NeuroSense Investor Relations

NeuroSense Announces Third Quarter 2023 Financial Results and Provides Business Update

- ***Topline clinical secondary efficacy results and primary safety endpoints from Phase2b ALS trial (PARADIGM) expected in early December 2023***
- ***Patients who completed the 18-month PARADIGM trial, including the 6-month double-blind study plus the 12-month open label extension, have requested to continue treatment with PrimeC***
- ***First patient in Phase 2 Alzheimer's disease study expected to be enrolledDecember 2023***
- ***Cash runway beyond topline clinical study readouts, into Q2 2024***

CAMBRIDGE, Mass., Nov. 28, 2023 /PRNewswire/ -- NeuroSense Therapeutics Ltd. (Nasdaq: NRSN) ("NeuroSense"), a company developing treatments for severe neurodegenerative diseases, today reported its financial results for the nine months ended September 30, 2023 and provided a business update.

"In early December, we look forward to reporting topline clinical results from our Phase2b ALS study. Additional data, including the biomarker results from our collaboration with Biogen and primary biomarker endpoints are expected within the first half of 2024. We believe that positive results would offer substantial hope to people living with ALS and would put PrimeC well on its path to a pivotal Phase 3 for regulatory approval," stated NeuroSense's CEO, Alon Ben-Noon. "With a cash runway extending towards the end of Q2 2024, we believe we are well positioned, upon a positive read out from the study, to advance our discussions with potential strategic partners."

Business Update

Phase 2b Amyotrophic Lateral Sclerosis (ALS) PARADIGM Trial Completed Double-Blind Segment

In November 2023, NeuroSense completed the 6-month double-blind segment of PARADIGM, a placebo-controlled, multi-center Phase 2b clinical trial using a unique upgraded formulation of PrimeC, which is designed to maximize the synergistic effect between the compounds in its combination drug. 96% of participants who completed the double-blind segment of the trial chose to continue in the study and be treated with PrimeC through a 12-month open-label extension. All participants who have completed the 18-month trial to date requested to continue treatment with PrimeC. NeuroSense supplies the drug to the participants through an Investigator Initiated Trial (IIT) and will continue to provide PrimeC to any participant who completes the trial and requests to stay on the Company's investigational ALS medication.

PARADIGM's secondary clinical endpoints which are expected to be reported inDecember 2023 include: Amyotrophic Lateral Sclerosis Functional Rating Scale-Revised (ALSFRS-R), Slow Vital Capacity (SVC), and overall survival to demonstrate an attenuation in disease progression. NeuroSense also expects to report primary safety and tolerability results from the double-blind segment of the trial in December 2023.

U.S. FDA Confirmed CMC Strategy for PrimeC Ahead of Pivotal Phase 3 for Commercial Readiness

NeuroSense recently concluded a successful Type D meeting with the U.S. Food and Drug Administration (FDA) for PrimeC in the treatment of ALS. FDA Type D meetings are focused on a narrow set of issues at key decision points to provide timely feedback critical to move a drug development program forward. The purpose of NeuroSense's meeting with the FDA was to discuss PrimeC's chemistry, manufacturing, and controls (CMC) development plans in advance of an expected Phase 3 pivotal study and potential subsequent marketing approval. The FDA agreed with NeuroSense's proposed CMC development plan, setting the stage for a smooth progression with the production PrimeC for a Phase 3 and subsequent commercialization.

Non-Sponsored Study Demonstrated PrimeC's Outstanding Effect on ALS Survival

At the Ichida Stem Cell Lab at University of Southern California, PrimeC was shown to significantly increase the survival rate of induced motor neurons in an *in vitro* study utilizing induced pluripotent stem cells (iPSCs) generated from people living with ALS. In another independent study carried out by Dr. Ichida in an innovative iPSC model, PrimeC performed among the best in improving motor neuron survival when compared to two FDA approved ALS drugs as well as several other ALS drugs in development. Together, these results reinforce previous findings on PrimeC's efficacy and mechanism of action.

Phase 2 Alzheimer's Disease (AD) Trial Under Preparation, First Patient Enrolled Expected in Q4 2023

NeuroSense published data from a biomarker study which revealed elevated levels of novel biomarker TDP-43 in AD as compared to healthy controls in the first quarter of 2023. These results demonstrate the therapeutic potential of NeuroSense's combination drug platform for AD. Currently, NeuroSense is preparing a Phase 2 double-blind proof-of-concept clinical study in AD. Regulatory submissions and site readiness have been ongoing during Q3 2023 and the first patient enrolled is expected in December 2023.

