UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **August 28, 2024**

NEUROCRINE BIOSCIENCES, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**0-22705**	**33-0525145**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

6027 Edgewood Bend Court	
San Diego, California	**92130**
(Address of Principal Executive Offices)	(Zip Code)

(858) 617-7600
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol**	**Name of each exchange on which registered**
Common Stock, $0.001 par value	NBIX	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).
Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

On August 28, 2024, Neurocrine Biosciences, Inc. ("Neurocrine" or the "Company") issued a press release announcing positive top-line data for its Phase 2 clinical study of NBI-1117568 in adults with schizophrenia, a copy of which is furnished as Exhibit 99.1 to this Current Report on Form 8-K. The Company will hold a live conference call and webcast to discuss the clinical data on August 28, 2024 at 8:00 a.m. Eastern Time (5:00 a.m. Pacific Time). The Company will make available a slide presentation to accompany the call, a copy of which is furnished as Exhibit 99.2 to this Current Report on Form 8-K.

The information in this Item 7.01, including Exhibit 99.1 and Exhibit 99.2 attached hereto, is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01. Other Events.

On August 28, 2024, Neurocrine announced positive top-line data for its Phase 2 clinical study of NBI-1117568 ("NBI-'568") in adults with schizophrenia. NBI-'568 is the first investigational, oral, muscarinic M4 selective agonist in development for the treatment of schizophrenia.

The NBI-'568-SCZ2028 dose-finding study met its primary endpoint for the once-daily 20 mg dose. It demonstrated a clinically meaningful and statistically significant reduction from baseline in the Positive and Negative Syndrome Scale (PANSS) total score at Week 6 with a placebo-adjusted mean reduction of 7.5 points (p=0.011 and effect size of 0.61) and an 18.2-point reduction from baseline. The once-daily 20 mg dose also demonstrated a statistically significant improvement for additional endpoints, including improvement in the Clinical Global Impression of Severity (CGI-S) scale, Marder Factor Score – Positive Symptom Change, and Marder Factor Score – Negative Symptom Change.

NBI-'568 was generally safe and well-tolerated at all doses studied in the Phase 2 clinical trial. Treatment discontinuation rates due to adverse events were similar between NBI-'568 and placebo. Adverse events with the highest incidence were somnolence, dizziness, and headache. Gastrointestinal adverse events including nausea and constipation were low in frequency and similar to placebo. Cardiovascular-related events were also low in frequency and were not deemed to have clinical relevance at any dose tested. NBI-'568 was not associated with a greater increase in weight than placebo. Few extrapyramidal symptoms adverse events were reported.

Neurocrine currently expects to advance NBI-'568 into Phase 3 development in early 2025.

Primary Endpoint Results Summary

Week 6 (Day 42)	**Placebo (N=68)**	**20 mg QD (N=35)**	**40 mg QD (N=38)**	**60 mg QD (N=34)**	**30 mg BID (N=26)**
PANSS Total Score LS Mean Change from Baseline*	-10.8	-18.2	-12.6	-13.7	-15.8
LS Mean Difference vs. Placebo*	-	-7.5 (p=0.011)	-1.9 (p=0.282)	-2.9 (p=0.189)	-5 (p=0.090)
Effect Size**	-	0.61	0.27	0.39	0.23

****Least-squares (LS) means are from a MMRM which includes treatment group, visit, and study period as fixed effects; treatment group-by-visit interaction; baseline PANSS total score as a covariate; and subject as a random effect.***

*****Effect size (Cohen's D) is based on observed data.***

About the NBI-1117568-SCZ2028 Phase 2 Clinical Study

The Phase 2, multicenter, randomized, double-blind, placebo-controlled, multi-arm, multi-stage inpatient dose-finding study was designed to assess the efficacy, safety, tolerability, and pharmacokinetics (PK) of NBI-'568 compared with placebo in adult subjects with a primary diagnosis of schizophrenia who are experiencing an acute exacerbation or relapse of symptoms. The study enrolled 210 participants.

Next Steps for Neurocrine's Muscarinic Portfolio

In addition to NBI-'568, Neurocrine has a broad portfolio of assets in clinical development that selectively target muscarinic receptors. The Company's muscarinic agonist portfolio also includes NBI-1117567, NBI-1117569, and NBI-1117570, which the Company acquired the rights to develop and commercialize from Nxera Pharma (formerly Sosei Heptares). Neurocrine is also developing NBI-1076986, a selective M4 antagonist that was discovered and is being developed internally at Neurocrine.

Forward-Looking Statements

In addition to historical facts, this Current Report on Form 8-K and certain of the materials furnished herewith contain forward-looking statements that involve a number of risks and uncertainties. These statements include, but are not limited to, statements regarding the clinical results from, and our future development plans with respect to, NBI-1117568, as well as the therapeutic potential and clinical benefits or safety profile of NBI-1117568. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are: top-line data that we report may change following a more comprehensive review of the data related to the clinical study and such data may not accurately reflect the complete results of the clinical study; risks that clinical development activities may not be initiated or completed on time or at all, or may be delayed for regulatory, manufacturing, or other reasons, may not be successful or replicate previous clinical trial results, may fail to demonstrate that our product candidates are safe and effective, or may not be predictive of real-world results or of results in subsequent clinical trials; risks that regulatory submissions for our product candidates may not occur or be submitted in a timely manner; our future financial and operating performance; risks associated with our dependence on third parties for development, manufacturing, and commercialization activities for our products and product candidates, and our ability to manage these third parties; risks that the FDA or other regulatory authorities may make adverse decisions regarding our products or product candidates; risks that the potential benefits of the agreements with our collaboration partners may never be realized; risks that our products, and/or our product candidates may be precluded from commercialization by the proprietary or regulatory rights of third parties, or have unintended side effects, adverse reactions or incidents of misuse; risks associated with U.S. federal or state legislative or regulatory and/or policy efforts which may result in, among other things, an adverse impact on our revenues or potential revenue; risks associated with potential generic entrants for our products; and other risks described in the Company's periodic reports filed with the Securities and Exchange Commission, including without limitation the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2024. Neurocrine disclaims any obligation to update these forward-looking statements after the date hereof other than required by law.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by Neurocrine Biosciences, Inc. on August 28, 2024
99.2	Slide Presentation dated August 28, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

