Neuren (NEU) – ASX Announcement **9 May 2024**

DAYBUE™ Q1 2024 net sales US$75.9 million, full-year guidance US$370-420 million

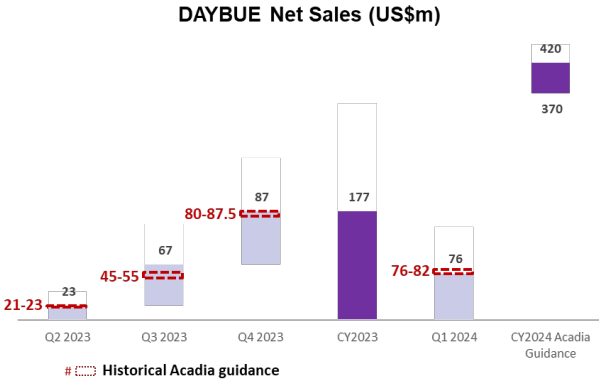
Melbourne, Australia: Neuren Pharmaceuticals (ASX: NEU) today reported highlights from the Q1 2024 earnings announcement and conference call of its partner Acadia Pharmaceuticals (Nasdaq: ACAD). Acadia announced Q1 net sales of DAYBUE™ (trofinetide) in the United States of US$75.9 million (compared with guidance of US$76 to US$82 million) and reiterated the full-year 2024 guidance for net sales of between US$370 and US$420 million.

Anticipated revenues to Neuren for DAYBUE are:

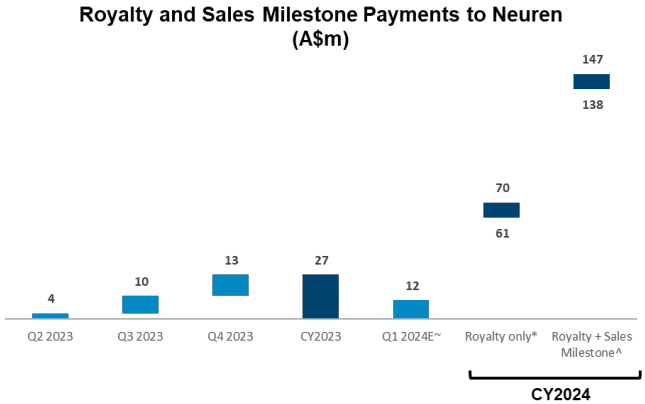
- Q1 2024 royalties of A$11.6 million
- Full-year 2024 royalties of between A$61 million and A$70 million plus sales milestone revenue of A$77 million (assuming Acadia guidance is met and exchange rate of 0.65)

As previously reported, Q1 2024 net sales were negatively impacted compared with Q4 2023 by seasonal effects, including refills due in January actioned in December prior to the holidays and reduced Rett clinic days in January. In addition, discontinuations during Q1 were higher following the surge in new patient starts in the previous quarters and gross to net discounts were slightly higher in Q1. Net patient additions have resumed, with increases in each of the last 6 weeks.

Approximately 25% of the 5,000 diagnosed Rett syndrome patients in the United States have initiated therapy. Persistence on therapy continues to track more than 10% higher than the clinical trial experience, with 58% remaining on therapy after treatment for 9 months. 862 patients are currently on therapy.



Q1 2024 net sales US$76m
2024E net sales of US$370 – 420m



Q1 2024E royalty of A$12m
2024E royalty of A$61 – 70m, plus A$77m sales milestone

~ Based on 10% of DAYBUE net sales and AUDUSD of 0.652294
* Based on 10% of DAYBUE net sales up to US$250m and 12% of DAYBUE net sales between US$250m and US$500m, and AUDUSD of 0.65
^ Neuren will be entitled to US$50m sales milestones (receivable in Q1 2025) if CY2024 DAYBUE net sales reaches US$250m; assumes AUDUSD of 0.65

DAYBUE is currently only approved in the United States, however Acadia made good progress on international expansion:

- A New Drug Submission in Canada was accepted for filing and priority review was granted, with potential for approval around the end of 2024.
- A pediatric investigation plan (PIP) was filed with and accepted by the European Medicines Agency, with a Marketing Authorisation Application anticipated in Q1 2025.
- A formal meeting with the Japanese regulatory agency (PMDA) to discuss the clinical plan is scheduled in Q2 2024.

