PAXMEDICA

Addressing Urgent Needs In Serious Neurologic Disorders

Nasdaq: PXMD
December 2022

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Overview

PaxMedica is a clinical stage biopharmaceutical company focusing on the development of anti-purinergic drug therapies (“APT”) for the treatment of disorders with intractable neurologic symptoms including Autism Spectrum Disorder (“ASD”).

PAX-101, an intravenous formulation of suramin, has been historically used as a life-saving drug to treat a rare and fatal tropical disease, Human African Trypanosomiasis. PaxMedica will seek accelerated approval for PAX-101 first in the treatment of HAT under the US Rare Tropical Disease Priority Review Voucher program to gain valuable program incentives.

We plan to initiate a pharmacokinetic study to develop additional dosing data in younger / female subjects and plan to submit an IND in 2024.

A global multi-centered clinical trial of PAX-101 in ASD will commence following US IND approval.

Investment Highlights

- Multiple potential catalysts expected through 2024
- Pursuing clinical indications with significant unmet needs and few options for drug therapy
  - Autism Spectrum Disorder (ASD)
  - Orphan Designated Rare Tropical Infectious Disease (African Sleeping Sickness – aka HAT)
  - Long Covid Syndrome (LCS) and Myalgic Encephalomyelitis (Chronic Fatigue Syndrome) - dose ranging studies to be initiated in 2023
- Potential to receive significant non-dilutive capital in 24-30 months
  - Submitting data to support an NDA submission and Priority Review Voucher (PRV) award for African Sleeping Sickness (HAT) indication which the company can potentially monetize
- Highly experienced management team and directors
  - Funded and operated by experienced industry entrepreneurs
  - Highly regarded industry executives as independent directors
- IPO completed in August 2022 and $8 million total proceeds

Management Team Led By Experienced Pharma Entrepreneurs

Michael Derby
Executive Chairman

Howard J. Weisman
Chief Executive Officer

Zach Rome
Chief Operating Officer

Stephen Sheldon
Chief Financial Officer

Stefan Schwabe, MD, PhD
Chief Medical Officer

Marathon Pharmaceuticals
ESP Pharma
DemeRx
PATAGONIA PHARMACEUTICALS
IHL Indochina Healthcare Ltd.
Castle Creek Biosciences
Forest Laboratories, Inc.
EKR THERAPEUTICS
TIMBER PHARMACEUTICALS
NOVARTIS
MERCK
novo nordisk®
PARKE-DAVIS
Supernus Pharmaceuticals
Johnson & Johnson
CIBA–GEIGY
SANOFI

Board of Directors

Michael Derby

Howard J. Weisman

Zach Rome

Karen LaRochelle

Dr. John F. Coelho

Charles J. Casamento

MERCK

ESP Pharma
Excellence in Specialty Pharmaceuticals

Forest Laboratories, Inc.

Marathon Pharmaceuticals

PATAGONIA PHARMACEUTICALS

IHL
Indochina Healthcare Ltd.

Castle Creek Biosciences

EKR THERAPEUTICS

Advent Life Sciences

TIMBER PHARMACEUTICALS

WindMIL THERAPEUTICS®

TardiMed Sciences

PsiOxus® THERAPEUTICS

PARKE-DAVIS

Artax BIOPHARMA

PAX-101 NDA Submission Plans

Potential Value and Liquidity Via Early NDA Submission

Priority Review Voucher Program for Neglected Tropical Diseases - HAT

- **IV suramin is the standard of care** in the treatment of potentially lethal infections caused by Stage 1 T. Brucei Rhodesiense Human African Trypanosomiasis (HAT), aka African Sleeping Sickness, for over 100 years
- **Currently only approved in Africa**, where PaxMedica has the exclusive license to suramin-treated patient data from key endemic hospitals
- **PAX-101 received FDA Orphan Drug Designation** for this neglected tropical disease in Nov. 2020
- **NDA Sponsors under this program may qualify for FDA benefits, including a Priority Review Voucher**
  - Market exclusivities up to seven (7) years are also expected to be granted
- **Priority Review Vouchers (PRV) have been be transacted at values > $100 million**
  - PRV Vouchers can potentially be sold to a third party upon receipt following NDA approval
- **PaxMedica intends to file an NDA** for the use of PAX-101 in HAT infections in 2024

Anticipated Near-term Milestone: Complete NDA for HAT

Plan for Potential Approval and Receipt of Transactable Voucher:

- Primary efficacy data expected to be from a retrospective data analysis of patients treated with suramin for HAT compared to a natural history cohort from a prior HAT epidemic before availability of suramin treatment
- PaxMedica has exclusive license to the only treatment records for hundreds of TbR HAT patients treated with suramin (2000-2020) in certain hospitals in Uganda and Malawi, the epicenter of recorded infections
- FDA feedback from two documented meetings confirm specific requirements for the NDA and PRV filing process
- Filing NDA anticipated in 2024
- Accelerated review/approval expected and, if approved, subsequent PRV award and potential sale

Program for NDA and PRV Underway

Regulatory – FDA Guidance Received

- HAT is listed as a neglected tropical disease in the FDA Tropical Disease PRV Program
- HAT submission will be a 505(b)(2) - NDA
  - FDA concurs that a prospective efficacy trial would not be feasible due to the rare incidence and the ethical challenges of conducting a placebo-controlled trial in a lethal illness
- Orphan drug designation awarded for HAT and the company expects to receive both new chemical entity (NCE) and orphan drug exclusivities, offering up to 7 years of market exclusivity in the US with respect to any new product that contains suramin, upon NDA approval

Clinical – Registrational Efficacy Study Underway in Africa

- Retrospective study using exclusively licensed data being converted into Clinical Reports per FDA feedback
- Topline results expected to be available in Q1 2023 following database lock and statistical analysis

CMC Supply Chain – API and Drug Product cGMP Process Currently expected to be Completed in 2023

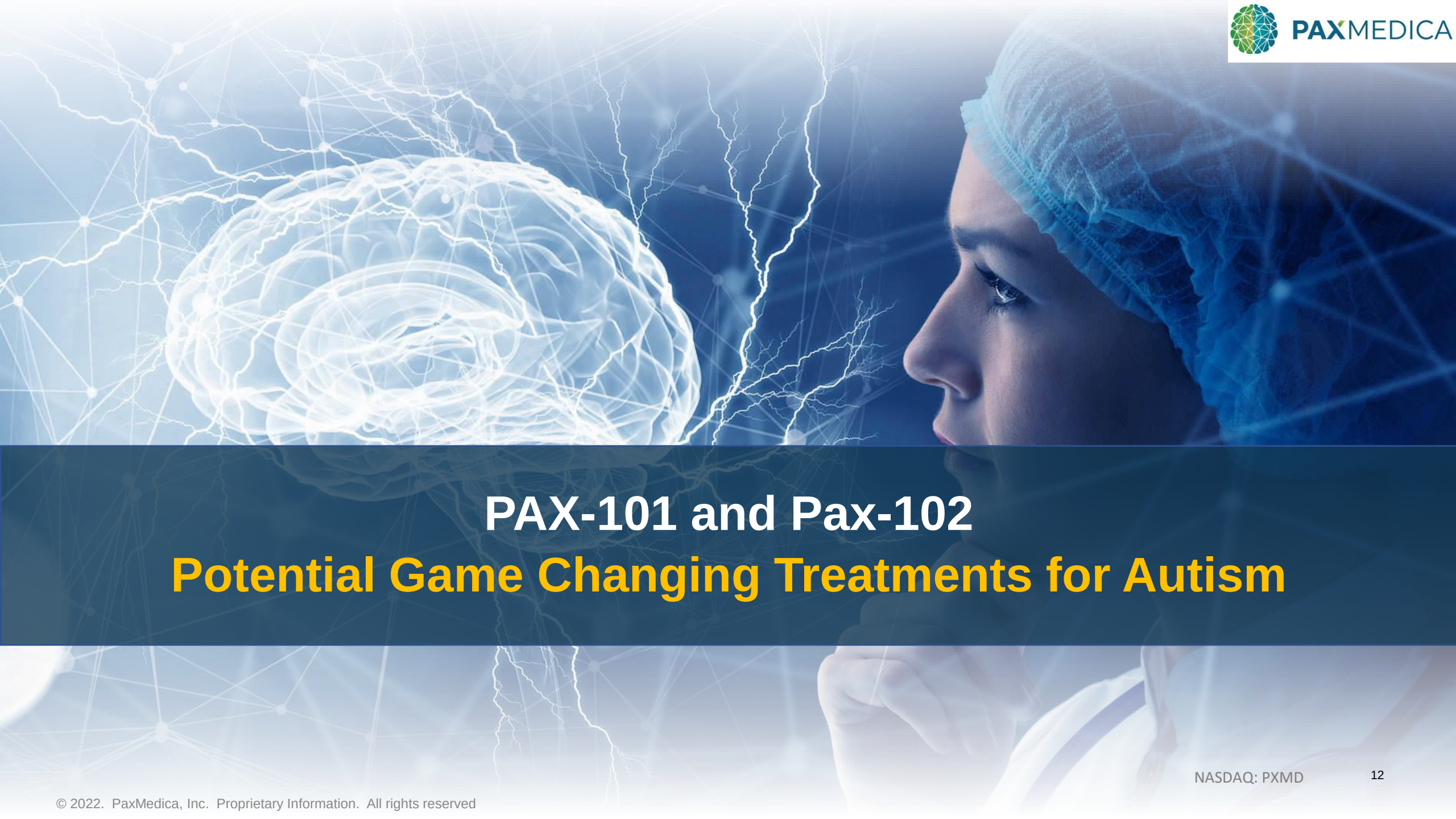
- Suramin API will be produced by a central Europe CDMO for final drug product development by 4th quarter 2022
- PAX-101 drug product manufacturing and release process is expected to be initiated in 2nd quarter 2023 with stability testing immediately following Quality Control release