NEUROCRINE BIOSCIENCES, INC.

Dated: August 28, 2024

/s/ Darin M. Lippoldt
Darin M. Lippoldt
Chief Legal Officer

Exhibit 99.1

Neurocrine Biosciences Reports Positive Phase 2 Data for NBI-1117568 in Adults with Schizophrenia

- **The Once-Daily 20 mg Dose Met the Primary Endpoint, Demonstrating a Statistically Significant 7.5-Point Improvement (p=0.011, 0.61 Effect Size) in the PANSS Total Score Compared to Placebo at Week 6 with an 18.2-Point PANSS Total Score Improvement from Baseline**
- **The Once-Daily 20 mg Dose Met Additional Endpoints, Demonstrating Statistically Significant Improvements in Clinical Global Impression of Severity Scale and Marder Factor Score Positive Symptom Change and Negative Symptom Change**
- **NBI-'568 Was Generally Safe and Well Tolerated at All Doses Studied**
- **The Once-Daily 20 mg Dose Efficacy, Safety and Tolerability Phase 2 Results Support Advancement to Phase 3 in Schizophrenia in Early 2025**
- **Company to Host Conference Call with Management at 8 a.m. EDT**

SAN DIEGO, August 28, 2024 – Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced positive top-line data for its Phase 2 clinical study of NBI-1117568 (NBI-'568) in adults with schizophrenia. NBI-'568 is the first investigational, oral, muscarinic M4 selective agonist in development for the treatment of schizophrenia.

The NBI-'568-SCZ2028 dose-finding study met its primary endpoint for the once-daily 20 mg dose. It demonstrated a clinically meaningful and statistically significant reduction from baseline in the Positive and Negative Syndrome Scale (PANSS) total score at Week 6 with a placebo-adjusted mean reduction of 7.5 points (p=0.011 and effect size of 0.61) and an 18.2-point reduction from baseline. The once-daily 20 mg dose also demonstrated a statistically significant improvement for additional endpoints, including improvement in the Clinical Global Impression of Severity (CGI-S) scale, Marder Factor Score – Positive Symptom Change, and Marder Factor Score – Negative Symptom Change.

"This Phase 2 dose-finding study delivered on our goal of identifying a once-daily, well tolerated dosing regimen with a compelling and competitive benefit-risk profile," said Eiry Roberts, M.D., Chief Medical Officer at Neurocrine Biosciences. "We recognize the significant need for new and innovative medicines to treat schizophrenia and look forward to advancing NBI-'568, the first M4 selective agonist, into Phase 3 development early next year."

"NBI-1117568 demonstrated a clinically meaningful and statistically significant reduction in PANSS scores and was well tolerated, importantly with minimal GI effects and no weight gain relative to placebo," said Dr. Maurizio Fava, Psychiatrist-in-Chief at Massachusetts General Hospital of Harvard University. "As a selective M4 orthosteric agonist, the potential of NBI-1117568 as an option that could reduce symptoms of schizophrenia with fewer side effects would be a welcome alternative to current treatments for patients and caregivers."

NBI-’568 was generally safe and well-tolerated at all doses studied in the Phase 2 clinical trial. Treatment discontinuation rates due to adverse events were similar between NBI-’568 and placebo. Adverse events with the highest incidence were somnolence, dizziness, and headache. Gastrointestinal adverse events including nausea and constipation were low in frequency and similar to placebo. Cardiovascular-related events were also low in frequency and were not deemed to have clinical relevance at any dose tested. NBI-’568 was not associated with a greater increase in weight than placebo. Few extrapyramidal symptoms adverse events were reported.

Primary Endpoint Results Summary

Week 6 (Day 42)	**Placebo (N=68)**	**20 mg QD (N=35)**	**40 mg QD (N=38)**	**60 mg QD (N=34)**	**30 mg BID (N=26)**
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*** Effect size (Cohen’s D) is based on observed data.*

Next Steps for Neurocrine Biosciences’ Muscarinic Portfolio

In addition to NBI-’568, Neurocrine Biosciences has a broad portfolio of assets in clinical development that selectively target muscarinic receptors. The company’s muscarinic agonist portfolio also includes NBI-1117567, NBI-1117569, and NBI-1117570, which the company acquired the rights to develop and commercialize from Nxera Pharma (formerly Sosei Heptares). Neurocrine Biosciences is also developing NBI-1076986, a selective M4 antagonist that was discovered and is being developed internally at Neurocrine.