The Acadia Q1 earnings presentation is attached to this announcement and a recording of the conference call can be accessed in the Investors section of the Acadia website www.acadia.com.

About Neuren

Neuren is developing new drug therapies to treat multiple serious neurological disorders that emerge in early childhood and have no or limited approved treatment options. Recognising the urgent unmet need, all programs have been granted "orphan drug" designation in the United States. Orphan drug designation provides incentives to encourage development of therapies for rare and serious diseases.

DAYBUE™ (trofinetide) is approved by the US Food and Drug Administration (FDA) for the treatment of Rett syndrome in adult and pediatric patients two years of age and older. Neuren has granted an exclusive worldwide licence to Acadia Pharmaceuticals Inc. for the development and commercialisation of trofinetide.

Neuren's second drug candidate, NNZ-2591, is in Phase 2 development for each of Phelan-McDermid syndrome, Angelman syndrome, Pitt Hopkins syndrome and Prader-Willi syndrome.

Contact:

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ASX Listing Rules information

This announcement was authorized to be given to the ASX by the CEO/Managing Director of Neuren Pharmaceuticals Limited, Suite 201, 697 Burke Road, Camberwell, VIC 3124

Forward-looking Statements

This announcement contains forward-looking statements that are subject to risks and uncertainties. Such statements involve known and unknown risks and important factors that may cause the actual results, performance or achievements of Neuren to be materially different from the statements in this announcement.

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First Quarter 2024 Earnings Call

May 8, 2024

Call Agenda

Welcome	**Al Kildani** | Senior Vice President, Investor Relations and Corporate Communications
CEO Opening Remarks	**Steve Davis** | President and Chief Executive Officer
Commercial Update	**Brendan Teehan** | Chief Operating Officer, Head of Commercial
R&D Update	**Kimberly Manhard** | Senior Vice President, Global Strategic Planning and Execution
Financial Update	**Mark Schneyer** | Chief Financial Officer
Closing Remarks	**Steve Davis** | President and Chief Executive Officer
Q&A Session	**Parag Meswani, Pharm D.** | Senior Vice President, Trofinetide – Rare Disease Franchise, *available for Q&A*

Forward-Looking Statements

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include all statements other than statements of historical fact and can be identified by terms such as “may,” “will,” “should,” “could,” “would,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “projects,” “predicts,” “outlook,” “potential” and similar expressions (including the negative thereof) intended to identify forward-looking statements. Forward-looking statements contained in this presentation, include, but are not limited to, statements about: (i) our business strategy, objectives and opportunities; (ii) plans for, including timing, development and progress of commercialization or regulatory timelines for, NUPLAZID, DAYBUE and our product candidates; (iii) benefits to be derived from and efficacy of our products, including the potential advantages of NUPLAZID and DAYBUE and expansion opportunities for NUPLAZID and DAYBUE in other indications, and for DAYBUE in jurisdictions outside the U.S.; (iv) estimates regarding the prevalence of the diseases targeted by our products and product candidates; (v) potential markets for any of our commercial products; and (vi) our estimates regarding our future financial performance, cash position, profitability or capital requirements.

Forward-looking statements are subject to known and unknown risks, uncertainties, assumptions and other factors that may cause our actual results, performance or achievements to differ materially and adversely from those anticipated or implied by our forward-looking statements. Such risks, uncertainties and other factors include, but are not limited to: our dependency on the continued successful commercialization of NUPLAZID and DAYBUE and our ability maintain or increase sales of NUPLAZID or DAYBUE; the costs of our commercialization plans and development programs, and the financial impact or revenues from any commercialization we undertake; our ability to obtain necessary regulatory approvals for our product candidates and, if and when approved, market acceptance of our products; our dependence on third-party collaborators, clinical research organizations, manufacturers, suppliers and distributors; the impact of competitive products and therapies; our ability to generate or obtain the necessary capital to fund our operations; our ability to grow, equip and train our specialized sales forces; our ability to manage the growth and complexity of our organization; our ability to maintain, protect and enhance our intellectual property; and our ability to continue to stay in compliance with applicable laws and regulations. Given the risks and uncertainties, you should not place undue reliance on these forward-looking statements. For a discussion of these and other risks, uncertainties and other factors that may cause our actual results, performance or achievements to differ, please refer to our annual report on Form 10-K for the year ended December 31, 2023 as well as our subsequent filings with the Securities and Exchange Commission from time to time, including our quarterly report on Form 10-Q for the period ended March 31, 2024. The forward-looking statements contained herein are made as of the date hereof, and we undertake no obligation to update them after this date, except as required by law.