PAX-101 Development Goals

Potential Milestones Through 2024

- **PAX-101 NDA for HAT**
- **Priority Review Voucher Sale**
- **Up to 7 Years of US Commercial Exclusivity**

PAX-101 NDA, if approved, will be the first approval of suramin in the US market



PAX-101 and Pax-102

Potential Game Changing Treatments for Autism

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Autism Spectrum – A Significant Clinical Opportunity

1 in 44 children in the US is diagnosed with ASD

No FDA approved treatments for Autism core symptoms:

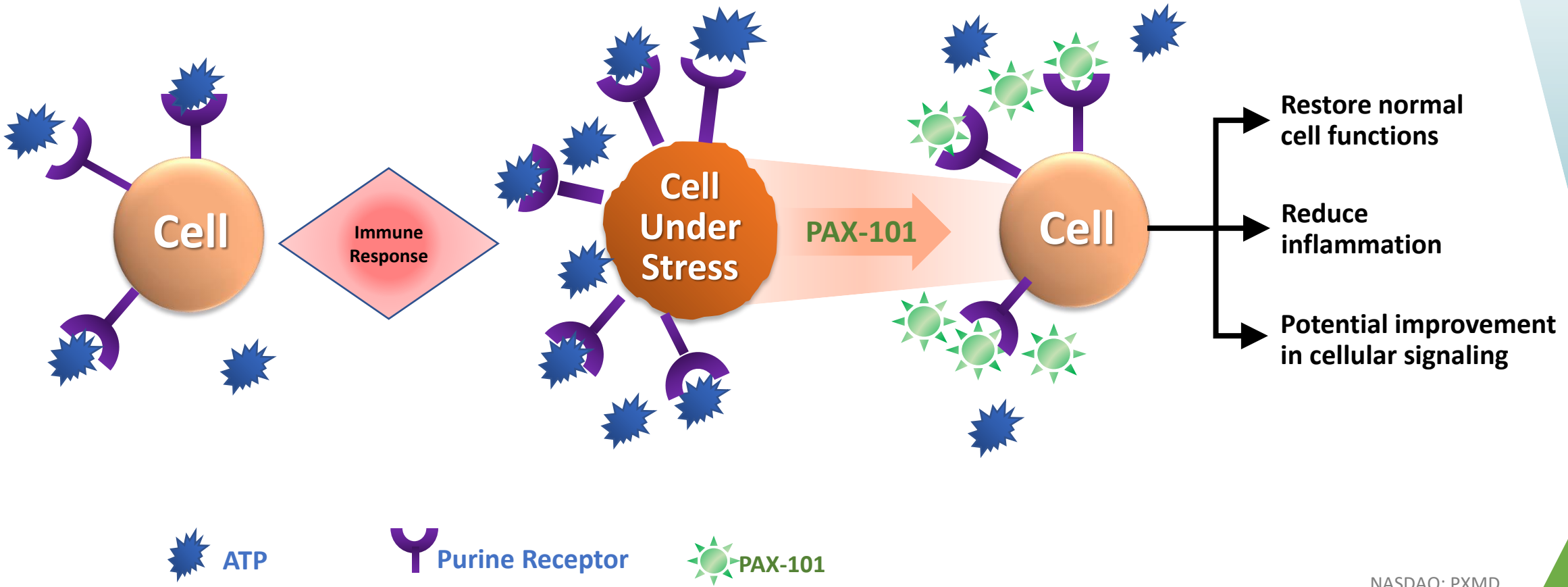
- Deficits in Social Communication
- Restricted and Repetitive Patterns of Behavior
- Significant Impairment in Functioning