Compound	**Primary Mechanism (M1-M4)**	**Phase**	**Therapeutic Areas**	**Potential Areas for Development**
NBI-1117568	M4 agonist	2	Psychosis Cognition	Alzheimer’s Disease Bipolar Disorder Lewy Body Dementia Parkinson’s Disease Schizophrenia
NBI-1117567	M1 agonist	1		
NBI-1117569	M4 agonist	1		
NBI-1117570	M1/M4 dual agonist	1		
NBI-1076986	M4 antagonist	1	Movement Disorders	Dystonia Parkinson’s Disease Tremor

Conference Call and Webcast Today at 8:00 AM Eastern Time

Neurocrine Biosciences will hold a live conference call and webcast today at 8:00 a.m. Eastern Time (5:00 a.m. Pacific Time). Participants can access the live conference call by dialing 800-579-2543 (U.S.) or 785-424-1789 (International) using the conference ID: NBIX. The live webcast and accompanying slides can be accessed on the investor relations section of Neurocrine Biosciences' website here. A replay of the webcast will be available on the website approximately one hour after the conclusion of the event and will be archived for approximately one month.

About NBI-1117568

NBI-'568 is the first and only M4 selective orthosteric agonist in clinical development. There are five muscarinic acetylcholine receptors involved in neurotransmission. Muscarinic receptors are central to brain function and validated as drug targets in psychosis and cognitive disorders. As an M4 selective orthosteric agonist, NBI-'568 offers the potential for a novel mechanism with an improved safety profile without the need of combination therapy to minimize off-target pharmacology-related side effects, while also not being dependent on the presence of acetylcholine for efficacy.

About the NBI-1117568-SCZ2028 Phase 2 Clinical Study

The Phase 2, multicenter, randomized, double-blind, placebo-controlled, multi-arm, multi-stage inpatient dose-finding study was designed to assess the efficacy, safety, tolerability, and pharmacokinetics (PK) of NBI-'568 compared with placebo in adult subjects with a primary diagnosis of schizophrenia who are experiencing an acute exacerbation or relapse of symptoms. The study enrolled 210 participants. For more information about this study, visit ClinicalTrials.gov.

About Schizophrenia

Schizophrenia is a serious and complex syndrome with heterogeneous symptoms. The World Health Organization estimates that the disorder impacts more than 20 million people worldwide. Annual associated costs for schizophrenia are estimated to be more than $150 billion in the United States. As one of the leading causes of disability worldwide, it often results in significant emotional and functional burden for those who experience symptoms, as well as their family and friends. This chronic and disabling mental health condition is thought to result from a complex interplay of genetic and environmental risk factors. Traditional treatment approaches for schizophrenia rely on the use of antipsychotic medications that can lead to considerable short- and long-term health impacts.

About Neurocrine Biosciences

Neurocrine Biosciences is a leading neuroscience-focused, biopharmaceutical company with a simple purpose: to relieve suffering for people with great needs, but few options. We are dedicated to discovering and developing life-changing treatments for patients with under-addressed neurological, neuroendocrine, and neuropsychiatric disorders. The company's diverse portfolio includes FDA-approved treatments for tardive dyskinesia, chorea associated with Huntington's disease, endometriosis* and uterine fibroids*, as well as a robust pipeline including multiple compounds in mid- to late-stage clinical development across our core therapeutic areas. For three decades, we have applied our unique insight into neuroscience and the interconnections between brain and body systems to treat complex conditions. We relentlessly pursue medicines to ease the burden of debilitating diseases and disorders, because you deserve brave science. For more information, visit neurocrine.com, and follow the company on LinkedIn, X (formerly Twitter, and Facebook.

(**in collaboration with AbbVie*)

Forward-Looking Statements

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# # #

Topline Results for Phase 2 Trial of NBI-1117568 (NBI-'568) in Schizophrenia

August 28, 2024

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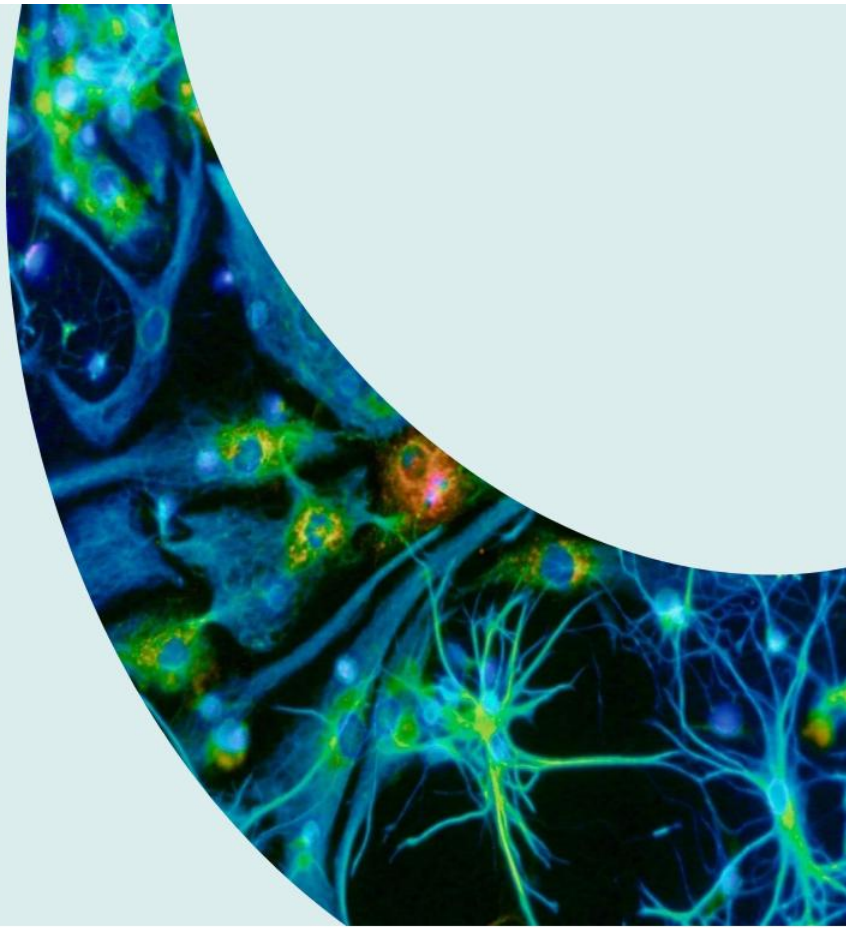

