NeuroSense Investor Relations

NeuroSense Provides Business Update and Third Quarter 2024 Financial Results

CAMBRIDGE, Mass., Dec. 18, 2024 /PRNewswire/ -- NeuroSense Therapeutics Ltd. (Nasdaq: NRSN) ("NeuroSense"), a late-stage clinical biotechnology company developing novel treatments for severe neurodegenerative diseases, today provided business update with corporate highlights to date and third quarter financial results.

"The completion of the 18-month Phase2b PARADIGM study was a major milestone for NeuroSense. The results highlight PrimeC's potential impact on slowing disease progression and survival benefits in people living with ALS. Furthermore, the positive feedback from a Type C meeting with the FDA on the pivotal study design has the Company on track to commence a Phase 3 study in mid-2025. In parallel, the Company is taking steps toward early commercialization in Canada, with an anticipated potential launch in 2026, bringing us closer to delivering a much-needed solution to the ALS community," stated Alon Ben-Noon, CEO of NeuroSense.

Upcoming Corporate Highlights for H1 2025 include:

- Additional results from the 18-month Phase2b PARADIGM study
- Meeting with EMEA
- Dossier Submission to Health Canada
- Phase 3 study commencement

Secured $5 Million Private Placement

In December 2024, NeuroSense announced a $5 million private placement at premium to market price. The Company entered into a definitive agreement with a single investor and with NeuroSense's Chief Executive Officer, Mr. Alon Ben-Noon, to purchase an aggregate of $5,000,000 of ordinary shares (or ordinary share equivalents) and warrants in a private placement. The transaction closed in December 2024.

Phase 2b Results Presented at the 2024 ALS/MND & ALS ONE Research Symposiums

At the 2024 International Symposium on ALS/MND on December 6-8, 2024, in Montreal,Canada, Prof. Merit Cudkowicz, Chair of Neurology at Massachusetts General Hospital, Director of the Sean M. Healey & AMG Center for ALS, and the Julieanne Dorn Professor of Neurology at Harvard Medical School, presented the compelling results of the 18-month Phase2b PARADIGM read-out. "The data strongly support the advancement of PrimeC to a Phase 3 trial," stated Prof. Cudkowicz, following her presentation. In addition, Prof. Cudkowicz and Dr. Shiran Zimri, NeuroSense's VP of R&D, presented the results from PARADIGM at the 7th Annual ALS ONE Research Symposium on November 14th, 2024.

Positive FDA Feedback on Future Phase 3 study

In November 2024, the Company concluded a Type C meeting with the U.S. Food and Drug Administration (FDA) for PrimeC in the treatment of ALS. The Company received positive feedback on the design of a proposed Phase 3 clinical study and the plan for submission of an eventual 505(b)(2) marketing application.

Study Completion Concludes PrimeC's Disease-modifying Potential

In October 2024, NeuroSense completed PARADIGM (NCT05357950), a multinational, randomized, double-blind, placebo-controlled, 18-month Phase 2b clinical trial of PrimeC in ALS. In participants who received PrimeC compared to those who were initially on placebo before transitioning to PrimeC, disease progression was slowed by 33% (p=0.007), demonstrated in a 58% improvement in survival rates. The 18-month results indicate the potential for PrimeC to deliver disease-modifying effects, with earlier treatment initiation possibly leading to more favorable outcomes.

Plans to File for Early Commercialization inCanada

The Company estimates that the potential market opportunity inCanada is between $100M to $150M in peak annual revenue. As such, NeuroSense has initiated the regulatory process to seek early commercialization approval for PrimeC under Health Canada. The Company expects to submit a dossier in Q2 2025, with a regulatory decision expected by Q1 2026.

Participation in 2024 Annual Northeastern Amyotrophic Lateral Sclerosis (NEALS) Consortium Meeting

NeuroSense presented two abstracts highlighting the groundbreaking data from the Phase 2b PARADIGM study at the NEALS Consortium meeting on October 21-24, 2024. Clinical outcomes were delivered by renowned clinician Prof. Cudkowicz. Biomarker analysis was presented by Dr. Cristian Lunetta, a leading neurologist and ALS specialist from the NeuroMuscular Omnicentre (NEMO) in Milan, Italy.

Key U.S. Patent Granted for Novel Formulation

In September 2024, a pivotal patent was granted by the United States Patent and Trademark Office (USPTO), entitled "Compositions comprising Ciprofloxacin and Celecoxib" (US Patent No. US 12,097,185), relating to the novel formulation of PrimeC. This patent is expected to extend PrimeC's protection by an additional four years, with coverage until 2042.