- **Global Autism treatment market reached $3.3B in 2018 and is expected to exceed $4.6 Billion in 2026 (CAGR 4.3%)[1]**
  - Irritability, a non-core symptom associated with ASD, is treated with available anti-psychotic drugs but tolerability and side effects can be treatment limiting

[1]Fortune Business Insights, Autism Spectrum Disorder Therapeutics Market Research Report, August 2019

A New Treatment Pathway Proposed for Autism

PAX-101 may improve symptoms of ASD by blocking the action of ATP on purine receptors that are over-expressed during immune system responses

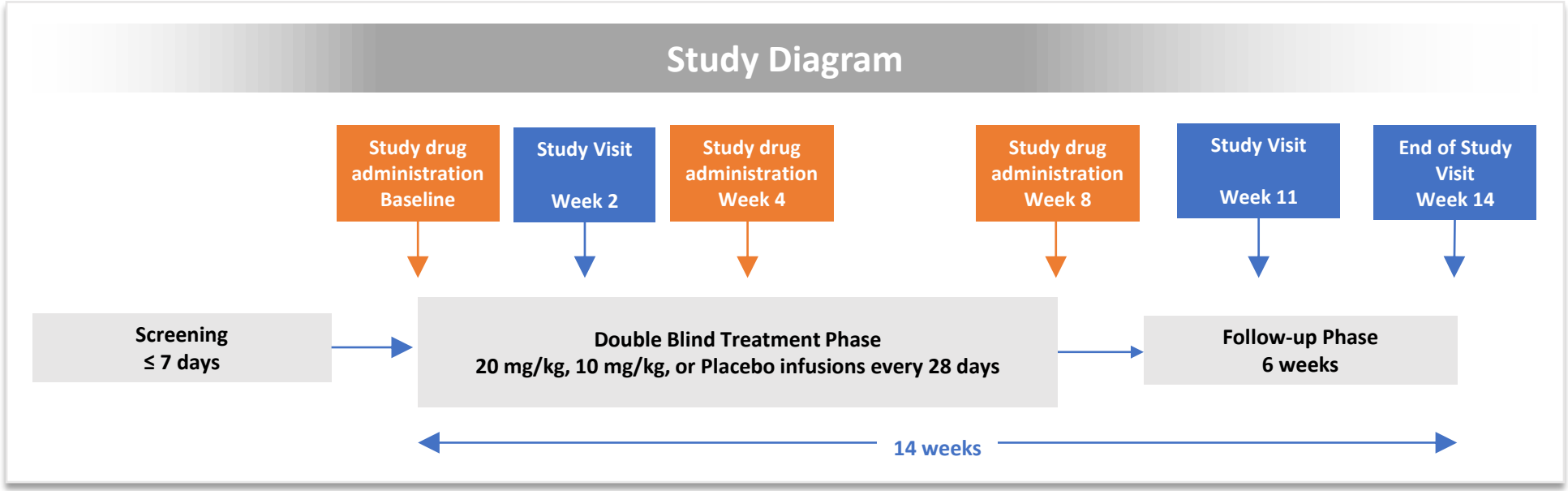


Forging a New Path in ASD Treatment:
PAX-101 Phase 2 Results in ASD

PAX-101 Clinical Trial Results - 2021

Randomized, double-blind, placebo controlled, dose-ranging proof of concept study

- **Primary:** ABC Core (subscales 2, 3, & 5)
- **Secondaries:** ABC Total Score, CGI-I, Autism Treatment Evaluation Checklist, Expressive One Word Picture Vocabulary Test
- **Dose Groups:** IV suramin (20 mg/kg), IV suramin (10 mg/kg) and IV placebo
- **Dosing Regimen:** Baseline, Week 4, and Week 8



