



# Redefining Central Nervous System Therapies

Investor Presentation

April 2021

Alexander Zwyer, CEO



**NLS Pharmaceuticals**  
Connecting Brains

# Forward Looking Statements

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This presentation contains express or implied forward-looking statements within the Private Securities Litigation Reform Act of 1995 and other U.S. Federal securities laws. For example, we are using forward-looking statements when we discuss the expected timing of our clinical trials, the receipt of the results from clinical trials and obtaining regulatory approval for Quilience®; clinical data readout; proposed trials that may occur in the future; our ability to generate revenue from licensing agreements or in compassionate use programs; compounds or product candidates that we may seek to develop or add to our pipeline; and the potential benefits and impact our products could have on improving patient health care. These forward-looking statements and their implications are based on the current expectations of our management only, and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. The following factors, among others, could cause actual results to differ materially from those described in the forward-looking statements: our ability to obtain additional capital; a global pandemic, such as COVID-19, or economic downturn and any resulting government actions therefrom; changes in technology and market requirements; we may encounter delays or obstacles in launching and/or successfully completing our clinical trials; our products may not be approved by regulatory agencies, our technology may not be validated as we progress further and our methods may not be accepted by the scientific community; we may be unable to retain or attract key employees whose knowledge is essential to the development of our products; unforeseen scientific difficulties may develop with our process; our products may wind up being more expensive than we anticipate; results in the laboratory may not translate to equally good results in real clinical settings; results of preclinical studies may not correlate with the results of human clinical trials; our patents may not be sufficient; our products may harm recipients; changes in legislation; inability to timely develop and introduce new technologies, products and applications; loss of market share and pressure on pricing resulting from competition, which could cause our actual results or performance to differ materially from those contemplated in such forward-looking statements. Except as otherwise required by law, we undertake no obligation to publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. For a more detailed description of the risks and uncertainties affecting us, reference is made to our reports filed from time to time with the Securities and Exchange Commission.

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As used in this presentation, “the Company,” “we” and “our” refer to NLS Pharmaceuticals Ltd.

# NLS Pharmaceuticals Overview



NLS discovers and develops drug treatments for rare and complex central nervous system (CNS) disorders



Quilience® is a proprietary formulation of mazindol, designed for once-daily dosing. Orphan Drug Designation granted in both the US and Europe Patent applications filed – expiry in 2037 if granted



Lead product candidate, Quilience®, entering Phase 2 for narcolepsy treatment, a \$2.4 billion annual market and growing\*\*



Phase 2 clinical trial planned to begin mid-year with topline results expected in Q4 2021



Mazindol, the active ingredient in Quilience® was used extensively off-label and in compassionate use programs to treat narcolepsy



Pipeline of additional compounds in research and development to address CNS disorders with high unmet need

# Management: Deep Expertise in Clinical Development & Drug Repurposing



## Alexander Zwyer, MBA, Chief Executive Officer

*A co-founder of the company with extensive operational, C-level pharmaceutical experience as well as a serial entrepreneur and strong leader with a proven track-record.* Served as Chief Operating Officer at Viforpharma AG, a specialty pharmaceutical company focused on Nephrology where he was globally responsible for marketing and sales, business development, and regulatory and medical affairs. He was named 'Healthcare CEO of the Year, Switzerland' in 2018 by Business Worldwide. Holds two MBAs incl. from the State University of New York, Albany and is a veteran Tank Captain of the Swiss Army.



## Silvia Panigone, PhD, Chief Operating Officer

*Track record in complex project management; former positions include: Global Project Manager in Quintiles for phase II/III trials in the US/EU and Asia, managing large teams including Regulatory, CMC and pharmacology, with full P&L responsibilities.* Executive position in R&D in Bracco Diagnostics, Managing Director at I-Bankers Direct, Investment Director at BSI Healthcapital, a VC firm focused on life sciences. Holds a Ph.D. in Molecular Oncology from National Cancer Institute, Milan and a Masters in Finance - Management of Economical Resources from SDA Bocconi, Milan, Italy.



## Subhasis Roy, MBA, interim Chief Financial Officer<sup>(1)</sup>

*Over 25 years of healthcare industry experience as a healthcare banker/advisor and more recently as a biopharmaceutical company leader.* Former top executive of Novaremed, a clinical stage Swiss biopharma company and Managing Partner and co-founder of Sirius Healthcare Partners, a healthcare advisory boutique. Previously, he was a healthcare banker at bulge bracket investments Banks (UBS, HSBC, DKB), where he executed numerous financing and M&A transactions. Holds an MBA in Finance and General Management from Fuqua School of Business at Duke University, and Masters and Bachelors degrees in Commerce from University of Mumbai, India.