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Opening Remarks

Steve Davis, President and Chief Executive Officer

Acadia Investment Thesis

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Two successful commercial franchises

- $205.8M in Q1 2024 revenues
  - NUPLAZID® $129.9M
  - DAYBUE™ $75.9M

Two late-stage assets with strong early-stage pipeline

- Ongoing P3 trial of ACP-101 in Prader-Willi syndrome
- Ongoing seamless P2 / P3 program of ACP-204 in Alzheimer's disease psychosis
- Numerous early-stage programs

Financial strength

- 74% YoY revenue growth in 1Q24
- Cash balance of $470.5M as of March 31, 2024

DAYBUE (trofinetide) is only approved in the U.S. by the FDA for the treatment of Rett syndrome in adults and pediatric patients two years of age and older.
NUPLAZID (pimavanserin) is only approved in the U.S. by the FDA for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis.

DAYBUE Overview

DAYBUE Today

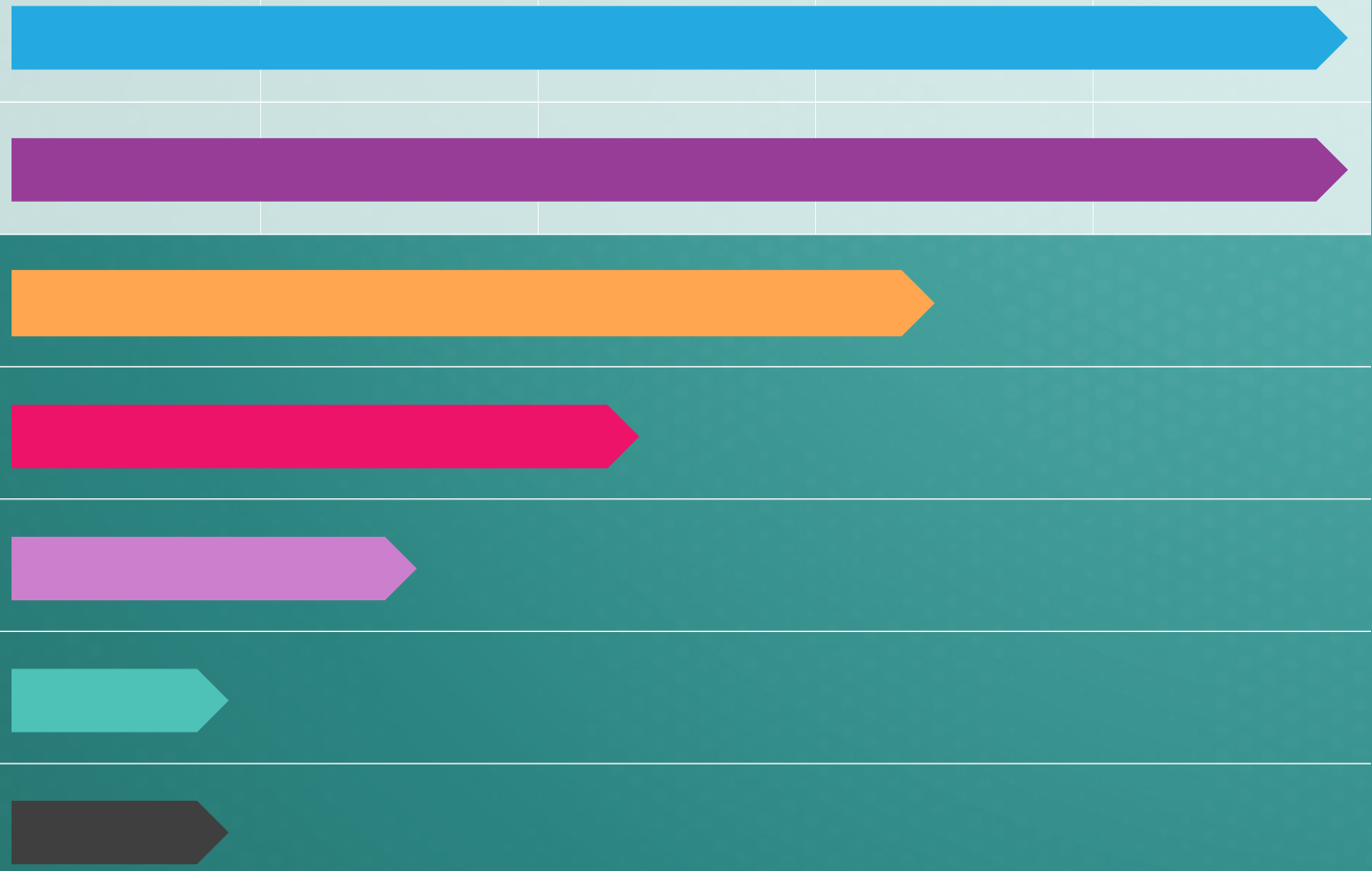
- 5,000 diagnosed population
  - 25% penetration to date
- Persistency continues to track ~10 percentage points above clinical experience
- Average dose (post titration) remains ~75-80%
- >650 prescribers to date
- Broad payor access