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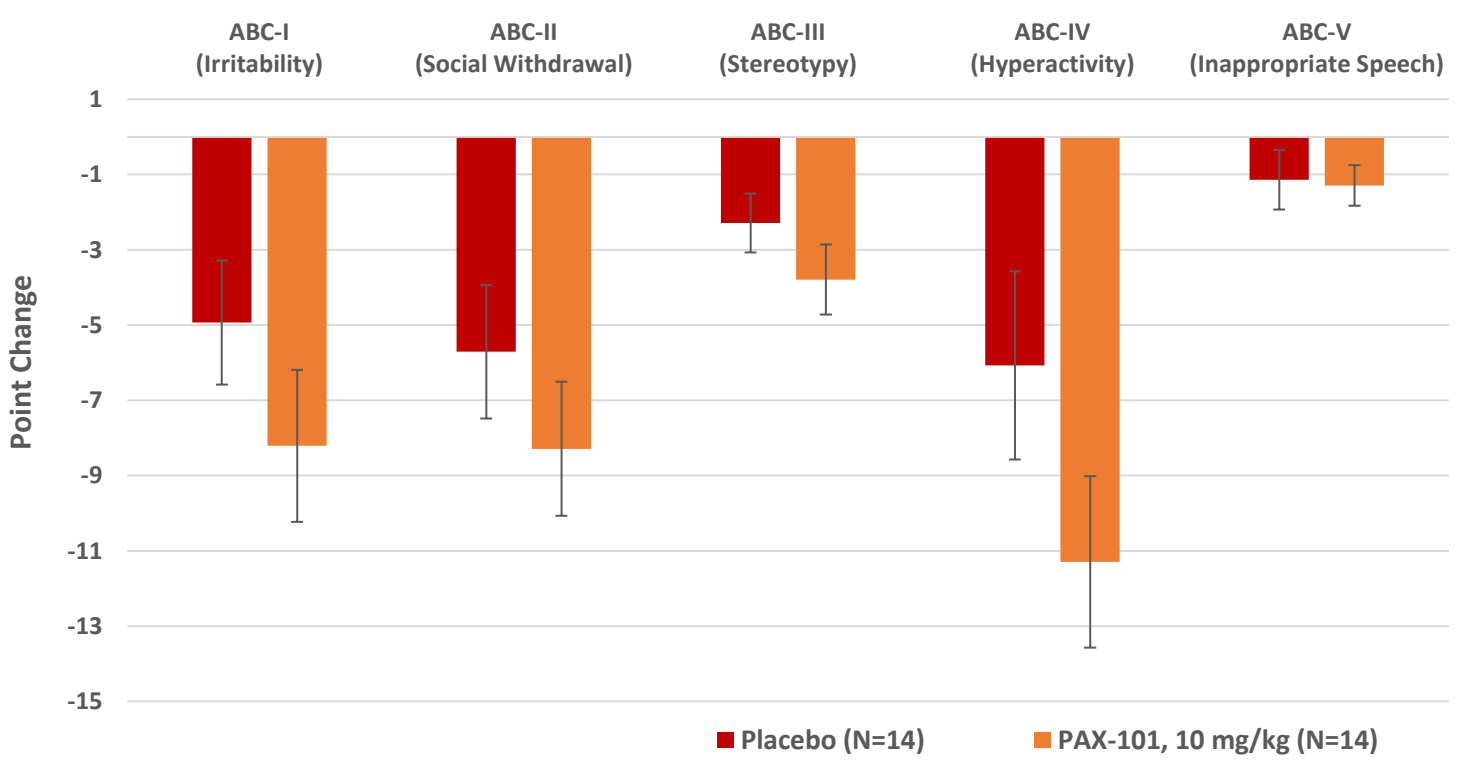
Patient Population - Autism Clinical Trial

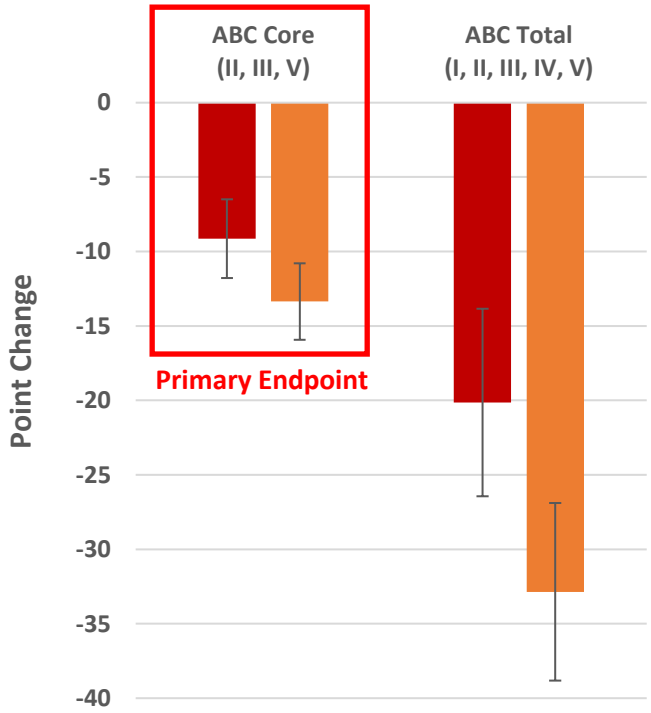
- **6 sites in South Africa**
- **Diverse population of 52 boys, mean age 8.4 years**
- **44 completers**
  - 5 withdrawals due to COVID-19 lockdowns and site closures
  - 1 for an adverse event
  - 2 for other reasons