Forward Looking Statements

In addition to historical facts, this presentation contains forward-looking statements that involve a number of risks and uncertainties. Th statements include, but are not limited to, statements regarding the clinical results from, and our future development plans with respec NBI-1117568, as well as the therapeutic potential and clinical benefits or safety profile of NBI-1117568. Among the factors that could ca actual results to differ materially from those indicated in the forward-looking statements are: top-line data that we report may change following a more comprehensive review of the data related to the clinical study and such data may not accurately reflect the complete results of the clinical study; risks that clinical development activities may not be initiated or completed on time or at all, or may be delay for regulatory, manufacturing, or other reasons, may not be successful or replicate previous clinical trial results, may fail to demonstrat that our product candidates are safe and effective, or may not be predictive of real-world results or of results in subsequent clinical tria risks that regulatory submissions for our product candidates may not occur or be submitted in a timely manner; our future financial and operating performance; risks associated with our dependence on third parties for development, manufacturing, and commercialization activities for our products and product candidates, and our ability to manage these third parties; risks that the FDA or other regulatory authorities may make adverse decisions regarding our products or product candidates; risks that the potential benefits of the agreeme with our collaboration partners may never be realized; risks that our products, and/or our product candidates may be precluded from commercialization by the proprietary or regulatory rights of third parties, or have unintended side effects, adverse reactions or incident misuse; risks associated with U.S. federal or state legislative or regulatory and/or policy efforts which may result in, among other things adverse impact on our revenues or potential revenue; risks associated with potential generic entrants for our products; and other risks described in the Company's periodic reports filed with the Securities and Exchange Commission, including without limitation the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2024. Neurocrine Biosciences disclaims any obligation to up the statements contained in this presentation after the date hereof other than required by law.

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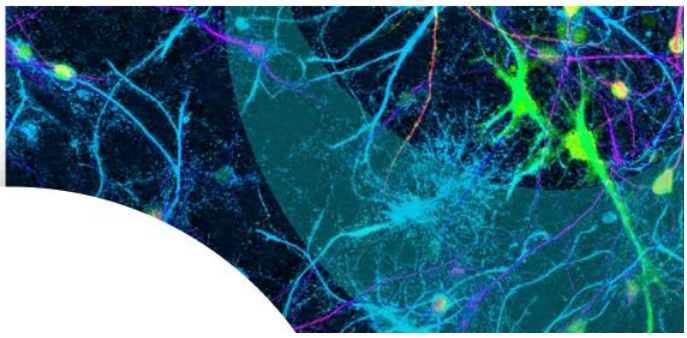
Agenda

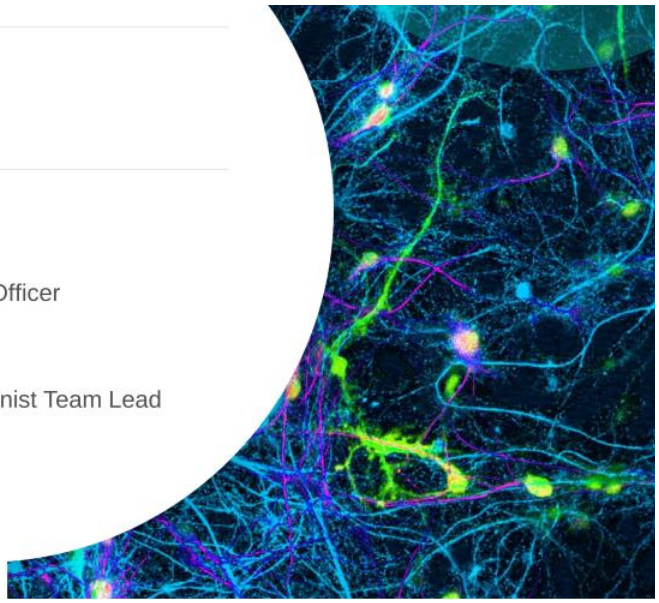


1 Introduction

Kevin Gorman, Ph.D. | Chief Executive Officer

2 **Trial Design & Results**
Eiry Roberts, M.D. | Chief Medical Officer

3 **Q&A**
Kevin Gorman, Ph.D. | Chief Executive Officer
Kyle Gano, Ph.D. | Chief Business Development and Strategy Officer
Jude Onyia, Ph.D. | Chief Scientific Officer
Eiry Roberts, M.D. | Chief Medical Officer
Samir Siddhanti | VP Business Development & Muscarinic Agonist Team Lead
Jaz Singh, M.D. | VP Clinical Development, Psychiatry