DAYBUE Outlook

- Sizeable untreated population
- Growing body of real-world benefits
- Facilitate consistent application of GI management strategies
- Drive depth of prescribing outside of COEs
- Continue net patient growth
  - Net patient adds in each of last six weeks

Deep CNS Pipeline

Program	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Marketed
NUPLAZID® (pimavanserin)	Parkinson's Disease Psychosis					
DAYBUE™ (trofinetide)	Rett Syndrome					
ACP-101[1,2]	Hyperphagia in Prader-Willi Syndrome					
ACP-204[2]	Alzheimer's Disease Psychosis					
ACP-2591[2]	Rett Syndrome; Fragile X Syndrome					
ASO Programs[2]	SYNGAP1; Rett syndrome; Undisclosed					
Multiple Undisclosed Programs	Neuropsychiatric and Rare Disorders					



[1] Acadia acquired Levo Therapeutics and its rights/licenses to ACP-101.
[2] The safety and efficacy of these investigational agents have not been established. There is no guarantee these investigational agents will be filed with or approved by any regulatory agency.
DAYBUE (trofinetide) is only approved in the U.S. by the FDA for the treatment of Rett syndrome in adults and pediatric patients two years of age and older.
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Commercial Update

Brendan Teehan, Chief Operating Officer, Head of Commercial

Key Drivers of Long-Term Value for DAYBUE

1 out of 4 diagnosed Rett patients have received treatment with DAYBUE; large remaining untreated patient population

- Successfully penetrated COEs; now have ~50% share of patients treated
- Driving further depth of prescribing outside of COEs, where large majority of patient population exists

Foundation of real-world experience across HCPs and families to drive adoption

- Real-world benefits serve as examples of clinical success on DAYBUE treatment
- Sharing successful GI management strategies broadly
- Time to benefit is a key consideration

Persistency continues to track 10 percentage points above clinical trial experience month over month

- 9-month persistency rate in real world vs. 9-month persistency in LILAC placebo rollover patients (58% vs. 47%)[1]

[1]Real-world persistency measures calculated excluding confirmed discontinuations and patients who have gone >60-days since last refill, compared with observation in placebo rollover patients from the LILAC-1 open label extension study.

Expanding DAYBUE Internationally

- Pediatric investigation plan (PIP) filed with and accepted by EMA in **Europe**
  - Filing anticipated in 1Q25
- Formal meeting with **Japanese** regulatory agency (PMDA) scheduled in 2Q24 to discuss clinical plan
- NDS in **Canada** accepted for filing and priority review granted; potential approval around YE24

EMA: European Medical Authority; PMDA: Pharmaceuticals and Medical Devices Agency

DAYBUE Real-World Experience

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"This child is 9 years old and just told her mom she loves her for the first time."