## Carlos Camozzi, MD, PhD interim Medical Director<sup>(1)</sup>

*Experienced Chief Medical and Corporate Governance Officer in the Biopharmaceuticals field with over 30 years of C-level expertise and experience in orphan drugs and other areas.* As CMO for several European Biotech companies, he generated innovative solutions for the design and execution of non-clinical, translational, and clinical development projects for several orphan drugs, paediatric, and oncology clinical trials. He successfully led several clinical development programmes, regulatory interactions, consultations, submissions and approvals of products with Orphan Drug Designations (ODD), Paediatric Investigational Plans (PIP) and Marketing Authorisations Applications (MAA) with both the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA). He received his medical doctorate and PhD from the National University of Buenos Aires, Argentina.



## Eric Konofal, MD, PhD, interim Chief Scientific Officer<sup>(1)</sup>

*IP expert and co-founder of NLS Pharmaceuticals AG. Active for more than 27 years in the field of sleep research, including narcolepsy and hypersomnia, as a clinician, scientific researcher, and drug hunter.* He is a senior medical consultant for the Pediatric Sleep Disorders Center and the Child and Adolescent Psychiatry Department at Robert Debré Hospital (APHP). His research interests are focused on brain- and iron-dopamine interactions in subjects with neurological sleep disorders (RLS, PLMS), and ADHD. He received his medical doctorate and Ph.D. from the University Pierre-Marie Curie, Paris / France.



## Hervé Girsault, MBA, Head of Business Dev./Licensing<sup>(1)</sup>

*Experienced C-level pharma/biotech executive, former positions include: Global Head M&A/BD Novartis Consumer Health, Head of Novartis Pharma Out-Licensing & Partnering; CBO of PIQUR Therapeutics AG (Basel); CEO, Synarc Inc. (now BioClinica Inc.) (San Francisco, CA); CEO Novartis Consumer Health, Benelux; CEO Gerber Products Company (France).*

# Focused on Rare and Complex CNS Disorders

## Strategic Priorities

Develop Quilience® (mazindol controlled-release) for the treatment of narcolepsy in both the US and EU

As a follow-on program, pursue development or licensure of Nolazol® (mazindol CR) to treat ADHD

Advance development of research and development stage product candidates/compounds

## Rationale

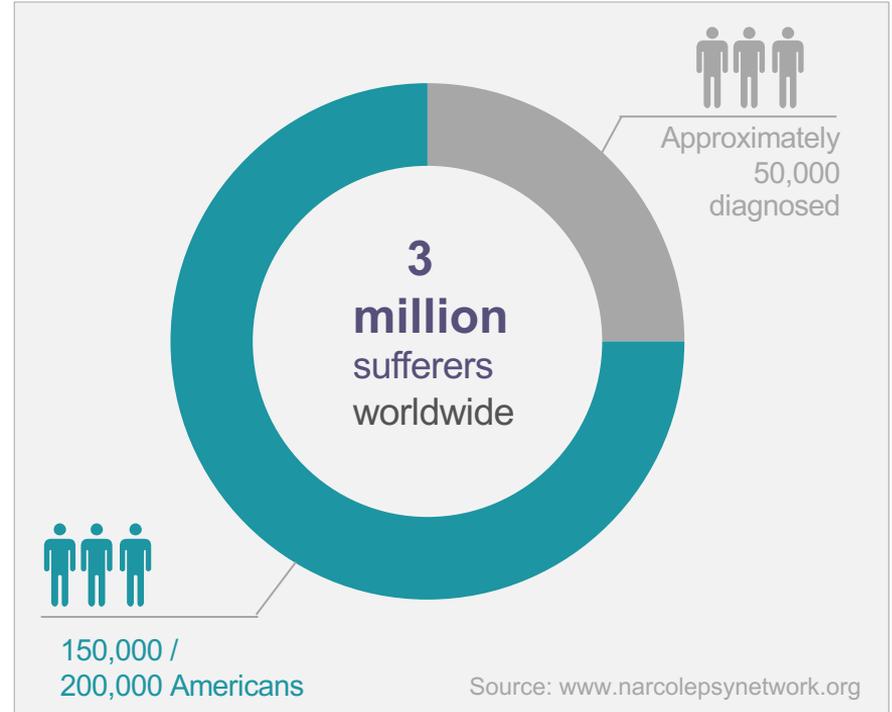
- Large market, need for more-effective treatments remains high
- Strong validation with decades of off-label use of mazindol in narcolepsy
- Novel mechanism of action addressing the root cause of the disease
- Given prior approval for obesity, relatively modest development costs anticipated to achieve regulatory approval in the US and Europe
- Several value inflection points expected in the 2021-2023 timeframe

