

COMBATTING URGENT VIRAL DISEASE THREATS

DR DAVID FOSTER, MANAGING DIRECTOR

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acquisition executed - expedited approval route defined

aggressive models

2x potential PRVs valued at ~A\$225m



**Major market** potential



Phase 2a/b PROTECT clinical trial in dengue completed



Dengue infects up to 400m per year\*

# CORPORATE OVERVIEW



#### Snapshot

Shares on issue <sup>1</sup> :	236,093,034
Price per share <sup>1</sup> :	\$0.145
Market capitalisation¹:	\$34.24m
Cash at bank (31 March 2024) <sup>2</sup> :	\$4.82m
May 2025 capital raise:	\$3.6m
DoD grant funding to directly support the Phase 2a/b PROTECT clinical study	US\$625k

# Substantial shareholders Dr William James Garner<sup>3</sup> Jason Carroll<sup>4</sup> MWP Partners Limited<sup>5</sup> Dr Daniel Tillett<sup>6</sup> 14.21% 13.26% 6.72%

#### 1. As at 7 July 2025

#### Price & volume (12 month)



#### **Board of Directors**

Jason Carroll, Non-Executive Chairman

Dr David Foster, CEO and Managing Director

Chris Ntoumenopoulos, Non-Executive Director

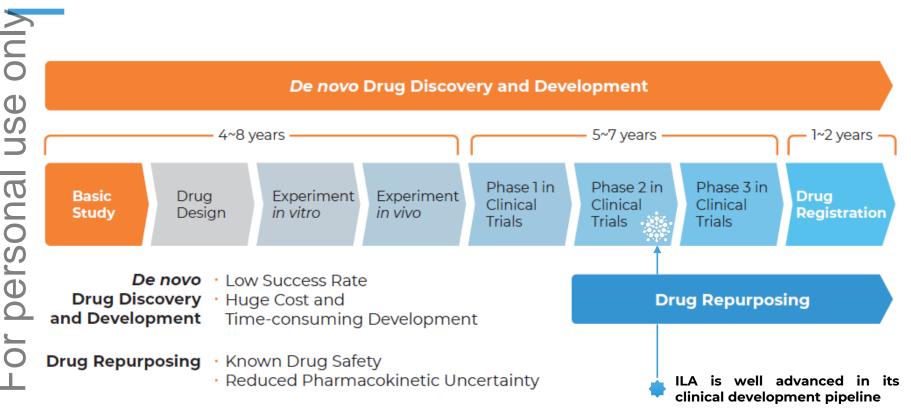
<sup>2.</sup> Does not take into consideration cash used since reporting date

<sup>3</sup> Per holding per Substantial interest notices lodged with ASX on 02 June 2025

<sup>4.</sup> Per holding per Substantial interest notices lodged with ASX on 29 May 2025 5 Per holding per Substantial interest notices lodged with ASX on 03 June 2025 6 Per holding per Substantial interest notices lodged with ASX on 19 March 2025

# BENEFITS OF DRUG REPURPOSING





# personal.

# **GALIDESIVIR ACQUISITION TRANSACTION**



Asset acquisition of galidesivir and related compounds

Clinical program and robust pre-clinical data package

International IP portfolio

Favourable terms:

- Upfront \$550,000 USD including \$50,000 option fee
- US\$500,000 upon completion of Phase 2 clinical trial
- US\$1M upon approval of New Drug Application in US or equivalent or US\$1.5M upon Animal Rule approval in which no Phase 2 is required
- Tiered royalties of 5-10% of Net Sales
- 25% of proceeds from sale of any Priority Review Voucher awarded due to FDA approval of the acquired program(s)

# **GALIDESIVIR PROGRAM**



Program was developed in collaboration with NIAID (><u>US\$70m in funding to date</u>) to prepare for and respond to high priority virus threats and emerging viral infections

Asset purchase agreement executed with NASDAQ-listed, BioCryst Pharmacueticals Inc. (Nasdaq: BCRX) with favorable transaction terms

Program commenced to target high-priority threats (Marburg and Ebola) and was expanded to include development for MERS, Zika and Yellow Fever as potential for emerging infectious disease outbreaks

Shown to be **active against more than 20 RNA viruses in nine different families** (filoviruses, togaviruses, bunyaviruses, arenaviruses, paramyxoviruses, coronaviruses, orthomyxoviruses, picornaviruses and flaviviruses)

**Demonstrated survival benefits in animal studies** against a variety of serious pathogens, including Ebola, Marburg, Yellow Fever and Zika viruses

Safe and generally well tolerated in Phase 1 clinical safety and pharmacokinetics trials by both intravenous and intramuscular routes of administration in healthy subjects

Potential to expedite approval with work underway to advance clinical trials

# **GALIDESIVIR PROGRAM SUMMARY**

# GALIDESIVIR UNLOCKS ANOTHER MAJOR MARKET



Demonstrated activity against 20+ viruses – many with no available treatment

Activity against potential bioterror threats

Potential markets:

- Government stockpile programs
- Numerous antiviral programs
- Ripe potential for partnering

