H (2010) PLoS ONE 5: e13349

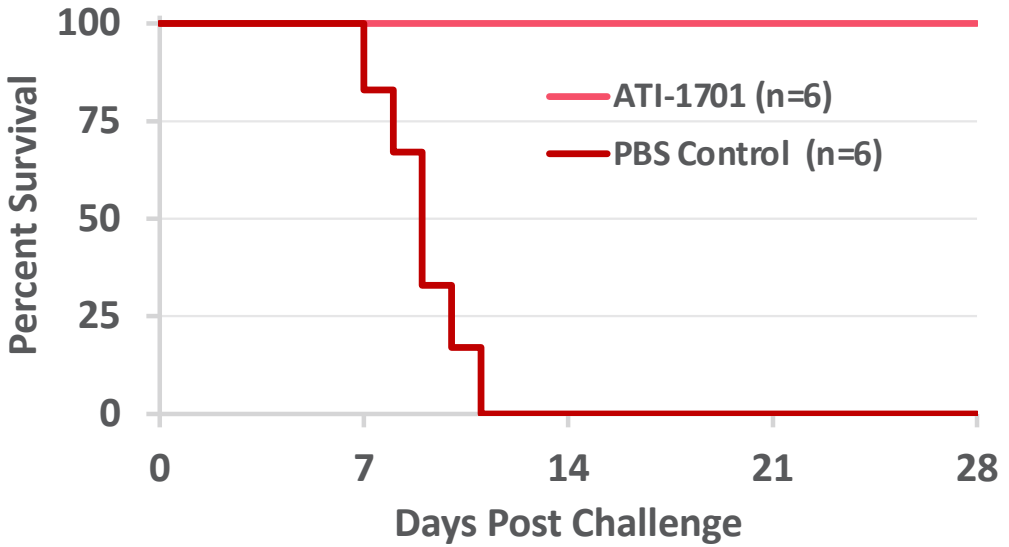
ONGOING NON-HUMAN PRIMATE STUDY

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

Balboni A (2019) MHSRS Poster
Gelhaus C (2019) DTRA CBD&ST Poster

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+)

CDC (2016) Strategic National Stockpile; https://www.cdc.gov/phpr/stockpile/history.htm
GPO (2013) PAHPRA: https://www.gpo.gov/fdsys/pkg/PLAW-113publ5/pdf/PLAW-113publ5.pdf
Belasco A (2009) CRS Report – Troop Levels in the Afghan and Iraq Wars FY2001-FY2012
Baiocchi D (2013) RAND – Measuring Army Deployments to Iraq and Afghanistan
Livingston IS (2017) Brookings Afghanistan Index
Emergent 2015 Annual Report
Emergent PR Mar 8 2012
Emergent PR Sep 30 2016
SIGA PR Sep 10 2018
SIGA PR Jul 13 2018
Project BioShield 2014 Annual Report
Bavarian Nordic PR Sep 27 2017

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

YOAV GOLAN, MD
CHIEF MEDICAL OFFICER
30+ years as an infectious disease physician; published research on *C. difficile* infections and invasive candidiasis

KENNETH HOWLING
ACTING CHIEF FINANCIAL OFFICER
25+ years of financial management and public company experience in pharma

DON CILLA, PHARMD, MBA
CHIEF DEVELOPMENT OFFICER
30+ years drug development experience, including clinical, clinical pharmacology and program leadership positions for many marketed compounds

STÉPHANE PAQUETTE , PhD
VICE PRESIDENT, CORPORATE DEVELOPMENT
10+ years infectious disease and industry R&D experience; PhD in virology & immunology

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.

BOARD OF DIRECTORS

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

XENON

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

bloom burton & co

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

Bristol-Myers Squibb

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Innovation for patient care

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MATINAS BIOPHARMA

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MEMBER
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Spartan

CYNAPSUS

Humber River Hospital

ARMAND BALBONI
MEMBER
Extensive drug development experience in civilian, academic, and military organizations

APPILI

bloom burton & co

FINANCIAL OVERVIEW AND CAPITAL STRUCTURE

FINANCING (As of October 15, 2021)

Capital Raised:

- **$80.9M** raised in total
  - **$52.1M** in equity
  - **$ 3.5M** in debt
  - **$25.3M** in government assistance

Cash & cash resources (Sept 30, 2021)

- **Cash & Short-term Investments:** **$10.2M**
- **Government grants (1-2 years):** **$3.8M USD**

CAPITAL STRUCTURE (As of November 16, 2021)

71.3M Common shares outstanding
21.3M Warrants
6.2M Options
98.8M Fully diluted

STOCK INFORMATION (As of November 16, 2021)

TSX: APLI Graduated to TSX September 16, 2020
$0.15 - $1.43 52 week low-high
$15M Market Cap