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Summary of Phase 2 Topline Results

Once-Daily 20mg Dose: Efficacy, Safety, and Tolerability Results Support Advancement to Phase 3

20mg Once-daily Demonstrated Statistically Significant and Clinically Meaningful Improvements Across Primary and Additional Endpoints

- PANSS Total Score Change: -18.2
- PANSS Total Score Change vs. Placebo: -7.5 (p=0.011)
- Effect Size: 0.61
- CGI-S Change vs. Placebo: -0.7 (p<0.001)
- Marder Factor Score Change vs. Placebo:
  - Positive: -3.0 (p=0.004)
  - Negative: -1.9 (p=0.028)

Generally Safe and Well-tolerated Across All Doses Tested

- Treatment discontinuation rates due to adverse events were similar between NBI-'568 and placebo
- Adverse events with the highest incidence were somnolence, dizziness, and headache
- Nausea, constipation and other gastrointestinal adverse events were low in frequency and similar to placebo
- NBI-'568 was not associated with a greater increase in weight than placebo

Efficacy, Safety and Tolerability Profile Combined With Once-daily Dosing Sup Advancement to Phase 3 Development

- NBI-'568 Phase 3 program in Schizophrenia expected to begin in early 2025
- Evaluating additional indications for NBI-'568
- Advancing follow-on compounds in muscarinic agonist portfolio

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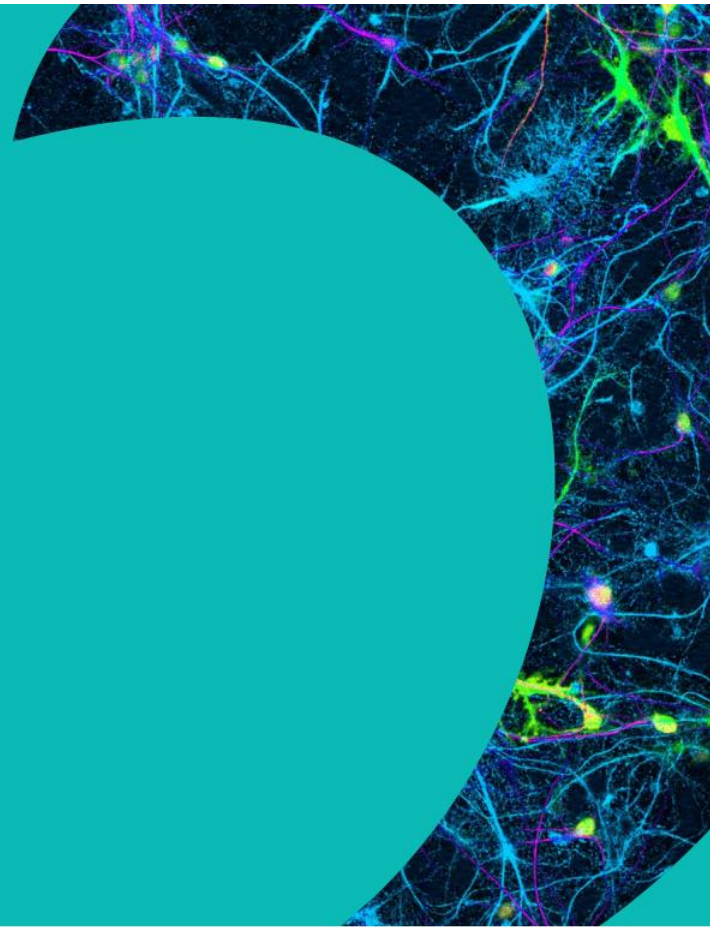
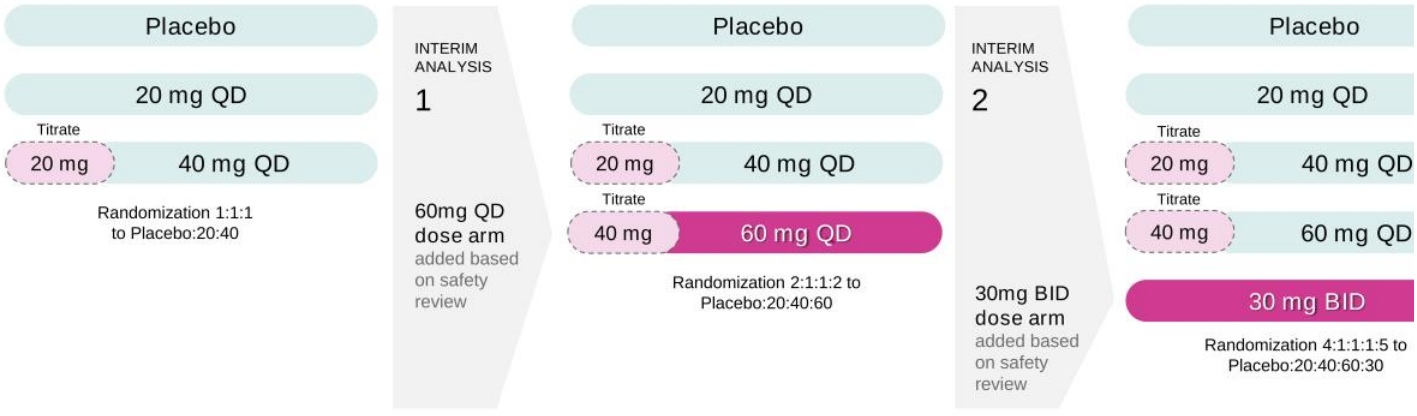
PANSS = Positive & Negative Syndrome Scale; P-values are one-sided. Effect size (Cohen's D) is based on observed data.

