

NeuroSense Therapeutics Reports Year End 2024 Financial Results and Provides Business Updates

- *Phase 2b study completed in amyotrophic lateral sclerosis (ALS) demonstrated lead asset PrimeC slows disease progression and functional decline*
- *Ongoing partnership discussions to advance PrimeC to Phase 3 study in ALS and commercialization*
- *Phase 3 study design for PrimeC in ALS aligned with FDA; planned initiation in 2025*

CAMBRIDGE, Mass., April 7, 2025 /PRNewswire/ -- NeuroSense Therapeutics Ltd. (Nasdaq: NRSN) ("NeuroSense"), a clinical-stage biotechnology company developing novel treatments for severe neurodegenerative diseases, today reports its financial results for the year ended December 31, 2024 and provides a business update.

Business highlights from 2024 and to date

- PrimeC achieved primary and secondary clinical endpoints in PARADIGM Phase2b study investigating PrimeC in ALS (n=68) with data showing the following:
 - PrimeC slowed disease progression (measured by ALSFRS-R) by approximately 33% after 18 months (p=0.007)
 - PrimeC reduced likelihood of mortality, hospitalization and respiratory support, resulting in an overall 58% improvement in survival rates.
 - PrimeC slowed functional decline, especially speaking and swallowing functions.
 - PrimeC demonstrated favorable safety and tolerability profile, achieving the study's primary endpoint.
- Phase 3 study design for PrimeC for ALS aligned with FDA following Type C meeting.
- Partnership discussions are continuing in order to advance PrimeC towards regulatory approval and eventual commercialization.
- Plans to file for early commercialization for PrimeC in Canada, with an estimated potential market opportunity of \$100m-\$150m in peak annual revenues.
- Key patent granted by U.S. Patent and Trademark Office (USPTO), extending the patent protection for the novel formulation of PrimeC until 2042.

"2024 was a year of significant clinical progress for NeuroSense," stated NeuroSense CEO, Alon Ben-Noon. "We successfully completed our Phase 2b study for PrimeC in ALS, with data showing transformative results in a neurodegenerative indication of immense medical need. The results conclude with PrimeC's disease-modifying potential and strongly support advancing PrimeC towards a Phase 3 study. With positive FDA feedback on the proposed study design, we are putting everything in place for the next stage of NeuroSense's growth, driven by PrimeC's continued clinical development."

Financial Results

Research and development expenses for the years ended December 31, 2024 and 2023 were \$5.7 million and \$7.3 million, respectively. The decrease of \$1.6, or 21.9%, was mainly attributed to a decrease in our expenses to subcontractors and consultants and a decrease in share-based payment expense.

General and administrative expenses for the years ended December 31, 2024 and 2023 were \$4.2 million and \$4.8 million, respectively. The decrease of \$0.6, or 12.5%, was mainly attributed to a decrease in share-based compensation and insurance costs and a decrease in salaries and social benefit expenses mainly due to decrease in the number of employees which were offset by an increase in professional services expenses.

As of December 31, 2024, NeuroSense had cash of approximately \$3.4 million.

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

A copy of the Company's annual report on Form 20-F for the year ended December 31, 2024 has been filed with the U.S. Securities and Exchange Commission at <https://www.sec.gov/> and posted on the Company's investor relations website at <https://neurosense.investorroom.com/sec-filings>. The Company will deliver a hard copy of its annual report, including its complete audited financial statements, free of charge, to its shareholders upon request at ir@neurosense-tx.com.