"It was her engagement level with the world outside of her; it just blossomed, and it was like a light was turned on."

"I've re-met my daughter."

"She is more alert, will move her head back and forth following a conversation between two people, she laughs appropriately during conversations."

Caregiver testimonials are sourced from AnovoRx as well as from poster titled Assessing Experiences With Trofinetide for Rett Syndrome: Interviews With Caregivers of Patients in LAVENDER, LILAC, and LILAC-2 Studies.

NUPLAZID Strategy: Optimize Cash Flow

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Real-world evidence has grown new patient starts and net sales

Carefully managed NUPLAZID SG&A spend

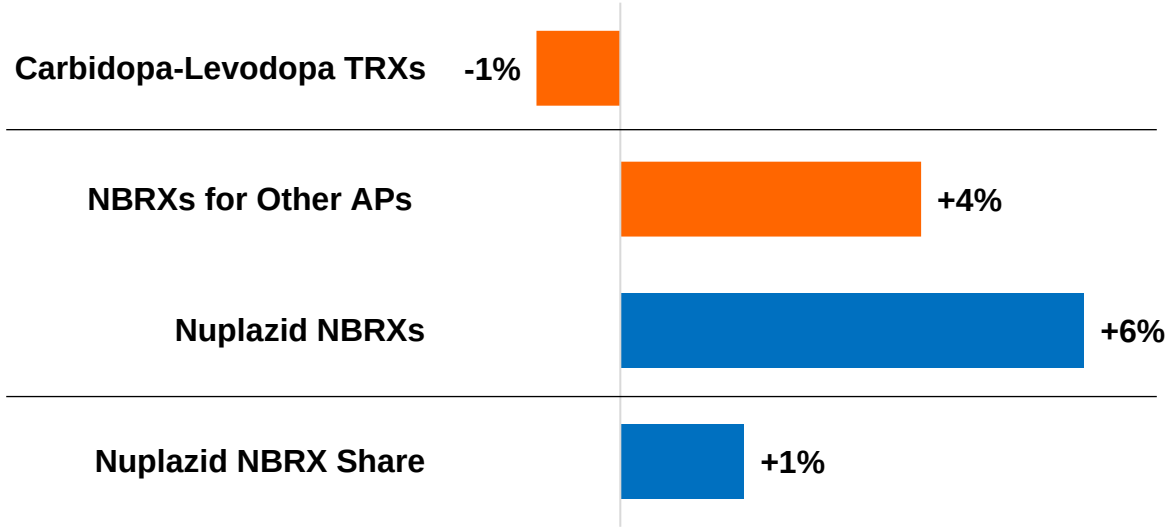
Franchise generates >$300 million in annual cash flow

NUPLAZID 1Q24 Commercial Update

Key takeaways

- $129.9M in net product sales in 1Q24
- NBRXs for both NUPLAZID and other atypical antipsychotics (APs) grew in 1Q24 relative to 4Q23; NUPLAZID outpaced market growth

PDP: Office-Based and LTC Channels 4Q23 vs 1Q24



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R&D Update

Kimberly Manhard, Senior Vice President, Global Strategic Planning and Execution

Prader-Willi Syndrome Opportunity

Significant Unmet Need

- **~8,000-10,000 patients in the U.S.**
- **No FDA approved medicine to treat hyperphagia in PWS**

- Rare and complex neurobehavioral genetic disorder that often leads to social isolation
- Hyperphagia is a defining characteristic of Prader-Willi syndrome (PWS) and commonly begins between the ages of 3-8
- Hyperphagia is characterized by unrelenting hunger
  - Often leads to obesity and behavioral challenges including anxiety and aggression
  - Extremely distressing for patients, parents and caregivers
- 30 years average life expectancy[1]