Trial Design & Results



NBI-’568 Phase 2 Study Design

Dose-finding Study Using a First-in-Class Selective M4 Agonist



Notes:

- Adults with PANSS ≥80, Ages 18-55 enrolled at 15 US sites (inpatient)
- Primary Endpoint: Change in PANSS total score from baseline at Week 6
- Doses of 60mg QD and 30mg BID were added in a prespecified, blinded fashion by an independent data review committee based on safety and tolerability of previous dose levels
- Maintained 2:1 rando ratio (all active doses in the study overall

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PANSS = Positive & Negative Syndrome Scale; QD = Once-Daily Dosing; BID = Twice-Daily Dosing

Baseline Characteristics and Demographics Summary

	Placebo N=70	20mg QD N=40	40mg QD N=39	60mg QD N=34	30mg BID N=27	All Subj N=21
Disease Characteristics At Baseline						

PANSS Total Score, mean	97	97	95	96	98	96
Demographics						
Age (years), mean	40	41	41	40	41	41
Male: n (%)	60 (85.7)	31 (77.5)	30 (76.9)	28 (82.4)	22 (81.5)	171 (8
Race: n (%)						
American Indian or Alaska Native	0	0	0	0	1 (3.7)	1 (0.
Asian	1 (1.4)	1 (2.5)	0	0	0	2 (1.
Black or African American	57 (81.4)	30 (75.0)	28 (71.8)	24 (70.6)	14 (51.9)	153 (7
White	11 (15.7)	9 (22.5)	10 (25.6)	7 (20.6)	11 (40.7)	48 (22
Other	0	0	0	1 (2.9)	1 (3.7)	2 (1.
Multiple	1 (1.4)	0	1 (2.6)	2 (5.9)	0	4 (1.

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Once-Daily 20mg Dose Met Primary Endpoint

PANSS Total Score vs Placebo

Week 6	Placebo N=68	20mg QD N=35	40mg QD N=38	60mg QD N=34	30mg BI N=26
PANSS Total Score					
LS Mean Change from Baseline*	-10.8	-18.2	-12.6	-13.7	-15.8
LS Mean Difference vs. Placebo, p-value*		-7.5 p = 0.011	-1.9 p = 0.282	-2.9 p = 0.189	-5.0 p = 0.09
Effect Size**		0.61	0.27	0.39	0.23

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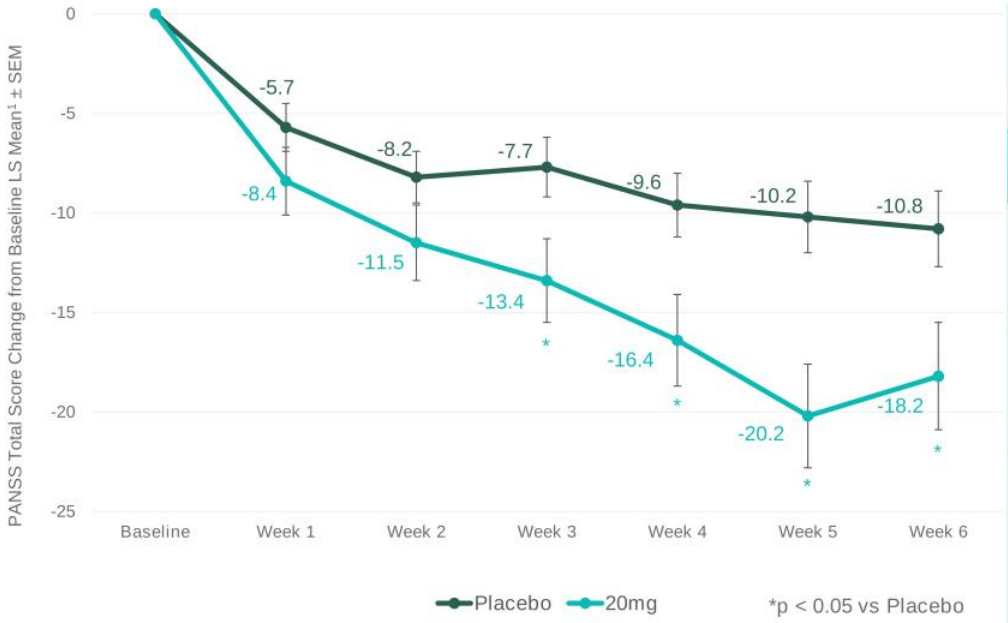
*Least-squares (LS) means are from a MMRM which includes treatment group, visit, and study period as fixed effects; treatment group-by-visit interaction; baseline PANSS total score as a covariate; and subject as a random effect.
**Effect size (Cohen's D) is based on observed data.

Once-Daily 20mg Dose Demonstrated Clinically Meaningful and Statistically Significant Efficacy at Week 3, 4, 5, and 6



20mg QD Efficacy Data
Week 4 – Week 6

Week	4	5
PANSS Total Score		
LS Mean[1]	-16.4	-20.2
LS Mean Difference vs. Placebo[1]	-6.8 p = 0.008	-10.0 p < 0.001
Effect Size[2]	0.53	0.72

** Primary En

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[2] Effect size (Cohen's D) is based on observed data.