Encouraging Biomarker Data from the Phase 2b PARADIGM Study Underscores Drug's Target Engagement

- *PrimeC Significantly Improves Key miRNAs*

In collaboration with Professor Noam Shomron, a world-leading scientist in the field of genetics from Tel Aviv University, PrimeC demonstrated beneficial regulation of key miRNAs, supporting the therapeutic potential to engage critical genetic targets involved in ALS progression. The two-fold reduction of several microRNAs (miRNAs) following PrimeC treatment is particularly striking, offering both a powerful biomarker for tracking ALS and a potential pathway for new therapeutic strategies.

- *PrimeC Regulates Iron Metabolism*

Data from the 12-month read-out of the PARADIGM study confirmed our hypothesis that positive changes in iron metabolism are aligned with improved clinical outcomes. Patients on PrimeC demonstrated a significant decrease in ferritin levels and an increase in transferrin levels, corresponding to slowing of disease progression. This new analysis highlights PrimeC's ability to regulate the iron in people living with ALS, underscoring the drug's target engagement.

Q3 2024 Financial Results:

- **Research and development expenses** for the nine months ended September 30, 2024 and 2023 were $4.61 and $5.39 million, respectively. Research and development expenses decreased by 0.78 million, or 14%, primarily due to a decrease in expenses to subcontractors and consultants as well as share-based compensation expenses. NeuroSense expects research and development expenses to remain steady through the remainder of 2024 as a result of the conclusion activities of the Phase 2b ALS clinical study and the ongoing of the Phase 2 AD study.
- **General and administrative expenses** for the nine months ended September 30, 2024 and 2023 were $3.52 and $3.62 million, respectively. General and administrative expenses remained at the same level primarily due to a decrease in salaries and social benefits, share-based compensation and insurance expenses, which were fully offset by an increase in professional services. NeuroSense expects general and administrative expenses to remain steady through the remainder of 2024.
- **Operating expenses** for the nine months ended September 30, 2024 and 2023 were $8.1 and $9 million, respectively due to the reasons described above.

As of September 30, 2024, NeuroSense had cash of $0.34 million, which does not include gross proceeds of $5 million from the financing completed in December 2024. As of the date of this report, the Company believes it has shareholders' equity above the $2.5 million required by Nasdaq's Listing Rule 5550(b) requiring a minimum stockholders' equity of $2.5 million ("Equity Rule"). Therefore, the Company believes it has regained compliance with the Equity Rule and awaits Nasdaq's confirmation that the Company has evidenced compliance with the Equity Rule and that the matter has been closed.

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

Ben-Noon concluded, "The most recent capital raise has strengthened our near-term financial position and supports the continuation of our clinical development plan. We are making steady progress toward partnering opportunities that will enable the pivotal Phase 3 study and advance efforts to bring PrimeC to the Canadian market. With significant milestones achieved this quarter, the coming months hold great potential for the Company to reach a key inflection point and move into the next phase of development."

NeuroSense Therapeutics Ltd.

Condensed Interim Balance Sheets

U.S. dollars in thousands except share and per share data

	September 30, 2024	December 31, 2023
Assets		

Current assets:		
Cash and cash equivalent	**344**	2,640
Other receivables	**406**	236
Restricted deposit	**35**	40
Total current assets	**785**	2,916
Non-current assets:		
Property, plant and equipment, net	**72**	85
Operating right of use assets	**104**	162
Restricted deposit	**23**	22
Total non-current assets	**199**	269
Total assets	**984**	3,185
Liabilities and Equity		
Current liabilities:		
Trade payables	**1,392**	1,459
Other payables	**2,391**	2,000
Total current liabilities	**3,783**	3,459
Non Current liabilities:		
Operating long term lease liability	**19**	73
Liability in respect of warrants	**-**	1,412
	19	1,485
Total liabilities	**3,802**	4,944
Shareholders' equity:		
Authorized: 60,000,000 shares at September 30, 2024 and December 31, 2023; Issued and outstanding: 19,808,909 and 15,379,042 shares at September 30, 2024 and December 31, 2023, respectively	**-**	-
Share premium and capital reserve	**31,712**	24,362
Accumulated deficit	**(34,530)**	(26,121)
Total Shareholders' equity (deficit)	**(2,818)**	(1,759)
Total liabilities and shareholders' equity (deficit)	**984**	3,185

NeuroSense Therapeutics Ltd.