SIGNIFICANT OWNERSHIP

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

CONTACT

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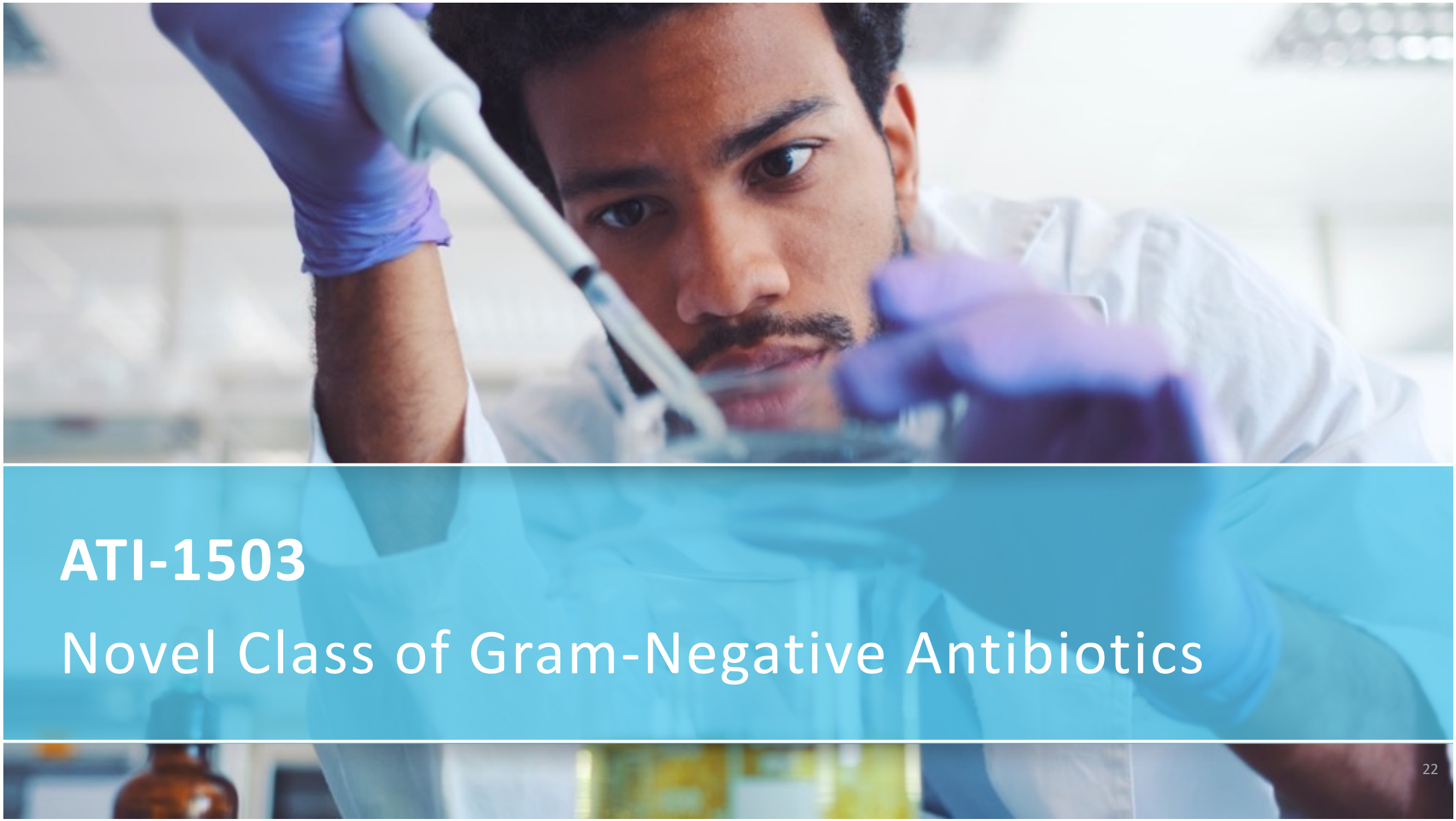
abalboni@appilitherapeutics.com