- Second mazindol-based product candidate with strong clinical evidence
- Build on success of Nolazol® Phase 2 clinical trial
- Ability to capture income from licensing deal with Eurofarma in Latin America

- Leverage current portfolio of compounds and core competency to identify compelling drug candidates through potential in-house innovation and in-house licensing and partnering/out-licensing deals
- Several product candidate leads in early research and development

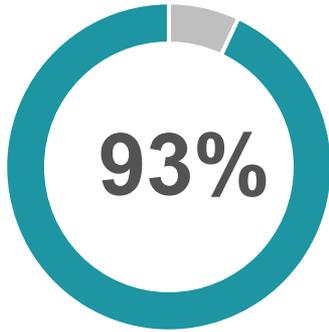
# Narcolepsy: Debilitating Disorder, Large & Underserved Market

- Narcolepsy is a chronic neurologic brain disorder caused by the brain's **inability to regulate sleep-wake cycles**
- Characterized by **excessive daytime sleepiness (EDS)**. **Sudden loss of muscle tone (cataplexy)**, sleep paralysis and hallucinations may also occur
- Classic (Type 1) narcolepsy is associated with very low or undetectable levels of the hormone **orexin** in the brain\*
- Narcolepsy treatments generated revenues of \$2.4 billion in 2018, and is projected to reach **\$5.4 billion by 2026**, growing at a CAGR of 10.3% by 2026\*\*
- Significant valuations are being assigned to public companies with narcolepsy treatments
- Despite newer treatments and use of older stimulants, no commercially available products address the orexin deficit; most patients remain unsatisfied with their treatment\*\*\*

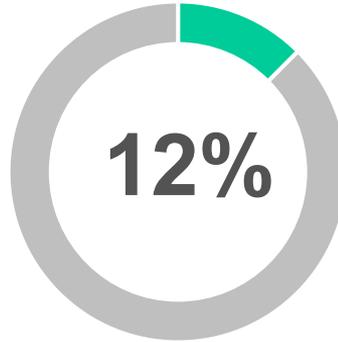


# Severe Rare Disease with Unmet Medical Need

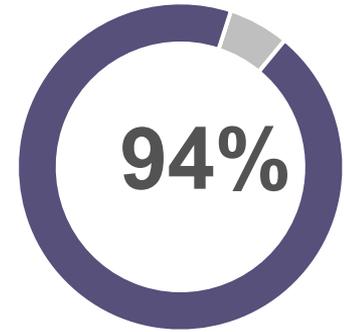
Results from 2018 National Know Narcolepsy Survey demonstrated need for more robust treatment options



Expressed frustration with current treatment options



Thought that their narcolepsy symptoms are completely or mostly under control



Stated that new treatment options are needed

- Management of narcolepsy symptoms remains a challenge for patients, their families, and providers
- 78%-85% of patients in Phase 3 trials for Xyrem® required stimulant therapy to manage their symptoms\*
- There is no cure and many patients report that their medicines do not improve their complete range of symptoms



- Long history of active ingredient (mazindol) used to treat narcolepsy (“compassionate use” programs)
- Novel mechanism of action (MOA) with partial orexin-2 receptor activation
- Anticipated Phase 2 trial initiation mid-year, top-line results expected Q4 2021
- Potential expedited development: intent to leverage 505(b)(2) and/or accelerated approval pathways (Breakthrough, FastTrack, PRIME designations)

