Appili Therapeutics Inc.

TSX: APLI / OTCQB: APLIF

CORPORATE DECK

APPILI THERAPEUTICS

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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 22, 2023. 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, commercializing 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 $14M in funding from USAFA
- Funding used to kick-off early-stage development and regulatory activities, which are currently ongoing

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+	***PRV Sales Since Program Inception***
$123M	***Average PRV Sale Price*** *(range from $67.5 to $350M)*

- **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*
  - *Biodefense*
- **PRVs are transferrable with a robust secondary market**

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

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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

- USAFA, in partnership with DTRA committed $14M in non-dilutive funding
- FDA's Animal Rule approval pathway
- PRV and Fast-Track designation applications planned

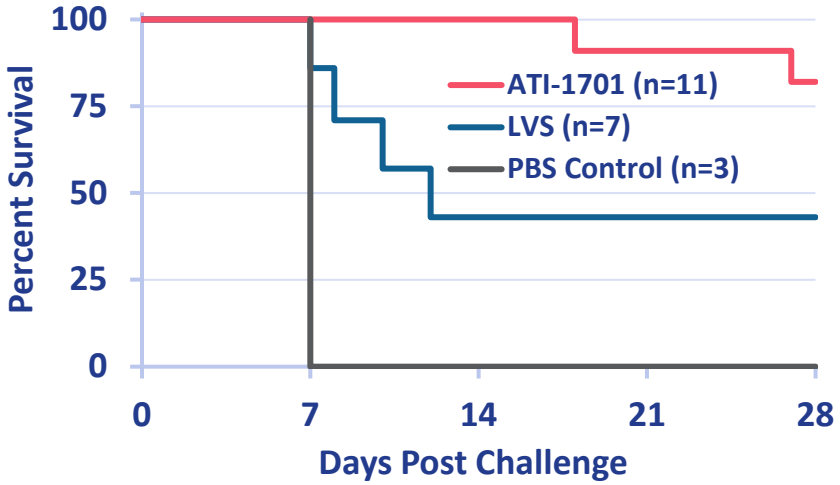
Tularemia Background: WHO (2007) Guidelines on Tularemia; PHAC PSDS (2011) Anthrax; PHAC PSDS (2011) Tularemia; Army Technology (2015); Mulligan MJ (2017) Vaccine 35: 4730-4737
ATI-1701 Data: Data On File, intranasal challenge with 75 CFU of *F. tularensis* SCHU S4; additional preclinical data: Shen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

Initial funding has been advanced to USAFA and will be available after negotiating definitive documentation governing the terms of such engagement.

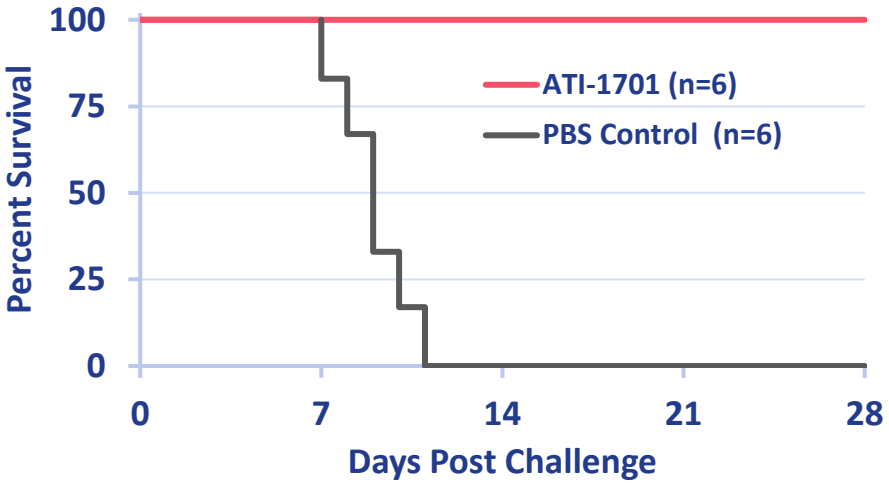
DEMONSTRATED EFFICACY IN NON-CLINICAL STUDIES

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

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

DTRA was the source of funding for these studies

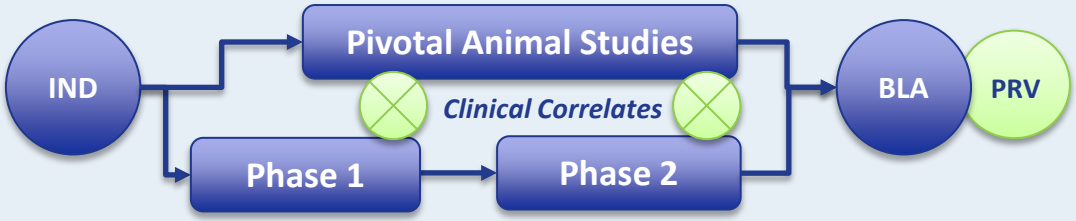
DEVELOPMENT PATH AND FUNDING

USAFA committed funds of $14M, in partnership with DTRA reaffirms DoD commitment to ATI-1701 through IND