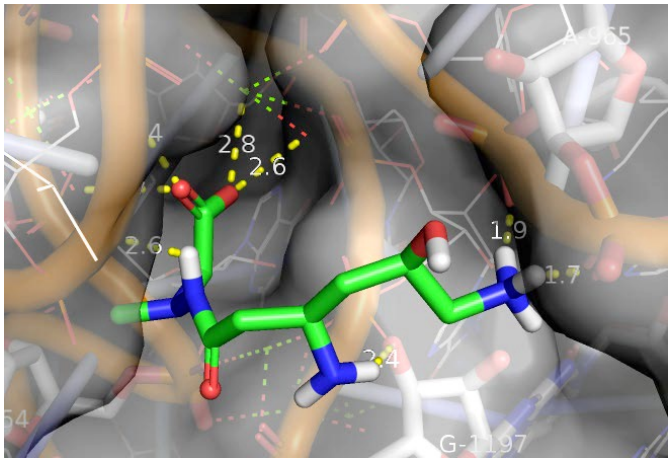
www.appilitherapeutics.com



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

USAMRIID United States Army Medical Research Institute of Infectious Diseases

NIH National Institute of Allergy and Infectious Diseases

Canada NRC·CNRC

Olivier NB (2014) Proc Natl Acad U S A 111: 16724-16729
Polikanov YS (2014) Mol Cell 56: 541-550
Guo J (2015) Xenobiotica 45: 625-633
Arakawa M (2003) J Biochem 134: 751-758

Appili Data on File

Favipiravir

Broad Spectrum Oral Antiviral

REEQONUS™ / AVIGAN®: BROAD SPECTRUM ORAL ANTIVIRAL

Global Coalition to Develop REEQONUS™ / Avigan® (favipiravir) for COVID-19

- Appili joined partners FUJIFILM, Dr. Reddy's, and Global Response Aid to develop favipiravir
- Advantages: Extensive clinical experience, oral dose, manufacturing + promising COVID-19 data
- Coalition leveraged each organization's skills to support rapid development and access
- Appili responsible for running pivotal clinical program to support global approvals

Phase 3 Trial PRESECO Top-Line Results

Evaluating Favipiravir for Early Treatment of Mild-to-Moderate COVID-19

- Phase 3 trial conducted by Appili, top-line results announced November 11 2021
- Enrolled 1,231 patients across 38 sites in United States, Mexico, and Brazil; 80% from US
- Study did not achieve primary endpoint of reducing time to sustained clinical resolution
- No new safety signals were noted
- Additional analyses ongoing

Exploring partnership opportunities to evaluate favipiravir in combination or for other viral indications

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

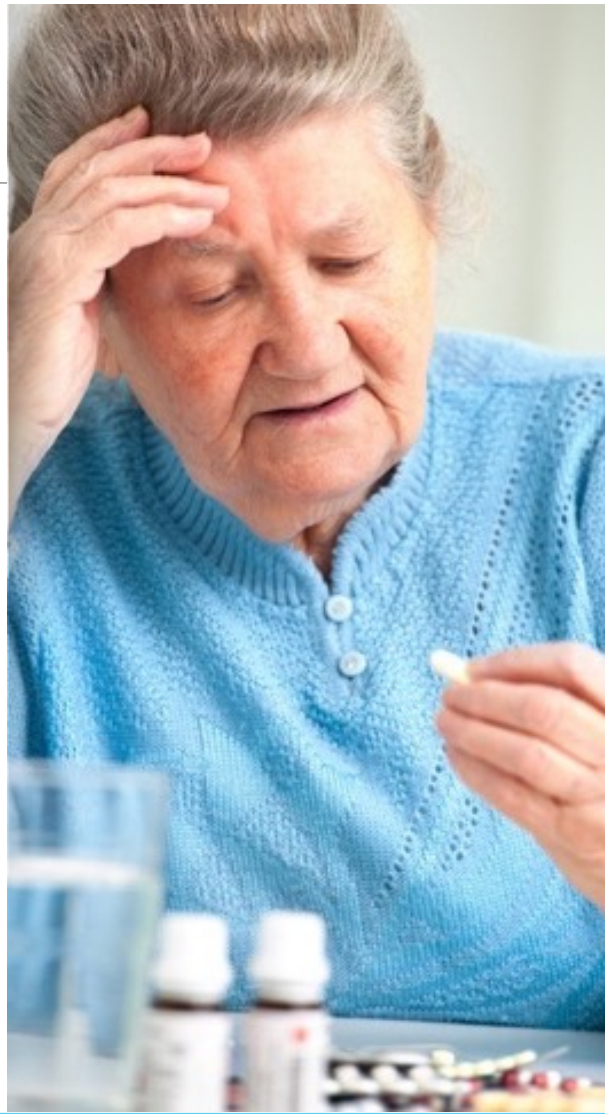
Solution

- 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 2022

SAPTALIS PHARMACEUTICALS, LLC.



Appili PR Jul 30 2018
Appili PR Dec 03 2019

Market Sizing: IQVIA™ 2014-2017 NPA; IQVIA™ 2016-2017 CDM; Sura L (2012) Clin Interv Aging 7: 287-298; NCHS 2013-2014 LTC Data; 2010-2013 NAMCS / NHAMCS / NHDS Surveys; 2005 NCHS US Health Report; Lessa FC (2015) N Engl J Med 372: 825-834; US Infectious Disease and Gastroenterology Treatment Guidelines; IQVIA™ 2017 Third Party and Institutional Payer Surveys

+ Appli Analyses

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