	As of December 31,	
	2024	2023
Assets		
Current assets:		
Cash and cash equivalent	\$ 3,378	\$ 2,640
Other receivables	989	236
Restricted deposits	35	40
Total current assets	4,402	2,916
Non-current assets:		
Property and equipment, net	66	85
Right of use assets	84	162
Restricted deposit	23	22
Total non-current assets	173	269
Total assets	\$ 4,575	\$ 3,185
Liabilities shareholders' and equity		
Current liabilities:		
Trade payables	\$ 1,160	\$ 1,459
Other current liabilities	832	2,000
Total current liabilities	1,992	3,459
Non-current liabilities:		
Lease liability less current maturity	-	73
Liability in respect of warrants	-	1,412
	-	1,485
Total liabilities	1,992	4,944
Shareholders' equity:		
Ordinary shares, no par value:		
Authorized: 90,000,000 shares at December 31, 2024 and 60,000,000 shares at December 31, 2023; Issued and outstanding: 23,228,941 and 15,379,042 shares at December 31, 2024 and 2023, respectively		-
Share Premium and Capital Reserve	39,243	24,362
Accumulated deficit	(36,660)	(26,121)
Total shareholders' equity (deficit)	2,583	(1,759)
Total liabilities and shareholders' equity	\$ 4,575	\$ 3,185

NeuroSense Therapeutics Ltd.
Consolidated Statements of Income and Comprehensive Loss
(U.S. dollars in thousands, except share and per share data)

	For the year ended December 31		
	2024	2023	2022
Research and development expenses	\$ (5,698)	\$ (7,274)	\$ (5,587)
General and administrative expenses	(4,204)	(4,775)	(4,967)
Operating loss	(9,902)	(12,049)	(10,554)
Financing income (expenses), net	(308)	1,942	62

Net loss and comprehensive loss	<u>\$ (10,210)</u>	<u>\$ (10,107)</u>	<u>\$ (10,492)</u>
Basic and diluted net loss per share	<u>\$ (0.54)</u>	<u>\$ (0.74)</u>	<u>\$ (0.91)</u>

NeuroSense Therapeutics Ltd.
Consolidated Statements of Changes in Equity (deficit)
(U.S. dollars in thousands, except share and per share data)

	Ordinary Shares		Share Premium and Capital Reserve	Accumulated Deficit	Total Equity (Deficit)
	Number	Amount			
Balance as of January 1, 2022	10,943,534	\$ -	\$ 16,356	\$ (5,522)	\$ 10,834
Repurchase of options	-	-	(96)	-	(96)
Exercise of warrants and vested RSUs	838,429	-	3,870	-	3,870
Share based payment compensation	-	-	1,728	-	1,728
Net loss and comprehensive loss	-	-	-	(10,492)	(10,492)
Balance as of December 31, 2022	11,781,963	\$ -	\$ 21,858	\$ (16,014)	\$ 5,844
Issuance of shares and pre-funded warrants, net	1,333,600	-	806	-	806
Exercise of pre-funded warrants, options and vested RSUs	2,263,479	-	-	-	-
Share based payment compensation	-	-	1,698	-	1,698
Net loss and comprehensive loss	-	-	-	(10,107)	(10,107)
Balance as of December 31, 2023	15,379,042	\$ -	\$ 24,362	\$ (26,121)	\$ (1,759)
Issuance of shares and pre-funded warrants, net	5,981,238	-	10,806	-	10,806
Exercise of pre-funded warrants, options and vested RSUs	1,573,000	-	(*)	-	(*)
Issuance of shares due to SEPA agreement	224,697	-	281	-	281
Reclassification of warrants into equity (see Note 8)	-	-	1,695	(329)	1,366
Bonus accrual reclassification to equity (see Note 14)	-	-	1,434	-	1,434
Share-based compensation	70,964	-	665	-	665
Net loss and comprehensive loss	-	-	-	(10,210)	(10,210)
Balance as of December 31, 2024	<u>23,228,941</u>	<u>\$ -</u>	<u>\$ 39,243</u>	<u>\$ (36,660)</u>	<u>\$ 2,583</u>

(*) less than \$1.

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 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 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 expected growth in the market. 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, lower than anticipated market opportunity in Canada and elsewhere, 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 development of PrimeC, 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.

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/2025-04-07-NeuroSense-Therapeutics-Reports-Year-End-2024-Financial-Results-and-Provides-Business-Updates>