Condensed Interim Statements of Operations and Comprehensive Loss
U.S. dollars in thousands except share and per share data

	Nine months ended September 30,	**Nine months ended September 30,**	**For the year ended December 31,**
	2024	**2023**	**2023**
	Unaudited		
Research and development expenses	**(4,612)**	(5,368)	(7,274)
General and administrative expenses	**(3,519)**	(3,619)	(4,775)

Operating loss	**(8,131)**	(8,987)	(12,049)
Financing income (expenses), net	**(278)**	2,067	1,942
Net loss and comprehensive loss	**(8,409)**	(6,920)	(10,107)
Basic and diluted net loss per share	**(0.48)**	(0.55)	(0.74)
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	**17,585,582**	12,464,189	13,640,168

NeuroSense Therapeutics Ltd.

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

	Ordinary shares		Share premium and capital reserve	Accumulated deficit	Total equity
	Number	Amount			
Balance as of January 1, 2024	15,379,042	$ -	$ 24,362	$ (26,121)	$ (1,759)
Issuance of shares and pre-funded warrants, net	2,532,000	-	4,794	-	4,794
Exercise of pre-funded warrants, options and vested RSUs	1,507,000	-	-	-	-
Issuance of shares following ATM	319,903		230	-	230
Reclassification of warrants into equity (Note 3)	-	-	1,695	-	1,695
Share-based compensation	70,964	-	631	-	631)
Net loss and comprehensive loss	-	-	-	(8,409)	(8,409)
Balance as of September 30, 2024	19,808,909	$ -	$ 31,712	$ (34,530)	$ (2,818)

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 people are diagnosed with ALS in the U.S. alone, with an annual disease burden of $1 billion. The number of people living with ALS is expected to grow by 24% by 2040 in the U.S. and EU.

About PARADIGM

PARADIGM is a prospective, multinational, randomized, double-blind, placebo-controlled Phase2b (NCT05357950) clinical trial of PrimeC in ALS. The trial included 68 participants living with ALS in Canada, Italy, and Israel.
During the first 6 months of the trial, 45 participants were randomized to receive PrimeC, and 23 participants were randomized to receive placebo. This was followed by a 12-month open-label extension with all participants receiving PrimeC in a blinded manner, where neither the participants nor the clinical staff were aware of the initial treatment allocation.

Most patients enrolled in both the active and placebo arms of the trial were concurrently treated with Riluzole, the ALS standard of care medication, indicating PrimeC slowed disease progression well beyond the level afforded by the FDA approved ALS drug.

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 ALS that contribute to motor neuron degeneration, inflammation, iron accumulation and impaired ribonucleic acid ("RNA") regulation to potentially inhibit the progression of ALS. NeuroSense completed a Phase 2a clinical trial which met its safety and efficacy endpoints including reducing functional and respiratory deterioration and statistically significant changes in ALS-related biological markers indicating PrimeC's biological activity. PrimeC was granted Orphan Drug Designation by the U.S. Food and Drug Administration and the European Medicines Agency.

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 ourwebsite and follow us on LinkedIn, YouTube and X. Information that may be important to investors may be routinely posted on our website and these social media channels.

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 of submission of regulatory submissions to the FDA or other regulatory authorites, the timing of commencement of enrollment for clinical trials, if any, the market opportunity in Canada for PrimeC, timing of anticipated commencement of commercialization in Canada and the belief that the Company has regained compliance with the Equity Rule 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 the risk of a delay in commencement of enrollment for the Phase 3 trial, if any, or a delay in regulatory submissions with the FDA, the risk that the trial will not be completed, lower than anticipated market opportunity in Canada, a delay in timing of anticipated commencement of commercialization inCanada, if any, meet regulatory expectations or provide sufficient data for drug approval, unexpected changes in trial design, delay in submission by the Company of its regulatory dossier, that regulatory approvals for PrimeC will be delayed or not obtained in the U.S., Canada or elsewhere; the risk of delisting from Nasdaq; unsuccessful results of the Phase 3 trial, unexpected R&D costs or operating expenses, insufficient capital to complete development of PrimeC, a delay in the reporting of additional results from PARADIGM clinical trial, the timing of expected regulatory and business milestones, risks associated with meeting with the FDA and Health Canada to determine the best path forward following the results from PARADIGM clinical trial, including a delay in any such meeting; the potential for PrimeC to safely and effectively target ALS; preclinical and clinical data for PrimeC; the uncertainty regarding outcomes and the timing of current and future clinical trials; timing for reporting data; the development and commercial potential of any product candidates of Neurosense; the ability of NeuroSense to remain listed on Nasdaq; 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 NeuroSense is contained under the heading "Risk Factors" in the Annual Report on Form 20-F filed with the Securities and Exchange Commission on April 4, 2024 and NeuroSense's subsequent filings with the SEC. Forward-looking statements contained in this announcement are made as of this date, and NeuroSense undertakes no duty to update such information except as required under applicable law.

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