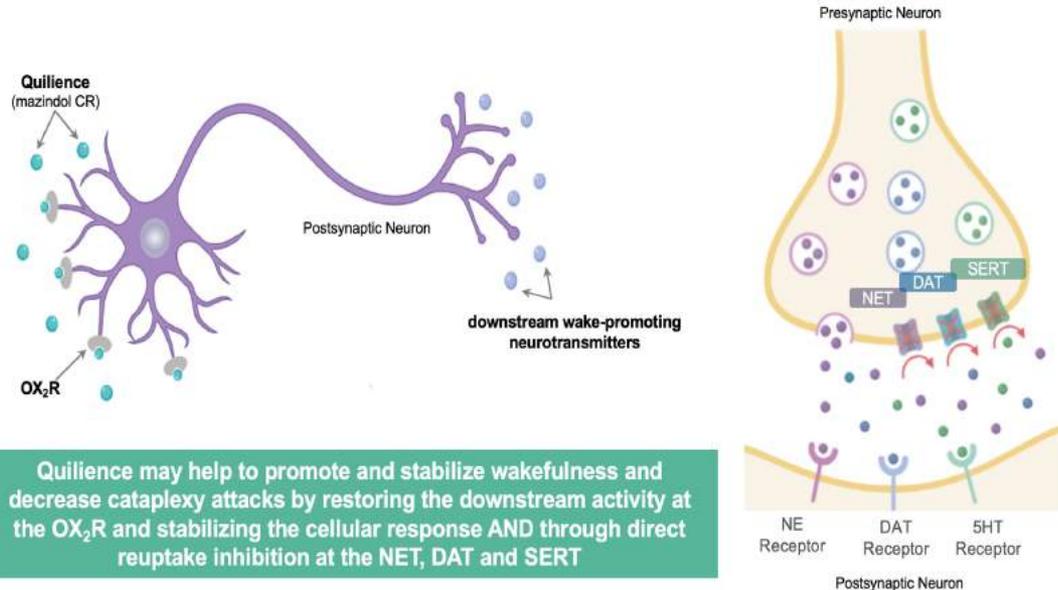
## Mazindol Controlled-Release (CR) - for the Treatment of Excessive Daytime Sleepiness and Cataplexy in Narcolepsy

# Mazindol – Unique Dual Mechanism of Action (“MoA”)

Dual – Pan – Monoamide – Reuptake – Inhibitor / Orexin-2 Receptor Partial-Agonist

- **Confirmed robust binding to dopamine and norepinephrine transporters**
  - enhances dopamine and norepinephrine neurotransmission
  - improves “top down” regulation of executive function and inhibitory control
- **Actions of Dual MoA**
  - **Robust binding to serotonin transporter** – i.e., triple reuptake inhibitor (serotonin–norepinephrine–dopamine reuptake inhibitor (SNDRI))
    - improved dopamine – serotonin balance
    - enhanced effects on hyperactivity and inhibitory control
  - **Orexin-2 partial agonist**
    - improved “bottom up” regulation of arousal, alertness, energy metabolism and reward mechanisms

## Novel Mechanism of Action Orexin 2 Receptor Partial Agonist and Triple Reuptake Inhibitor



# Long Term Benefit/Risk Ratio of Mazindol in Patients with Drug-Resistant Narcolepsy

- Retrospective study conducted by a third party, funded by the French Health Ministry, to provide benefit and risk measures of the long-term use of mazindol in children & adults with narcolepsy or hypersomnia
- The data from this study demonstrated that “mazindol has a major effect on sleepiness, possibly greater than that of modafinil (Provigil)”
- Mazindol has extensive, published, history of chronic, off-label use in narcolepsy
  - Efficacy and sustained benefits, even in patients refractory to standard treatments
  - Adult and pediatric patients treated for years, demonstrating safety profile with long-term chronic use

ESS <sup>1</sup> Score - Mean Change From Baseline			
Before Mazindol	After Mazindol	Change	P-value
18.0 ± 3.1	13.6 ± 5	<b>-4.2</b>	<b>&lt;0.0001</b>

<sup>1</sup> Epworth Sleepiness Scale\*

Change in Weekly Cataplexy Rate			
Before Mazindol	After Mazindol	Change	P-value
4.6 ± 3.1	2.0 ± 2.8	<b>-2.7</b>	<b>&lt;0.0001</b>

Source: Nittur et.al, Sleep Med. 2013 Jan;14(1):30-6

N=139

**Study Conclusion: “Mazindol has a long-term, favorable benefit/risk ratio in 60% of drug-resistant hypersomniacs, including a clear benefit on cataplexy”**

# Quilience® – Competitive Advantages

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**Once-Daily Monotherapy** addressing the main narcolepsy symptoms



**Novel MoA\*** partially targeting the orexin system



**Validated Efficacy** of drug substance in chronic use off-label



**Schedule IV: Low Potential for Abuse, misuse & diversion**



**Well-Tolerated** drug substance



**Excessive Daytime Sleepiness**

**Cataplexy**

# Quilience® Regulatory Exclusivity & Patent Protection



**FDA Orphan Drug Designation (ODD) secures up to 7.5 years of marketing exclusivity from launch in the US (incl. pediatric exclusivity)**

**EMA ODD secures up to 12 years (if approved for use in children) of marketing exclusivity from launch in the EU**

**Controlled-release mazindol patent provides coverage until 2037; Issued in Canada, European Notice of Allowance received January 2021, Application pending review in U.S.**

**Life-cycle management formulation strategies may offer additional patent protection through or beyond 2037**

# Quilience® Planned Phase 2 Clinical Study Design

To evaluate the efficacy and safety of Quilience® (mazindol CR) for the treatment of excessive daytime sleepiness (EDS) and cataplexy in adult patients with narcolepsy



## Study Design

- 4-week, double-blind, placebo-controlled, randomized, multicenter, titrated fixed dose (3 mg) parallel group study.