UNITED STATES AIR FORCE ACADEMY

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

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

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

Croddy (2001) Military Medicine
166; 10:837

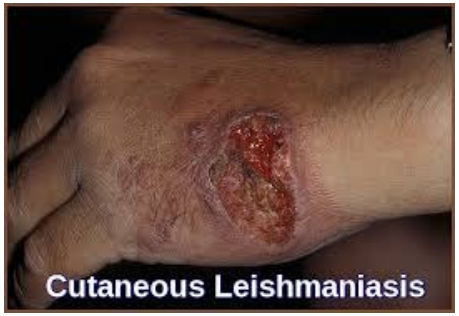
ATI-1801

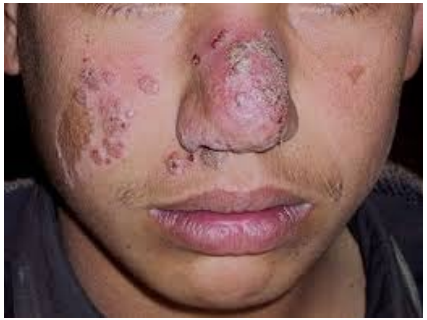
Topical Treatment for Cutaneous Leishmaniasis

CUTANEOUS LEISHMANIASIS (CL) HAS SIGNIFICANT UNMET NEED

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

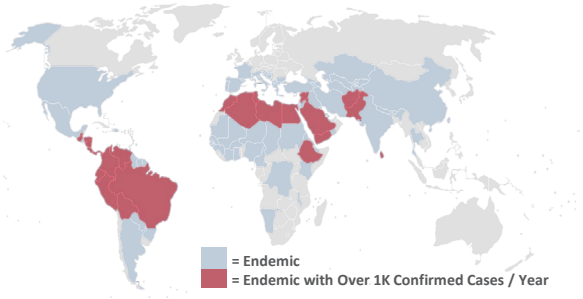
- Leishmaniasis is an obligate intracellular parasite that is transmitted to humans by sandfly bites
- Skin lesions (ulcers/papules) are the typical clinical manifestation of CL infections
- Infection leads to scarring and stigmatization





- Most common in Latin America, Middle East, North Africa but increasing in US / EU
- WHO estimates over 1M 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

Bennis *et al* (2018) *BMC Public Health* **18**:358
https://www.who.int/leishmaniasis/
https://apps.who.int/neglected_diseases/ntddata/leishmaniasis/leishmaniasis.html

Source: World Health Organization
Status of endemicity of cutaneous leishmaniasis, 2020

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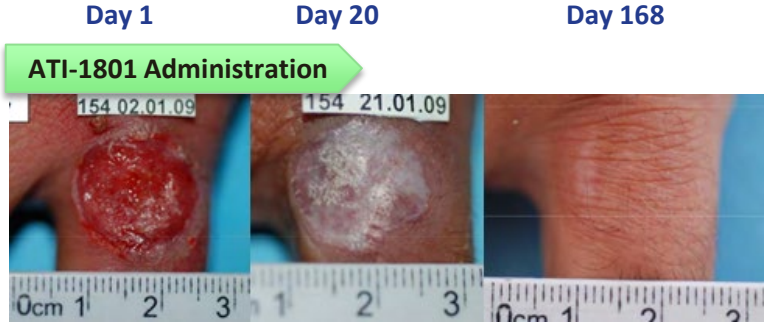
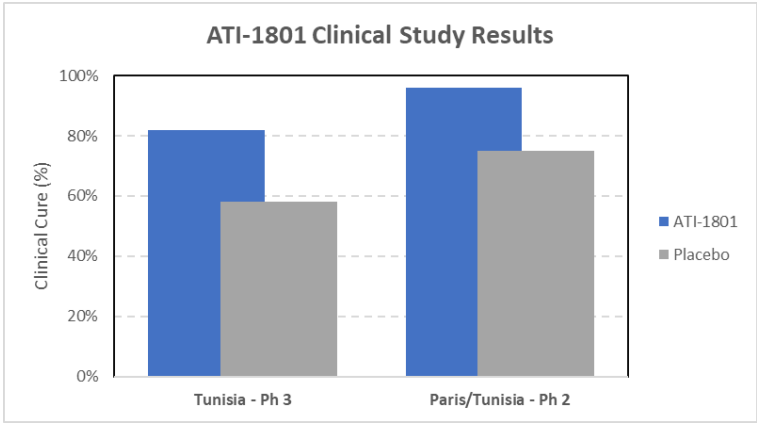
ATI-1801: NOVEL TOPICAL TREATMENT FOR CL