Patents Granted in Europe, Japan, and Israel for PrimeC Valid Through 2038

Patents have been granted in Europe, Japan, and Israel for a key patent relating to "Compositions comprising an anti-inflammatory drug and a dicer activator for use in treatment of neuronal diseases." These patents address NeuroSense's unique fixed-dose combination of ciprofloxacin and celecoxib, two FDA approved drugs that are the active ingredients in PrimeC.

SME Status Received from European Medicines Agency & NeuroSense Opens EU Office

The European Medicines Agency's (EMA) Small and Medium-Sized Enterprise (SME) status offers NeuroSense regulatory guidance and engagement in dialogue with the EMA. The Company plans to enroll patients at multiple sites across Europe in its planned Phase 3 pivotal ALS study of PrimeC. As Europe is a key market, in addition to the U.S., NeuroSense opened an office in Ulm, Germany to lead its regulatory dialogue with the EMA and clinical operations during the planned Phase 3 study.

Financial Summary

- **Research and development expenses** for the nine months ended September 30, 2023 increased to $5.6 million compared to $4.9 million for the nine months ended September 30, 2022. This increase was primarily attributable to an increase in expenses to subcontractors and consultants as well as salaries and social benefits as a result of the commencement of a Phase 2b ALS clinical study in the second quarter of 2022, which were partially offset by a decrease in share-based compensation expenses. NeuroSense expects research and development expenses will remain steady through 2023.
- **General and administrative expenses** for the nine months ended September 30, 2023 decreased to $4.4 million compared to $5.3 million for the nine months ended September 30, 2022. This decrease was primarily attributable to a decrease in directors and officers insurance expenses and share-based compensation, which were partially offset primarily by an increase in payroll and related expenses. NeuroSense expects that general and administrative expenses will remain steady through 2023.
- **Operating expenses** for the nine months ended September 30, 2023 were $10.02 million compared to $10.17 million for the nine months ended September 30, 2022 due to the reasons described above.

As of September 30, 2023, NeuroSense had cash of approximately $4.8 million.

In October 2023, the Company terminated its previously established "at-the-market" ("ATM") equity offering program.

A summary of NeuroSense's unaudited consolidated financial results is included in the tables below.

About ALS

Amyotrophic lateral sclerosis (ALS) is an incurable neurodegenerative disease that causes complete paralysis and death within 2-5 years from diagnosis. Every year, more than 5,000 patients are diagnosed with ALS in the U.S. alone, with an annual disease burden of $1 billion. The number of patients with ALS is expected to grow 24% by 2040 in the U.S. and EU.

About PrimeC

PrimeC, NeuroSense's lead drug candidate, is a novel extended-release oral formulation composed of a unique fixed-dose combination of two FDA-approved drugs: ciprofloxacin and celecoxib. PrimeC is designed to synergistically target several key mechanisms of amyotrophic lateral sclerosis (ALS) that contribute to motor neuron degeneration, inflammation, iron accumulation and impaired RNA regulation to potentially inhibit the progression of ALS. PrimeC was granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

About NeuroSense

NeuroSense Therapeutics, Ltd. is a clinical-stage biotechnology company focused on discovering and developing treatments for patients suffering from debilitating neurodegenerative diseases. NeuroSense believes that these diseases, which include amyotrophic lateral sclerosis (ALS), Alzheimer's disease and Parkinson's disease, among others, represent one of the most significant unmet medical needs of our time, with limited effective therapeutic options available for patients to date. Due to the complexity of neurodegenerative diseases and based on strong scientific research on a large panel of related biomarkers, NeuroSense's strategy is to develop combined therapies targeting multiple pathways associated with these diseases. For additional information, we invite you to visit our website and follow us on LinkedIn and X, formerly known as Twitter.

Forward-Looking Statements

This press release contains "forward-looking statements" that are subject to substantial risks and uncertainties. All statements, other than statements of historical fact, contained in this press release are forward-looking statements. Forward-looking statements contained in this press release may be identified by the use of words such as "anticipate," "believe," "contemplate," "could," "estimate," "expect," "intend," "seek," "may," "might," "plan," "potential," "predict," "project," "target," "aim," "should," "will" "would," or the negative of these words or other similar expressions, although not all forward-looking statements contain