Primary Endpoint - Aberrant Behavior Checklist (ABC)

Individual ABC Subscale Changes

Change from Baseline through Week 14





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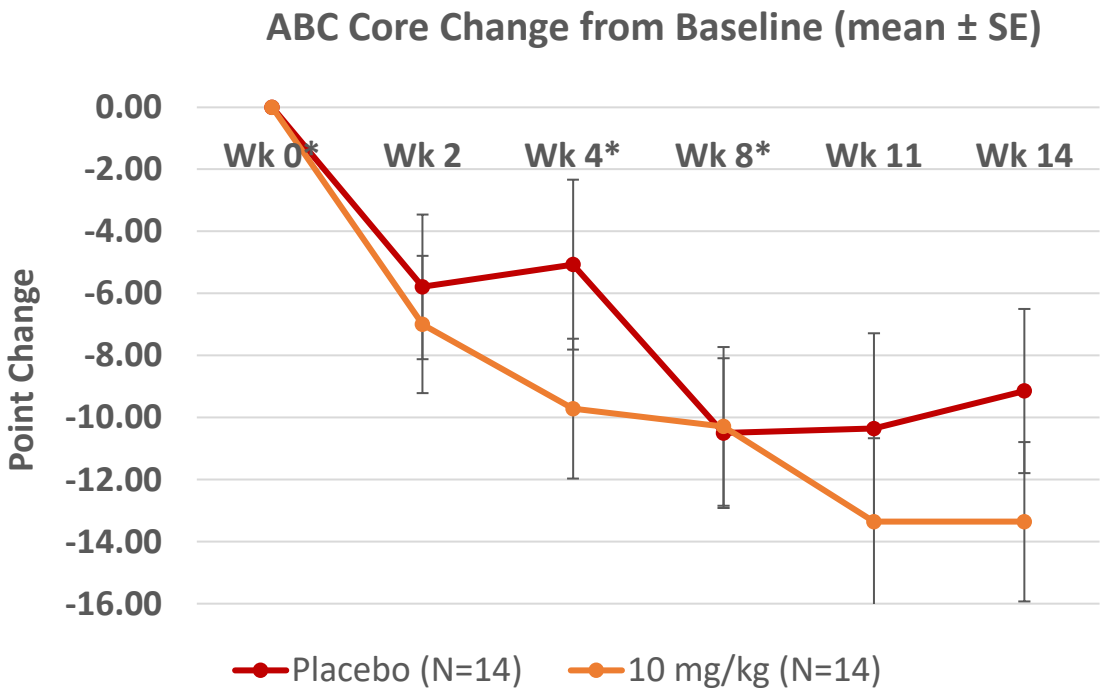
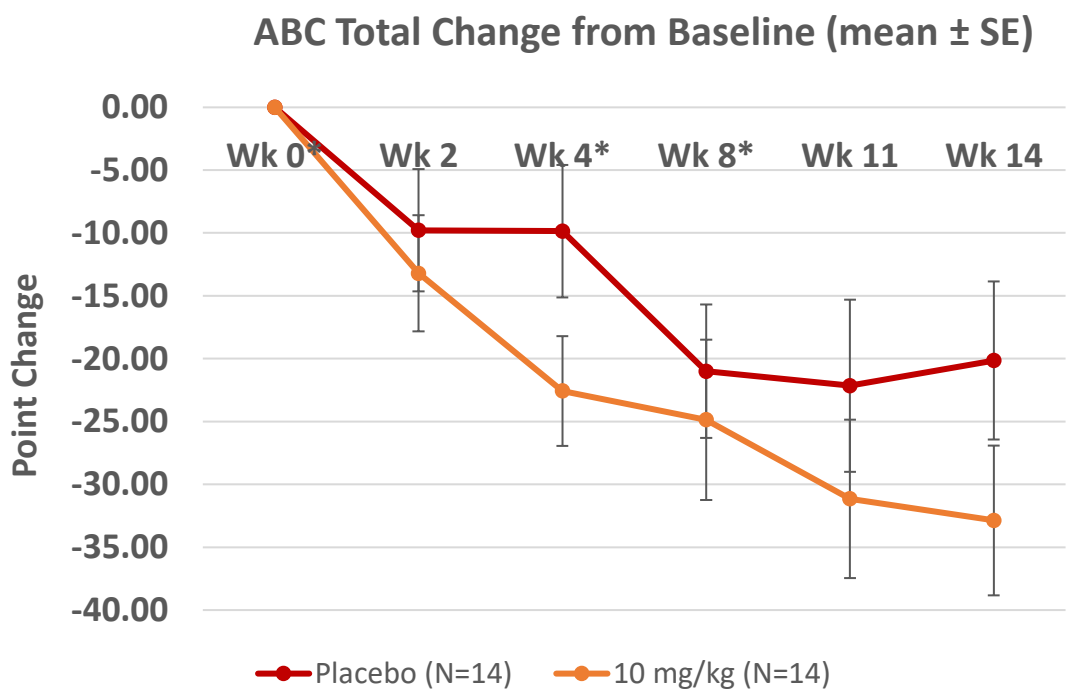
Primary Endpoint - Aberrant Behavior Checklist (ABC)