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

U.S. Army Medical Materiel Development Activity
USAMMDA





Ben Salah A (2013) N Engl J Med 368: 524-532

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PATHWAYS TO MONETIZE ATI-1801

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

FDA

CDMO Tech Transfer initiates the next steps

World Health Organization

- **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™ (ATI-1501)

Metronidazole Liquid Oral Suspension

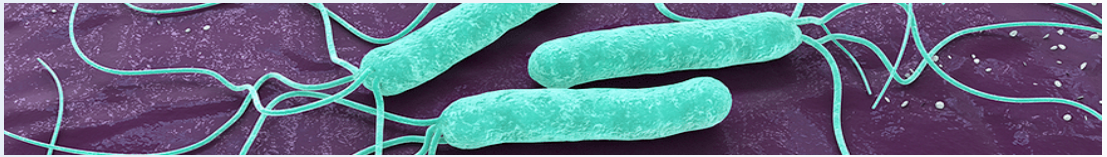
LIKMEZ™ - METRONIDAZOLE ORAL SUSPENSION 500MG/5ML

LIKMEZ™ 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



LIKMEZ™ - METRONIDAZOLE ORAL SUSPENSION 500MG/5ML

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' **NDA approval** (2023) and **commercialization** (2024)

SAPTALIS PHARMACEUTICALS, LLC.

Appili PR Dec 03 2019
Appili PR Feb 8 2022
Appili PR May 24 2023

Market Sizing: IQVIA™ 2014-2017 NPA; IQVIA™ 2016-2017 CDM; Sura L (2012) Clin Interv Aging 7: 287-298; NCHS 2013-2014 LTC + Appli Analyses 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

All financial data in USD

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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*
		Costs:	$14.0M				
		Funding:	$14.0M	*Seeking*	*Seeking*		
ATI-1801 Topical Paromomycin	*Search ongoing*	Complete			Ongoing		2027 / 2028 *Potential PRV & NGO Contracts*
					Costs:		
					Funding:	*Seeking*	
Out-Licensed Program							
LIKMEZ™ Metronidazole Oral Suspension	SAPTALIS	Complete			505(b)(2) *Phase II/III trials not required*		Complete *Milestones & Royalties – early 2024*
					Costs:		
					Funding:	$0M	

Complete In Progress Planned

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

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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

Takeda
AstraZeneca

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

BIOVAIL
ACERUS PHARMA

GARY NABORS, PHD
CHIEF DEVELOPMEENT OFFICER
25+ years experience leading vaccine and antibody product development for infectious disease indications

integrated biotherapeutics
DVC LLC
A GDIT COMPANY

CARL GELHAUS, PHD
DIRECTOR, NON-CLINICAL RESEARCH
20+ years infectious disease and animal model experience; founding member of the tularemia international society

USAMRIID
United States Army Medical Research Institute of Infectious Diseases
BATTELLE
MRIGlobal

ARTHUR BARAN, MBA, PMP
DIRECTOR, NEW PRODUCT DEVELOPMENT
20+ years CMC and global product operations leadership experience in the pharmaceutical industry

Takeda
Catalent

LEONA SAUNDERS, PHD
DIRECTOR, REGULATORY AFFAIRS
20+ regulatory experience for pharmaceutical, biotech, and medical device companies.

Innovative Regulatory Science Group
NORTHEASTERN UNIVERSITY

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

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

JUERGEN FROEHLICH, MD
MEMBER
30+ years of biotech experience including all phases of drug development and regulatory interactions

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 June 30, 2023)

TSX: APLI
Listed June 25, 2019

$0.025 - $0.075
52 week low-high

$6.7M
Market Cap @$0.055/share

SIGNIFICANT OWNERSHIP (As of June 30, 2023)

Bloom Burton & Co.	11.8%

All financial data in CDN unless specified USD

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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

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