

## NeuroSense Therapeutics Releases Letter to Shareholders Outlining Clinical Progress, Regulatory Strategy, and Partnership Update

*Letter outlines Phase 3 timeline for PrimeC in ALS, provides update on Canadian regulatory pathway and strategic partnership discussions; Company optimistic about ongoing partnership discussions with global pharmaceutical company*

CAMBRIDGE, Mass., April 24, 2025 /PRNewswire/ -- NeuroSense Therapeutics Ltd. (NASDAQ: NRSN) ("NeuroSense"), a late-stage clinical biotechnology company developing novel treatments for severe neurodegenerative diseases, today issued a shareholder letter from Chief Executive Officer Alon Ben-Noon. The letter provides an update on the company's ongoing partnership discussions, regulatory and commercial pathway for PrimeC in ALS, clinical progress, and financial outlook. The full text of the letter is included below.

Dear Valued Shareholders,

The last few months have been a transformative period for NeuroSense in all aspects – from clinical success and a positive meeting with the FDA, to commercialization milestones, and of course, to the signing of a binding term sheet with a global pharmaceutical company for a potential major partnership. As we move forward in 2025, I want to express my sincere gratitude for your continued support and confidence in NeuroSense Therapeutics and provide a brief update and overview on each of these key areas.

### Strategic Partnership Update

In December 2024, we announced entering into a binding term sheet with a leading global pharmaceutical company. While we initially anticipated finalizing this agreement in Q1 2025, the complexity of this multi-regional partnership has required additional time.

Communications with our potential partner remain active and constructive. All information disclosed in our December announcement was mutually agreed upon with our potential partner. We remain optimistic about this collaboration, and we believe our discussions with our partner have the potential to bring forth a transformative result which will mark a true inflection point for NeuroSense—strategically, operationally, and financially. In parallel, we are also maintaining alternative pathways to advance PrimeC's development should circumstances change.

### Regulatory and Commercial Pathway

Following the positive FDA feedback we announced in December from our Type C meeting, we are continuing to advance toward the initiation of our Phase 3 clinical trial in the second half of 2025. As previously communicated, this pivotal study would be global in scope, with clinical sites mostly across the United States and Europe.

In Canada, we are making important progress toward early access, guided by productive discussions with Health Canada around a potential Notice of Compliance with Conditions (NOC/c) pathway. This regulatory route is specifically designed to provide patients facing serious and life-threatening conditions with earlier access to promising treatments, and we are encouraged by the possibility of bringing our therapy to those in urgent need—sooner.

While commercial forecasts suggest a potential peak annual revenue of \$100–150 million in Canada, our primary motivation is to address the unmet needs of the ALS community. If and when approved, early commercialization in Canada would mark not only a significant regulatory milestone, but also a vital opportunity to offer hope to patients, generate resources to build operational infrastructure, and strengthen real-world data collection to support global regulatory and market access efforts.

We believe that this patient-focused early access program could serve as a foundational step in expanding NeuroSense's global footprint—demonstrating both our commitment to patients and the tangible commercial potential of our lead asset. We expect to provide further updates on our Canadian regulatory progress by June 2025.

### Clinical Program Progress

As previously [reported](#) in December 2024, our Phase 2b PARADIGM study has delivered positive results that validate our approach and strengthen our conviction in PrimeC's potential. The 18-month data demonstrated a statistically significant 33% slowing of disease progression ( $p=0.007$ ) and a 58% improvement in survival rates compared to participants who began on placebo. These outcomes represent clinically meaningful advancements in addressing this devastating disease.

Throughout our communications, we've highlighted PrimeC's favorable safety and tolerability profile across the entire study duration. The high retention rate of participants, with many requesting to continue treatment beyond the study's conclusion, underscores both the favorable safety profile and the perceived clinical benefit among those living with ALS.

## **Scientific Validation and Mechanism Insights**

Building on our previously reported clinical data, we recently [presented](#) our biomarker findings at the American Academy of Neurology Annual Meeting earlier this month. These results further demonstrate PrimeC's ability to modulate key disease-related biomarkers, including microRNAs (miRNAs) and iron-related proteins, confirming our multi-targeted approach to addressing the complex pathophysiology of ALS.

This biomarker data strengthens our previously shared clinical outcomes by validating PrimeC's mechanism of action with objective biological evidence of target engagement. Distinguished neurologists Dr. Jeremy Shefner and Dr. Jeffrey Rosenfeld presented these findings, reinforcing PrimeC's position as a promising disease-modifying therapy.

## **Financial Outlook**

Our financial strategy continues to focus on maximizing shareholder value while ensuring adequate resources to advance our clinical programs. The potential strategic partnership is structured to significantly strengthen our financial position through upfront capital and funding for our Phase 3 program.

While we have no immediate plans for additional capital raising, we maintain strong relationships with the investment community and will evaluate strategic opportunities as they arise to support our needs and long-term growth objectives.

## **Looking Forward**

The coming months will be pivotal for NeuroSense as we prepare for our Phase 3 trial, advance regulatory discussions in Canada, and work toward finalizing our strategic partnership. Throughout this journey, we remain steadfastly committed to our mission of bringing meaningful treatments to people living with devastating neurodegenerative diseases.

Our work in ALS began with a deeply personal mission - inspired by my friend, Shay Rishoni, who battled the disease with remarkable courage. While time wasn't on his side, Shay's spirit lives on in our unwavering commitment to reclaim precious time for others. This isn't just research - it's a legacy in motion.

We are deeply grateful for your continued trust and investment in NeuroSense. Your support empowers our work and gives hope to the patients we serve. I look forward to sharing further updates as we progress, and as always, we welcome your questions and feedback.

With sincere appreciation,

### **Alon Ben-Noon**

Chief Executive Officer  
NeuroSense Therapeutics Ltd.

## **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](#), [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 ongoing partnership discussions, the timing of initiation of studies, regulatory filings, meetings and regulatory decisions, market potential and future capital raising. 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 that the partnership discussions will not lead to execution of a definitive agreement, or that, if executed, will not lead to the current anticipated benefits to NeuroSense, a delay in the planned Phase 3 study for PrimeC in ALS or that its scope will be different than anticipated, lower than anticipated

market opportunity in Canada and elsewhere, the risk that NeuroSense will need capital earlier than currently anticipated, that regulatory approvals for PrimeC will be delayed or not obtained in Canada or elsewhere; 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 7, 2025 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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Additional assets available online:  [Photos \(1\)](#)

<https://neurosense.investorroom.com/2025-04-24-NeuroSense-Therapeutics-Releases-Letter-to-Shareholders-Outlining-Clinical-Progress,-Regulatory-Strategy,-and-Partnership-Update>