# **BROAD SPECTRUM ACTIVITY DEMONSTRATED**



# —Data highlights activity in vitro against multiple RNA viruses from diverse families

Virus Family	Virus	Strain/Variant
Filoviridae	Marburg	Musoke
	Marburg	Ci67
	Marburg	Angola
	Ebola	Kikwit
$\boldsymbol{\sigma}$	Sudan	Boniface
$\Box$	VEE	SH3
Togaviridae	EEE	FL93-939
	WEE	California
	Chikungunya	AF 15561
Bunyaviridae	Rift Valley Fever	ZH501
	LaCrosse encep	Wisc 1960
	Maporal virus	HV97021050
Arenaviridae	Lassa	Josiah
	Junin	Romero

Virus Family	Virus	Strain/Variant
Paramyxo	Nipah virus	Malaysia
	HRS	A2
	Measles	Chicago
Corona	SARS-CoV	Urbani
	MERS-CoV	Jordan
Orthomyxo	Influenza	рН1N1
Picornaviridae	Rhinovirus-2	HGP
Flaviviridae	West Nile	New York
	Yellow fever	17D
	Jap. Enceph.	SA14
	Powassan Virus	LB
	Dengue 2	New Guinea C
	Zika	PRVABC59

# MULTIPLE PHASE 1 HUMAN SAFETY CLINICAL STUDIES



Phase1 HV - SAD / MAD IM Sudy 101

#### SAD

Highest Dose: 10 mg/kg

**MAD** 

Highest Dose: 10 mg/kg 7

days



Phase1 HV – SAD IV Study 106

Cohort 1: 5 mg/kg Cohort 2: 10 mg/kg Cohort 3: 15 mg/kg Cohort 4: 20 mg/kg



# Phase 1b YF & COVID-19 – MAD

Study 108

(Part 1 Dosing Ranging)

Cohort 1: 10 mg/kg then 2 mg/kg q12h×13 Cohort 2: 10 mg/kg then 5 mg/kg q12h×13 Cohort 3: 20 mg/kg then 5 mg/kg q12h×13

Enrolled 24 subjects but trial terminated early

Opened but terminated prior to completion

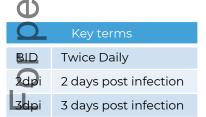
Key Terms	
SAD	Single Ascending Dose
MAD	Multiple Ascending Dose

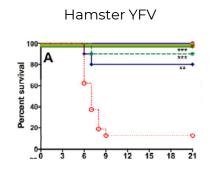
# **DEMONSTRATED IN VIVO ANTIVIRAL EFFECTS**

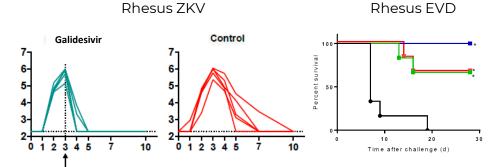


# impact achieved with delayed dosing across a broad range of viruses

nimal Species	Virus	Dose Regimen	Key Results
Hamsters	Yellow Fever	100 mg/kg BID 7 days	100% survival initial dose 3dpi, 80% survival initial dose 4dpi <sup>a</sup> ; 12.5% survival control
Rhesus NHP	Zika	100 mg/kg BID, 25 mg/kg BID 9 days	Viral load suppression initial dose 3dpi <sup>b</sup> ; 0% survival control.
ynomolgus NHP	Marburg	15 mg/kg BID 14 days	100% survival initial dose 2dpi°; 0% survival control.
Rhesus NHP	Ebola	100 mg/kg BID loading, 25 mg/kg BID 10 days	100% survival initial dose 2dpi, 67% survival initial dose 3 dpi <sup>d</sup> ; 0% survival control.

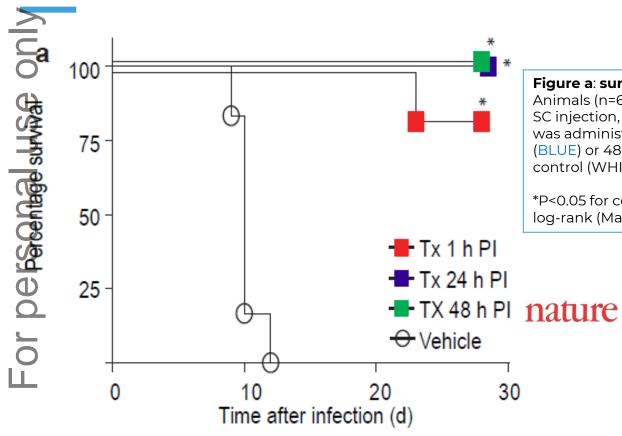






# EFFICACY IN NHPS INFECTED WITH MARV





#### Figure a: survival

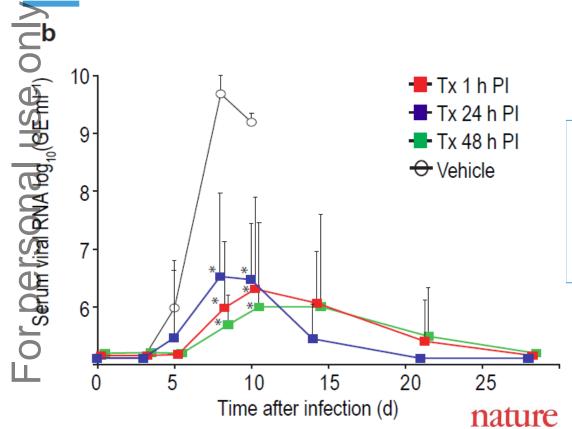
Animals (n=6/group) were challenged with MARV by SC injection, and Galidesivir (15mg/kg BID) or vehicle was administered IM beginning 1 hr (RED) 24 hr (BLUE) or 48 hr (GREEN) after challenge. Vehicle control (WHITE).