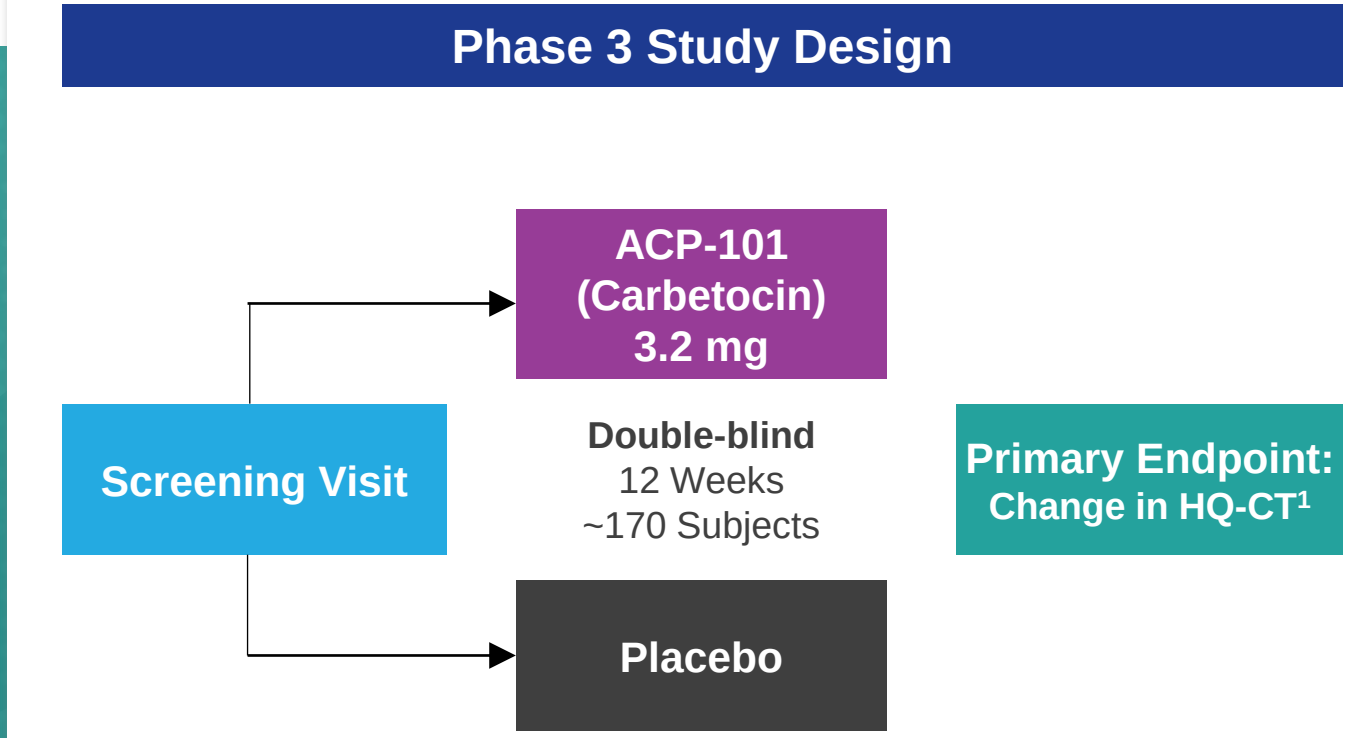
[1]Causes of Death in Prader-Willi Syndrome: Prader-Willi Syndrome Association (USA) 40-Year Mortality Survey. Genet Med. 2017 June ; 19(6): 635–642.

Ongoing Phase 3 Study of ACP-101 for the Treatment of Hyperphagia in PWS

COMPASSPWS

Trial builds on previous Phase 3 clinical trial experience

3.2 mg dose was observed to significantly reduce hyperphagia-related behaviors



[1]Hyperphagia Questionnaire for Clinical Trials (HQ-CT) is an observer-reported outcome measure that has been widely used in interventional studies to assess changes in hyperphagic behaviors in individuals with PWS.