## Primary Endpoint

- Change from baseline in daytime sleepiness as measured by the Epworth Sleepiness Scale (ESS).

## Key Secondary Endpoint

- Change from baseline in the mean weekly number of cataplexy attacks in the subset of patients with cataplexy.

# Phase 2 Trial Design & Implications

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**Phase 2  
study design  
optimized for  
success**

**Objective to demonstrate safety & efficacy of mazindol CR in a prospective clinical trial for the treatment of narcolepsy**

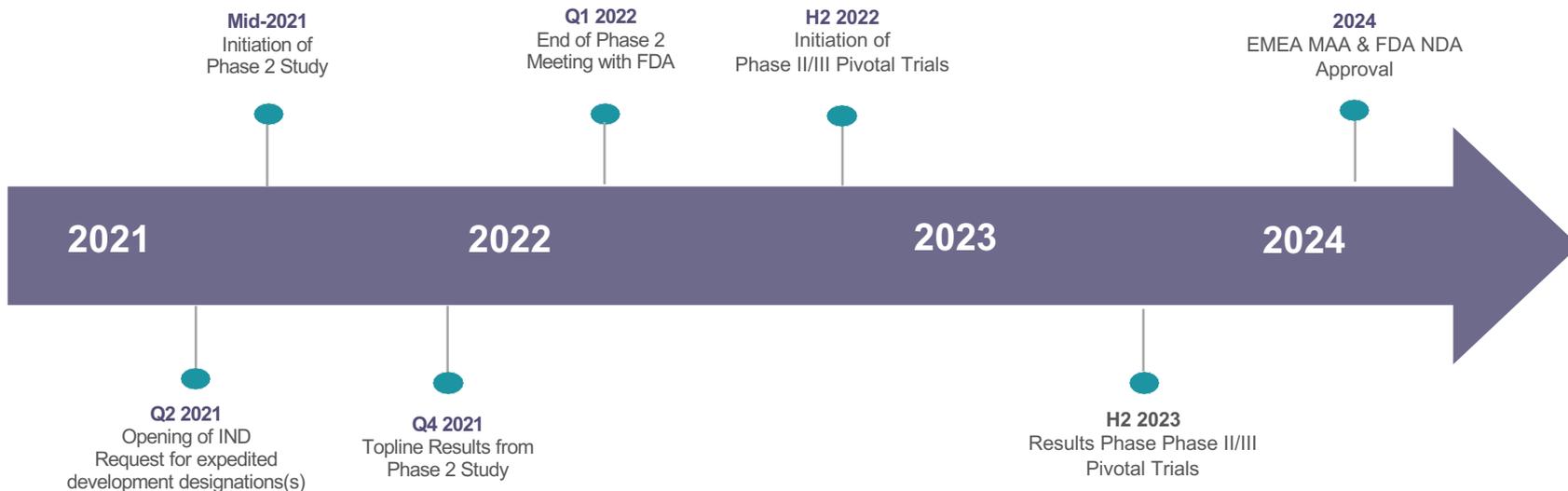
**Trial designed to be COVID-19 friendly and compliant to aid recruitment**

**Data are expected to inform a high-probability pivotal clinical trial program following advice from FDA & EMA**

**Potential for value inflection if the Phase 2 results confirm benefits seen in mazindol IR retrospective study**

**If positive Phase 2 results, deploy accelerated late-stage development strategy leveraging 505(b)(2) pathway in US**

# Quilience® – Anticipated Development Timeline



## PROF. Dr. G.J. LAMMERS



“I know some narcolepsy patients who had a very good response on mazindol, and never reached a comparable level with any other pharmacological treatment including the most recently approved substances.”

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Prof. of Neurology at Leiden University, current Chair of the Dutch Society for Sleep Medicine and co-founder of the European Narcolepsy Network (EU-NN) and served as President from 2007-2014.