Once-Daily 20mg Dose Demonstrated Statistically Significant Improvement in Additional Endpoints

Week 6	CGI-S		Marder Factor — Positive		Marder Factor — Negative	
	Placebo N=68	20mg QD N=35	Placebo N=68	20mg QD N=35	Placebo N=68	20mg QD N=35
LS Mean Change from Baseline*	-0.5	-1.2	-2.8	-5.8	-1.2	-3.1
LS Mean Difference vs. Placebo*		-0.7 p < 0.001		-3.0 p = 0.004		-1.9 p = 0.028

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*Least-squares (LS) means are from a MMRM which includes treatment group, visit, and study period as fixed effects; treatment group-by-visit interaction; baseline value as a covariate; and subject as a random effect.

NBI-'568 Was Generally Safe and Well Tolerated at All Doses Stu

Treatment-Emergent Adverse Events Occurring in ≥ 5% of NBI-'568 All Treated Group

Placebo N=70	20mg QD N=40	40mg QD N=39	60mg QD N=34	30mg BID N=27	All Tre N=14

Somnolence	2 (2.9)	5 (12.5)	2 (5.1)	7 (20.6)	1 (3.7)	15 (10
Dizziness	1 (1.4)	5 (12.5)	3 (7.7)	4 (11.8)	1 (3.7)	13 (9.
Headache	14 (20.0)	1 (2.5)	5 (12.8)	1 (2.9)	5 (18.5)	12 (8.
Nausea	2 (2.9)	2 (5.0)	3 (7.7)	3 (8.8)	0	8 (5.
Constipation	2 (2.9)	2 (5.0)	3 (7.7)	1 (2.9)	1 (3.7)	7 (5.

5.0% Treatment Discontinuation Rate Due to Adverse Events
Across All NBI-'568 Arms vs. 4.3% For Placebo

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NBI-'568 is the First and Only Muscarinic M4 Selective Orthosteri Agonist in Clinical Development

Type of Muscarinic Activation	Subtype Selectivity	Requires Endogenous Ligand (Acetylcholine)
Pan Agonism	Low Targets M1-M5	No
Positive Allosteric Modulation	High Targets only M4	Yes
Selective Agonism (NBI-'568)	High Targets only M4 >500-fold agonist selectivity for the M4 receptor over other muscarinic receptors	No

Large Opportunity For NBI-'568, A Novel And Differentiated Asset

- With no reliance on innate acetylcholine le NBI-'568 is the first and only highly selec orthosteric M4 agonist, potentially introdu new modality for treatment.
- NBI-'568 potentially offers a compelling an competitive benefit-risk profile
- Convenience of once-daily dosing with o without food
- Increased conviction in indication expans opportunities for NBI-'568 and Neurocrine muscarinic portfolio

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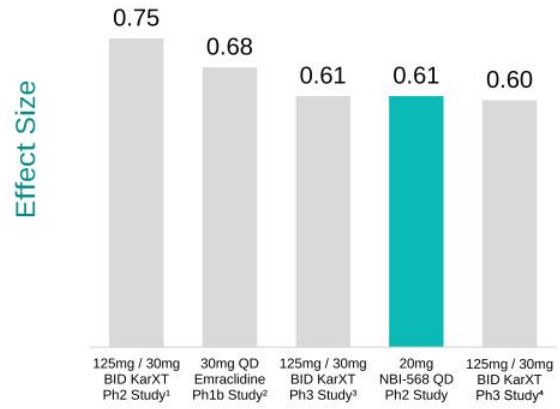
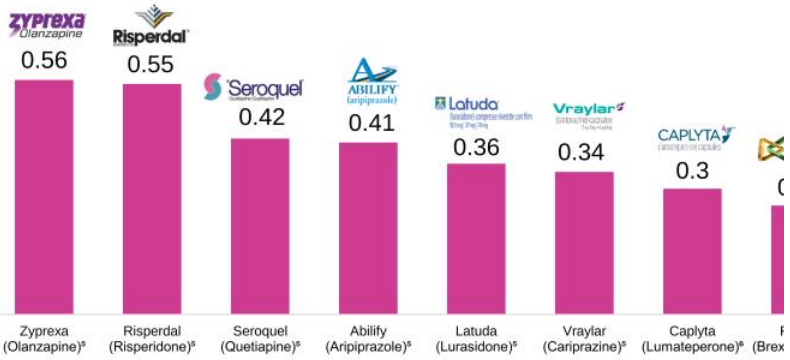
NBI-’568 Effect Size Comparable to Known Muscarinic Programs and Leading Antipsychotics

Clinical-Stage Muscarinic Programs



Sites	12	5	22	15	30
Randomization Ratio (active:placebo)	1:1	2:1	1:1	2:1	1:1
Weeks of Treatment	5	6	5	6	5
Date	**Nov ‘19**	**Jun ’21**	**Aug ’22**	**Aug ’24**	**Mar ‘23**

Leading Approved Treatments



Source: 1. Brannan S, et al. N Engl J Med. 2021;384(8):717-726. 2. Krystal J, et al. Lancet. 2022;400(10369):2210–2220. 3. Kaul I, et al. Lancet. 2024;403(10422):160–170. 4. Kaul I, et al. JAMA Psychiatry. 2024;81(8):749-756. 5. Huhn M, et al. Lancet. 2019;394(10202):939-951. 6. Correll CU, et al. JAMA Psychiatry. 2020;77(4):349-358.