Core Symptoms and Total Symptoms - Change from Baseline over time

PAX-101 Low Dose (10mg/kg) Outperforms Placebo in Core and Total Symptoms Measures





* Drug administration visit

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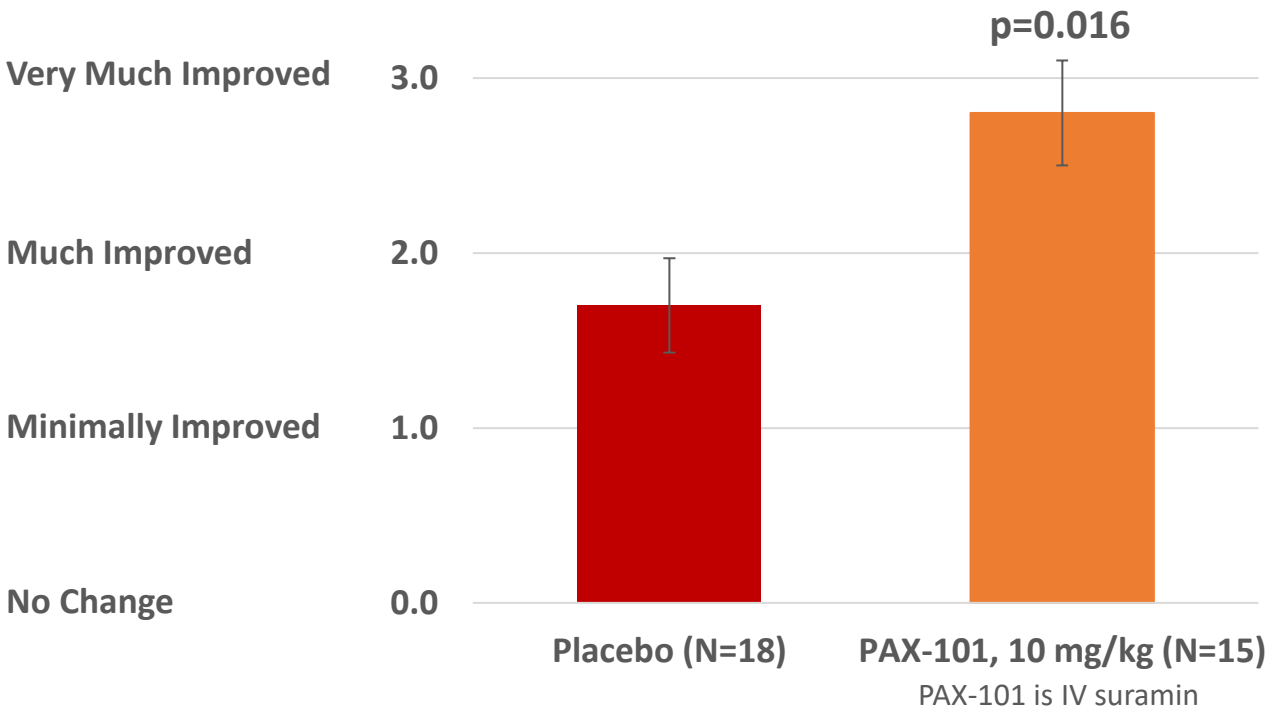
Secondary Endpoint - Clinical Global Impression of Improvement in Overall Severity of Symptoms - Change from Baseline

CGI-I Overall Severity Score, Scaled

Change from Baseline to Week 14 (ITT population, mean ± SE)