# Quilience<sup>®</sup> Compassionate Use Strategy



Named Patient Program (NPP)  
Individual patients



National regulations  
Different nomenclature



Patients with severe conditions  
Exhausted treatment options  
Cannot join clinical trials



Cohort Program  
Defined group of patients



Uniform intentions  
Complex operations

## First Wave Countries

Austria  
Belgium  
France  
Italy  
Switzerland

Potential Revenue  
Generation

*Note:* country prioritization  
within each wave remains  
to be refined (listed in  
alphabetical order)

## Second Wave

Brazil / LatAm  
Czech Rep.  
Denmark  
Spain  
UK

Potential Revenue  
Generation

## Third Wave

China  
Germany  
Japan  
Sweden  
Taiwan

Early Market Presence  
& Rapid Uptake

## Commercial Objectives

- Generate pre-licensing revenues in selected countries
- Post-authorization revenues in non-priority countries for commercial launch (global NPP support)
- Establish an early market presence with a Key Opinion Lead/Center of Excellence strategy
- Rapid revenue uptake upon commercial availability

## Additional Objectives

- Bridge patients from the end of clinical trials to commercialization
- Leverage real-world and patient-centric data collected (broad populations, quality of life, satisfaction)
- Professionally address patient and physician requests (formal published policy and process)



## Mazindol CR - for the Treatment of Attention Deficit Hyperactivity Disorder (ADHD)

# Positive Phase 2 Results for Mazindol CR Demonstrated in ADHD Trial

## Strong Links Between ADHD and Narcolepsy

### Nolazol® (mazindol CR)

- ✓ NLS-sponsored Phase 2 trial in ADHD demonstrated efficacy comparable to first-line CII stimulants with favorable tolerability
- ✓ Trial validated the Company's once-daily formulation
- ✓ Mazindol CR had an advantageous sleep profile
- ✓ Studies suggest ADHD and narcolepsy are genetically related with possible common underlying biologic mechanisms<sup>1</sup>
- ✓ Approximately 1/3 of patients with narcolepsy have ADHD symptoms, making it an important comorbidity<sup>2</sup>
- ✓ Narcolepsy is often treated with the same stimulants approved for ADHD (methylphenidate, amphetamine products)
- ✓ DEA Schedule IV classification vs. Schedule II for most stimulants; Reduced risk of abuse, misuse, and diversion

# Phase 2 Trial Primary Endpoint Results – Effect Size Greater Than or Equal to C-II Stimulant Levels

→ Adult patients receiving Nolzol® (mazindol CR) showed effect size greater than current ADHD best-in-class drugs

Phase 2 clinical trial at seven sites in US

Outpatient, multicenter, randomized, double-blind, placebo-controlled trial to assess efficacy, safety, tolerability, and pharmacokinetics (N=85)

Flexible dose (1mg, 2mg, 3mg)

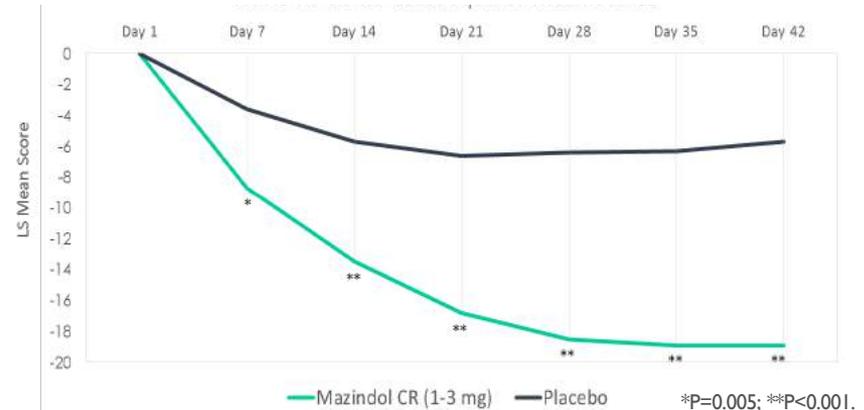
Mean change from baseline in the ADHD-RS-DSM5 score at Day 42 of -18.9 (and -5.7 for placebo) was statistically significant in favor of Nolzol® (mazindol CR) (P<0.001)

## ADHD-RS Effect size

**Gold standard endpoint** in the field for describing the difference between drug and placebo calculated as the mean difference in ADHD-RS score between arms from baseline to Day 42 / pooled standard deviation at Day 42