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Validation of Selective Orthosteric Agonist Mechanism Strengthens Conviction In Opportunities For Industry Leading Muscarinic Portfolio

	Primary Mechanism (M1-M4)	Phase	Therapeutic Areas	Potential Areas For Develop
NBI-1117568	M4 agonist	2	Psychosis Cognition	Alzheimer’s Disease Bipolar Disorder Lewy Body Dementia Parkinson’s Disease Schizophrenia
NBI-1117567	M1 agonist	1		
NBI-1117569	M4 agonist	1		
NBI-1117570	M1/M4 dual agonist	1		
NBI-1076986	M4 antagonist	1	Movement Disorders	Dystonia Parkinson’s Disease Trem

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Summary of Topline Results

NBI-'568 20mg once-daily dose demonstrated meaningful improvement in PANSS Total Score at

Week 6:

- 18.2 point improvement in PANSS Total Score
- 7.5 point placebo-adjusted improvement
- Effect size of 0.61

NBI-'568 was well tolerated across all doses:

- 5.0% treatment discontinuation rate due to adverse events across all NBI-'568 active arms vs. 4.3% for placebo
- Nausea, constipation and other gastrointestinal adverse events were low in frequency and similar to placebo
- No weight gain relative to placebo

Data support advancing NBI-'568 into Phase 3 for schizophrenia

NBI-'568 Has A Differentiated Profile Vs. Other Antipsychotics:

- Novel Mechanism of Action
- Simple once-daily dosing with or without f
- GI effects and weight gain similar to place

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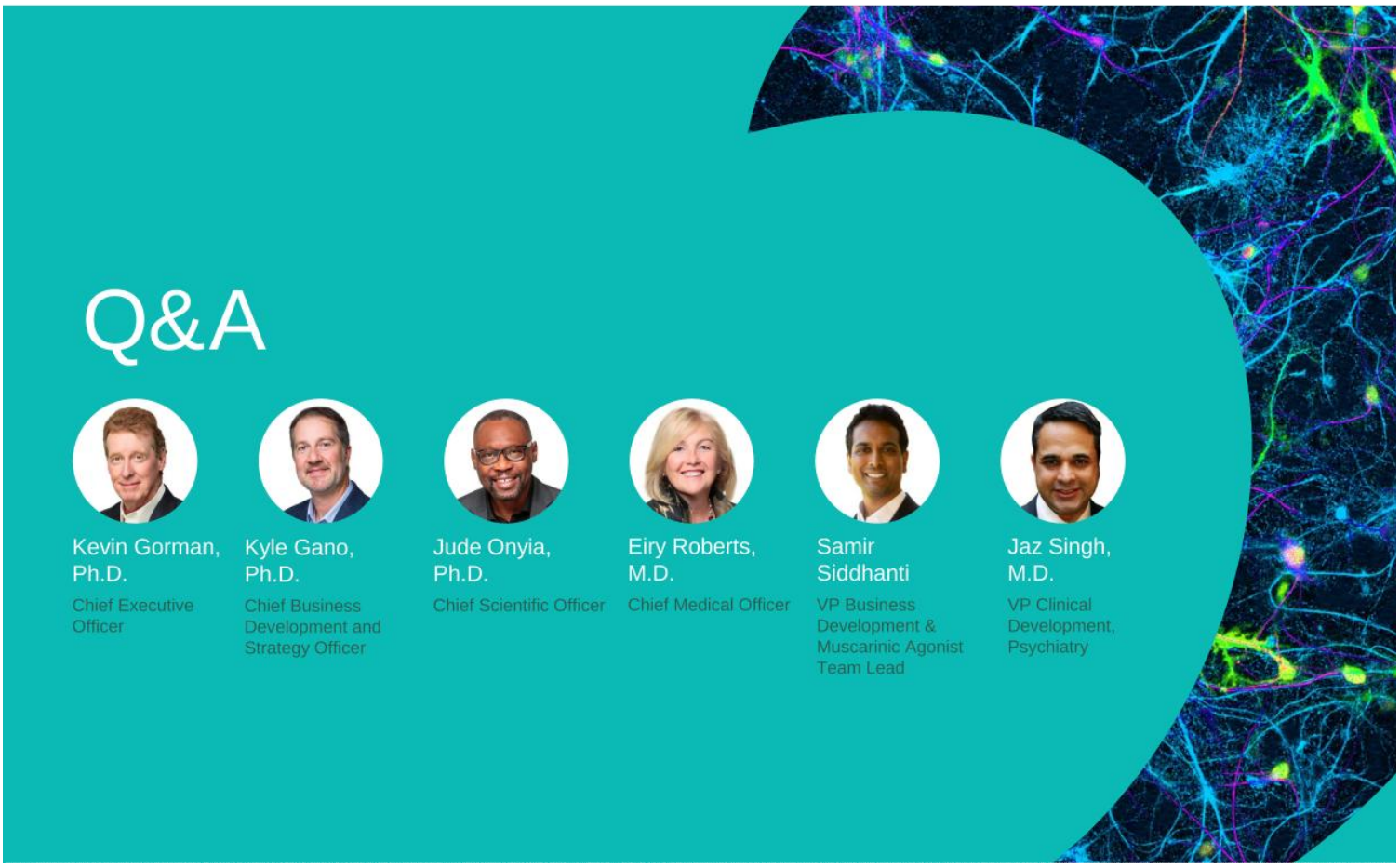
PANSS = Positive & Negative Syndrome Scale. Effect size (Cohen's D) is based on observed data.



Q&A

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