\*P<0.05 for comparison of treatment versus vehicle by log-rank (Mantel-Cox) test

	Key Terms
NHPS	Non-human primates
MARV	Marburg virus
BID	Twice daily
Vehicle	Placebo injection containing no active treatment
PI	Post infection
SC	Subcutaneous
IM	Intramuscular

# SUPPRESSION OF MARBURG VIRUS PROLIFERATION IN INFECTED NHPS





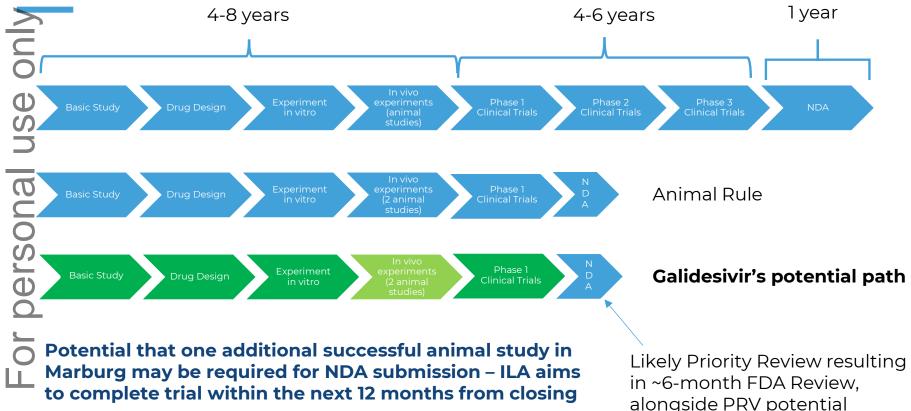
#### Figure b: viral load

Serum viral RNA load was determined in animals (n=6 per group) treated IM beginning 1 hr (RED) 24 hr (BLUE) or 48 hr (GREEN) after challenge. Vehicle control (WHITE).

\*P<0.05 for comparison of treatment versus vehicle by two-tailed analyses using the Holm– Sidak method

# POTENTIAL REGULATORY PATH





# **IMMEDIATE NEXT STEPS**



# dsland focused on a near term program to unlock value

Completion of all asset transfer from BioCryst to Island

Finalise enquiries with US FDA

Consult US FDA regarding potential for Animal Rule inclusion

Ongoing review of data package

Preparations for NHP studies



# **APPENDIX 1: SOURCES**



#### Slide 12:

📆 Julander J. G et al. BCX4430, a novel nucleoside analog, effectively treats yellow fever in a Hamster model. Antimicrob Agents Chemother 2014;58(11):6607—14

Whitney, J. B. et al. Galidesivir, a direct-acting antiviral, abrogates viremia in rhesus macaques challenged with Zika virus. Oral Presentation ID Week 2017

Warren, T. K. et al. Protection against filovirus diseases by a novel broad-spectrum nucleoside analogue BCX4430. Nature 508, 402-405, doi:10.1038/nature13027 2014)

Warren, T. K. et al. Efficacy of Galidesivir Against Ebola Virus Disease in Rhesus Monkeys. Poster Presentation ID Week 2017

#### Slide 13:

Warren, T. K., J. Wells, R. G. Panchal, K. S. Stuthman, N. L. Garza, S. A. Van Tongeren, L. Dong, C. J. Retterer, B. T. Eaton, G. Pegorago, S. Honnold, S. Bantia, P. Kotian, B. Taubenheim, L. S. Welch, D. M. Minning, Y. S. Babu, W. P. Sheridan and S. Bavari (2014). "Protection against filovirus diseases by a novel broad-spectrum nucleoside analogue BCX4430." Nature: Advance Online Publication (AOP) March 2, 2014,

#### Slide 14:

Warren, T. K., J. Wells, R. G. Panchal, K. S. Stuthman, N. L. Garza, S. A. Van Tongeren, L. Dong, C. J. Retterer, B. T. Eaton, G. Pegorago, S. Honnold, S. Bantia, P. Kotian, B. R. Taubenheim, L. S. Welch, D. M. Minning, Y. S. Babu, W. P. Sheridan and S. Bavari (2014). "Protection against filovirus diseases by a novel broad-spectrum nucleoside analogue BCX4430." Nature: Advance Online Publication (AOP) March 2, 2014, http://dx.doi.org/10.1038/nature13027