ACP-204 in Alzheimer's Disease Psychosis (ADP)

ACP-204 is a next generation $5HT_{2A}$ blocker that builds on the learnings of pimavanserin

Target Product Profile

- Mitigate or eliminate QT prolongation
- Explore doses higher than pimavanserin 34 mg equivalent
- Improved time to onset of action

Phase 1 Results

- No sign of QT prolongation
- Wide dose range established supporting potential for ~2x pimavanserin 34 mg equivalent
- Steady state PK (5 days) achieved in less than half the time of pimavanserin (12 days)

ACP-204: Phase 2 / Phase 3 Seamless Program for the Treatment of ADP

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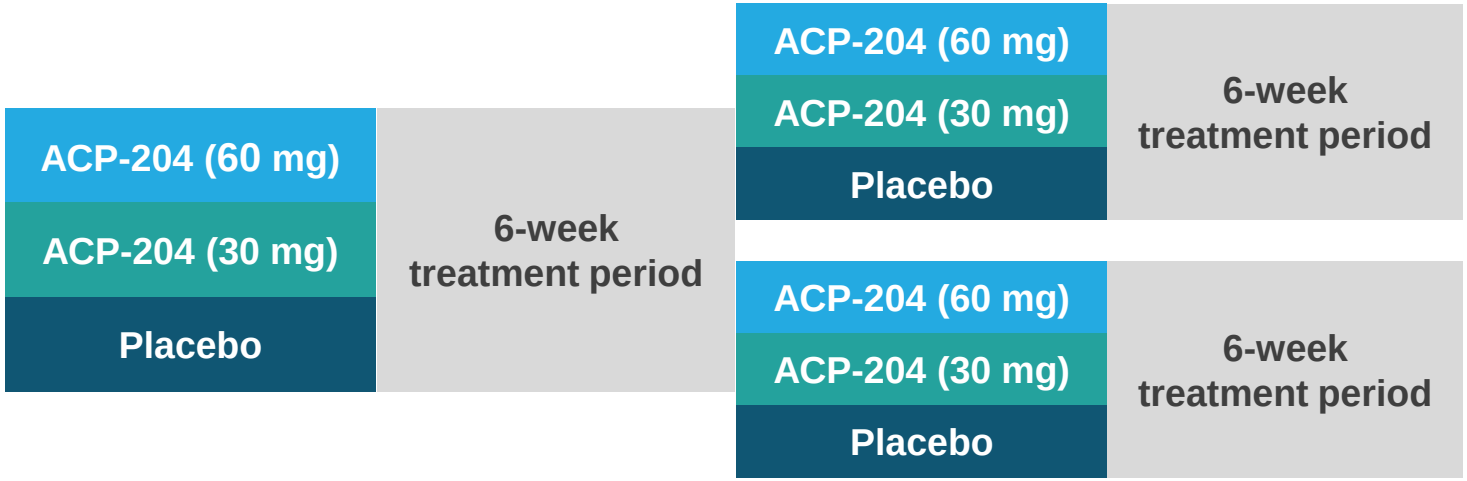
Our clinical experience with pimavanserin supports seamless P2 / P3 program

Phase 2 and each Phase 3 study designed and sized to be considered pivotal study if successful

Phase 2
N=318, double-blind, randomized 1:1:1

Two Phase 3 Studies
of similar size and design

Seamless Enrollment



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Financial Update

Mark Schneyer, Chief Financial Officer

1Q24 Financial Highlights

Millions, Except EPS	1Q24	1Q23	*YoY Change*
TOTAL Net Sales	$205.8	$118.5	74%
NUPLAZID Net Product Sales	$129.9	$118.5	10%
DAYBUE Net Product Sales	$75.9	-	-
R&D	$59.7	$69.1	-14%
SG&A	$108.0	$101.2	7%
Net Income (Loss)	$16.6	($43.0)	
EPS	$0.10	($0.27)	
		Year End 2023	
Cash Balance	$470.5	$438.9	

Reiterating FY 2024 Financial Guidance

	FY24 Guidance
DAYBUE Net Sales	$370 - 420 Million
NUPLAZID Net Sales	$560 - $590 Million
NUPLAZID Gross-to-Net	25% - 29%
R&D Expense	$305 - $325 Million
SG&A Expense	$455 - $480 Million

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Building On Our Success

2024 and Beyond

- Penetrate substantial market opportunity for DAYBUE in the U.S.
- Strong growth from both DAYBUE and NUPLAZID franchises
- Bring trofinetide to new markets outside the U.S. including Europe, Japan and Canada
- Progress P3 study of ACP-101 in Prader-Willi syndrome
- Progress seamless P2 / P3 program for ACP-204 in Alzheimer’s disease psychosis
- Substantial and growing cash flow from operations

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Q&A Session