PAX-101 is IV suramin

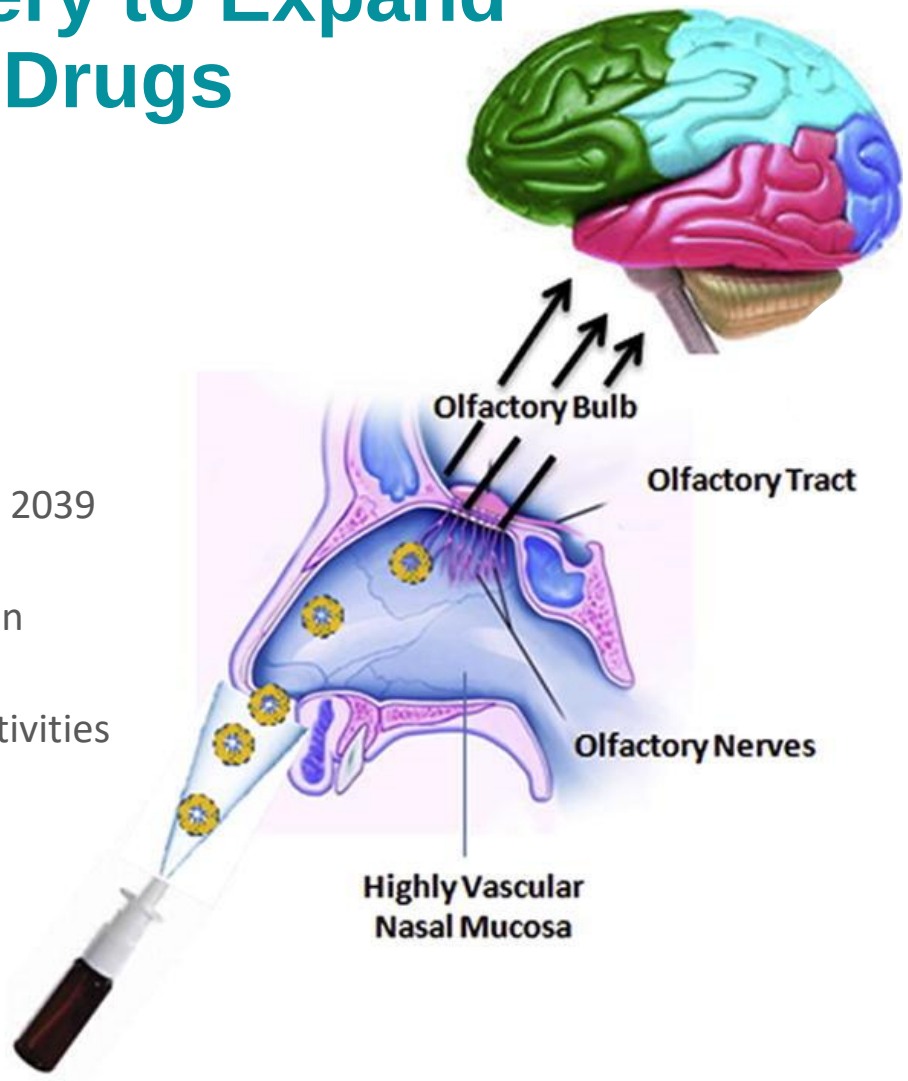
Results	Chg from BL	P Value	Adj P Value
10 mg/kg	-2.8 ± 0.30	0.008	0.016
Placebo	-1.7 ± 0.27		

PAX-101 – Phase 2 Trial Summary Results

- **Both dose regimens showed improvement trends from baseline on ABC Core, but study was not statistically powered**
- **10 mg/kg dose group showed a statistically significant and clinically meaningful change on the CGI-I**
- **Confirmation of these results needed in a larger study**

PAX-102 – Proprietary Intranasal Delivery to Expand Clinical Applications of Antipurinergic Drugs

- **Promising pre-clinical data**
- **Patents pending** which would potentially extend exclusivity through at least 2039
- **More convenient and cost-effective** as “use at home” versus IV infusion
- **An IND for PAX-102** will be filed pending further funding and partnering activities



PaxMedica Business Goals 2022-24

- Raise awareness of company mission to develop therapeutics for urgent and unmet needs in serious neurologic disorders
- Complete all necessary pre-clinical, non-clinical and clinical studies to support NDA submission for HAT indication
- Complete manufacturing validation of PAX-101 in preparation for NDA submission in 2023
- Advance development of PAX-102 formulation and drug/device intranasal delivery product
- Market and sell Priority Review Voucher if received

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THANK YOU!

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