ADHD-RS score – scale from 0-54

## ADHD-RS-DSM5 Least Squares Mean Scores



**Effect size: 1.09**

Effect Size >1 indicating high efficacy of Nolzol® (mazindol CR)  
- low efficacy would be <0.4; moderate: 0.6; high: 0.8

Least Squares Mean improvements:

**-18.9** (mazindol CR) and **-5.7** (placebo)

Mean difference:

**-13.2** (-18.7, -7.6)

# Mazindol CR Well-Tolerated in Phase 2 Study

► **No treatment-related SAEs, withdrawals, no clinically significant AEs**

Treatment-Emergent Adverse Events Occurring  $\geq$  5% of Subjects in Either Treatment Group  
During the Double-Blind Phase (Safety Population)

Primary System Organ Class / Preferred Term	Mazindol CR (n=43), n (%)		Placebo (n=42), n (%)	
<b>Subjects with any TEAEs</b>	<b>31</b>	<b>72.1%</b>	<b>21</b>	<b>50.0%</b>
<b>Gastrointestinal disorders</b>	<b>19</b>	<b>44.2</b>	<b>7</b>	<b>16.7</b>
• Constipation	3	7.0	0	0
• Dry mouth	10	23.3	2	4.8
• Nausea	5	11.6	0	0
<b>General disorders</b>	<b>6</b>	<b>14.0</b>	<b>2</b>	<b>4.8</b>
• Fatigue	5	11.6	1	2.4
<b>Infections and infestations</b>	<b>8</b>	<b>18.6</b>	<b>7</b>	<b>16.7</b>
• Upper respiratory tract infection	4	9.3	3	7.1
<b>Laboratory/Cardiovascular investigations</b>	<b>6</b>	<b>14.0</b>	<b>2</b>	<b>4.8</b>
• Heart rate increased	5	11.6	0	0
<b>Metabolism and nutrition disorders</b>	<b>4</b>	<b>9.3</b>	<b>5</b>	<b>11.9</b>
• Decreased appetite	4	9.3	3	7.1
<b>Nervous system disorders</b>	<b>10</b>	<b>23.3</b>	<b>7</b>	<b>16.7</b>
• Headache	6	14.0	5	11.9
• Somnolence	3	7.0	1	2.4
<b>Psychiatric disorders</b>	<b>7</b>	<b>16.3</b>	<b>6</b>	<b>14.3</b>
• Middle insomnia	3	7.0	0	0
<b>Skin and subcutaneous tissue disorders</b>	<b>3</b>	<b>7.0</b>	<b>2</b>	<b>4.8</b>

# Nolazol® – Highly Differentiated on Major Attributes vs. Leading C-II Stimulants and Recent Launches

**Vyvanse**®  
(lisdexamfetamine dimesylate)

**Mydayis**™

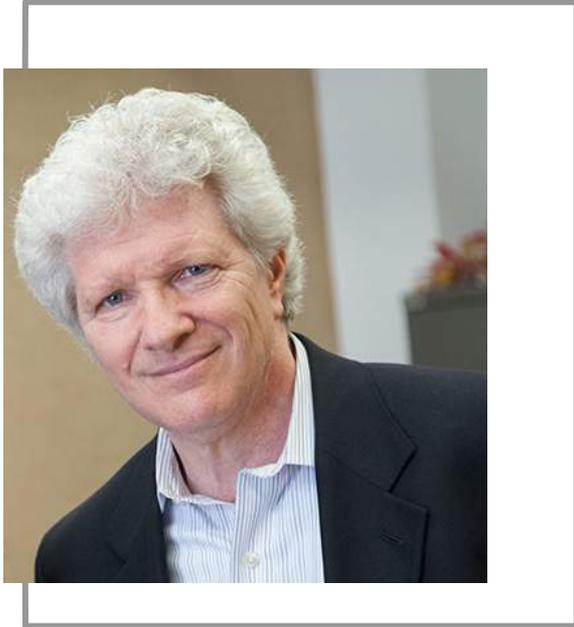
**Adzenys XR-ODT**®  
(amphetamine dimesylate extended-release orally disintegrating tablets)