these words. Forward-looking statements are based on NeuroSense Therapeutics' current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict and include statements regarding the timing for release of results from the double-blind segment of the Company's Phase 2b trial, the timing of enrollment of the first patient in the Phase 2 Alzheimer's disease study, the cash runway and regarding an expected Phase 3 pivotal study. Further, certain forward-looking statements are based on assumptions as to future events that may not prove to be accurate. The future events and trends may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward looking statements. These risks include unexpected a delay in the reporting of results from PARADIGM clinical trial, the failure to meet the primary or secondary endpoints of the trial, a delay in patient enrollment for a Phase 2 trial for Alzheimer's disease or its planned Phase 3 pivotal ALS trial of PrimeC; incurrence of greater than anticipated expenses; the potential for PrimeC to safely and effectively target ALS; preclinical and clinical data for PrimeC; the timing of current and future clinical trials, timing for reporting data; the development and commercial potential of any product candidates of the company; and other risks and uncertainties set forth in NeuroSense's filings with the Securities and Exchange Commission (SEC). You should not rely on these statements as representing our views in the future. More information about the risks and uncertainties affecting the Company is contained under the heading "Risk Factors" in the Annual Report on Form 20-F filed with the Securities and Exchange Commission on March 22, 2023. Forward-looking statements contained in this announcement are made as of this date, and NeuroSense Therapeutics Ltd. undertakes no duty to update such information except as required under applicable law.

NeuroSense Therapeutics Ltd.

Condensed Interim Unaudited Statements of Financial Position
U.S. dollars in thousands

	September 30, 2023	**December 31, 2022**
Assets		
Current assets:		
Cash	**4,759**	3,543
Short term deposits	**-**	3,547
Other receivables	**309**	255
Restricted deposit	**37**	36
Total current assets	**5,105**	7,381
Non-current assets:		
Property, plant and equipment, net	**88**	77
Right of use assets	**172**	229
Non-current restricted deposit	**21**	23
Total non-current assets	**281**	329
Total assets	**5,386**	7,710
Liabilities and Equity		
Current liabilities:		
Trade payables	**913**	498
Other payables	**1,896**	1,228
Total current liabilities	**2,809**	1,726
Non Current liabilities:		
Long term lease liability	**84**	147
Liability in respect of warrants and pre-funded warrants	**2,689**	218
	2,773	365

Total liabilities	**5,582**	2,091
Shareholders' equity:		
Ordinary shares	**-**	-
Share premium and capital reserve	**28,920**	26,405
Accumulated deficit	**(29,116)**	(20,786)
Total Shareholders' equity (deficit)	**(196)**	5,619
Total liabilities and shareholders' equity (deficit)	**5,386**	7,710

NeuroSense Therapeutics Ltd.

Condensed Interim Unaudited Statements of Income and ComprehensiveLoss
U.S. dollars in thousands except share and per share data

	Nine months ended September 30, 2023	Nine months ended September 30, 2022	For the year ended December 31, 2022
Research and development expenses	**(5,630)**	(4,872)	(6,416)
General and administrative expenses	**(4,385)**	(5,301)	(7,136)
Operating loss	**(10,015)**	(10,173)	(13,552)
Financing expenses	**(2,208)**	(68)	(45)
Financing income	**3,893**	1,051	1,257
Financing income, net	**1,685**	983	1,212
Net loss and comprehensive loss	**(8,330)**	(9,190)	(12,340)
Basic and diluted net loss per share	**(0.67)**	(0.8)	(1.07)
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	**12,464,189**	11,394,085	11,504,521

NeuroSense Therapeutics Ltd.

Condensed Interim Unaudited Statements of Changes in Equity
U.S. dollars in thousands

	Ordinary Shares	Share Premium And Capital Reserve	Accumulated Deficit	Total Equity (Deficit)
Nine months ended September 30, 2023:				
Balance as at January 1, 2023	-	26,405	(20,786)	5,619

Share-based compensation	-	2,510	-	2,510
Exercise of options	-	5	-	5
Net loss and comprehensive loss	-	-	(8,330)	(8,330)
Balance as at September 30, 2023	**-**	**28,920**	**(29,116)**	**(196)**
Nine months ended September 30, 2022:				
Balance as at January 1, 2022	-	17,452	(8,446)	9,006
Share-based compensation	**-**	3,812	-	3,812
Net loss and comprehensive loss	**-**	-	(9,190)	(9,190)
Cancelation of options		(96)	-	(96)
Exercise of warrants	**-**	4,314	-	4,314
Balance as at September 30, 2022	-	25,482	(17,636)	7,846
For the year ended December 31, 2022:				
Balance as at January 1, 2022	-	17,452	(8,446)	9,006
Share-based compensation	-	4,735	-	4,735
Net loss and comprehensive loss	-	-	(12,340)	(12,340)
Cancelation of options	-	(96)	-	(96)
Exercise of warrants	-	4,314	-	4,314
Balance as at December 31, 2022	-	26,405	(20,786)	5,619

Logo: https://mma.prnewswire.com/media/1707291/NeuroSense_Therapeutics_Logo.jpg

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Additional assets available online: Photos (1)

https://neurosense.investorroom.com/2023-11-28-NeuroSense-Announces-Third-Quarter-2023-Financial-Results-and-Provides-Business-Update