**Cobemply XR-ODT**®  
(methylphenidate extended-release orally disintegrating tablets)

**CONCERTA**®  
(methylphenidate HCl)  
CONCENTRATED SALT TABLETS

**Nolazol® (mazindol CR)**

Manufacturer	Shire	Shire	Neos	Neos	J&J / Janssen	NLS Pharmaceuticals	
<b>Generic Name</b>	Lisdexamfetamine	Amphetamine	Amphetamine	Methylphenidate	Methylphenidate	<b>Mazindol</b>	only non-amphetamine or non-methylphenidate containing product
<b>Novel MOA</b>	No	No	No	No	No	<b>YES</b> (SDNRI and Orexin 2 partial agonist)	Dual Mechanism: validated and novel targets
<b>DEA Schedule</b>	C-II	C-II	C-II	C-II	C-II	<b>C-IV*</b>	Only C-IV stimulant (highly differentiated)
<b>Effect Size</b>	0.99 <sup>1</sup>	0.91 <sup>2</sup>	n/a (similar to other AMP)	n/a (similar to other MPH)	0.8 <sup>3</sup>	<b>1.09</b> Phase 2 (adult)	At par or better than Amphetamine and better than Methylphenidate
<b>Risk of Abuse / Misuse / Diversion</b>	Yes	Yes	Yes	Yes	Yes	<b>NO</b>	Major advantage; improved scheduling
<b>Withdrawal / Tolerance</b>	Yes (Class Label)	Yes (Class Label)	Yes (Class Label)	Yes (Class Label)	Yes (Class Label)	<b>NO</b>	None reported in clinical trials nor in decades of use in narcolepsy
<b>Black Box Warning</b>	Yes (Class Label)	Yes (Class Label)	Yes (Class Label)	Yes (Class Label)	Yes (Class Label)	<b>NO</b>	Increased MD and Parent comfort
<b>Insomnia</b>	Yes	Yes	Yes	Yes	Yes	<b>NO</b>	Only 7% seen in Phase 2
<b>Call-in and Rx Available</b>	No	No	No	No	No	<b>YES</b>	Higher convenience (MD & Parents)
<b>Available Dosage (mg)</b>	10, 20, 30, 40, 50, 60, 70	12.5, 25, 37.5, 50	3.1, 6.3, 9.4, 12.5, 15.7, 18.8	8.6, 17.3, 25.9, 34.6, 51.8	18, 27, 36, 54, 72	<b>1, 2, 3 mg (likely)</b>	Ease of use: simple dosing



## PROF. Dr. J. NEWCORN

Associate Professor of Psychiatry and Pediatrics and  
Director of the Division of Child and Adolescent Psychiatry  
at Mount Sinai Medical Center in New York

“ We have not seen any potential treatment for ADHD that had effects as robust as we saw in the Phase 2 adult study, except for C-II stimulants. The prospect of a medication with efficacy as high as is seen with the C-II stimulants that would be a DEA Schedule IV drug would be most welcome and no doubt very well received. This would especially be true for prescribers who have not had a track record of using C-II stimulants - and who would prefer not to, all things being equal.”

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Dr. Newcorn is a founding member of the board of directors of the American Professional Society for ADHD and Related Disorders (APSARD), and has served as the Chair of the APSARD Program Committee for the past three years. He is also Chair of the Advisory Board of the Klingenstein Third Generation Foundation and Head of the SAB for NLS in ADHD.

# Pipeline for Future Value Creation

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## ▶ **Mazindol CR Product Candidates (Quilience® & Nolazol®)**

Narcolepsy, Idiopathic Hypersomnia (IH), Obstructive Sleep Apnea (OSA), Substance Use Disorder (SUD), and Attention Deficit Hyperactivity Disorder (ADHD)

## ▶ **Assets with Patents Issued or Patent Applications Filed**

Laufлумide (NLS-4): IH, Narcolepsy  
Phacetoperane (NLS-3): ADHD

## ▶ **Assets with Patent Applications Planned for Submission**

6 potential projects, additional disclosures planned – disease areas of focus include Kleine-Levin Syndrome, CDH & Opioid Dependence, Intellectual Disability & MCI, Lewy Body Dementia, SUD, and Central Disorders of Hypersomnolence

## ▶ **R&D Leads/In-licensing Opportunities**

2 identified projects, additional disclosures upon licensure – disease areas of focus include Covid-19 “Long-Hauler” CFS, Parkinson’s Disease / Lewy Body Dementia, and Epilepsy.

# Anticipated Milestones & Corporate Priorities

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File IND in U.S. to initiate Quilience® Phase 2 trial in patients with narcolepsy; potential for accelerated regulatory pathway designations



Patent applications for mazindol controlled-release formulation anticipated to mature in the U.S. and Europe



Initiate compassionate use programs outside the U.S. with potential for revenue generation



Disclosures and updates for the Company's CNS drug pipeline



Complete Phase 2 trial for Quilience®; results anticipated in late 2021



Potential for business development activity including license agreements or partnerships with other drug companies



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