

NeuroSense Management Provides Corporate Update and First Quarter 2024 Financial Results

Following positive 6-month clinical outcomes from phase 2b (PARADIGM) clinical trial, Company expects additional biomarker and 12-month clinical in the near term

CAMBRIDGE, Mass., June 24, 2024 /PRNewswire/ -- [NeuroSense Therapeutics Ltd.](#) (NASDAQ: NRSN) ("NeuroSense"), a company developing novel treatments for severe neurodegenerative diseases, today provides a corporate update following its recently announced analyses from its Phase 2b PARADIGM clinical trial, which demonstrated a statistically significant slowing of disease progression in high-risk ALS patients treated with PrimeC by 43% (p=0.02) as compared to placebo in the pre-specified per protocol (PP) population analysis after six months of treatment.^[1] As previously indicated, the slowing of disease progression demonstrated by PrimeC versus placebo translates to a 5.04-point difference in the ALSFRS-R in favor of PrimeC (Confidence Interval: 0.862, 9.214; n=38).

Corporate Highlights for the near term include:

- 12-month clinical results, including survival, expected in June 2024
- FDA meeting anticipated in Q3 2024
- Started preparations for Phase 3 clinical trial in the US, including protocol submission expected by year-end 2024

NeuroSense CEO Alon Ben-Noon states, "We are continuing to see additional results coming in from the PARADIGM trial and as they are being analyzed and verified, we intend to share them with shareholders. We anticipate sharing 12-month survival data, ALSFRS-R –as well as providing some additional biomarker data. These will include iron, ferritin and transferrin. We are looking forward to presenting target-engagement biomarkers alongside the clinical outcomes. In the meantime, we continue our discussions with several potential partners in order to drive our clinical programs forward efficiently."

In addition, the Company hereby provides its Q1 2024 financial results:

- **Research and development expenses** for the three months ended March 31, 2024 and 2023 were \$1.88 and \$1.85 million, respectively. Research and development expenses remained at the same level primarily due to an increase in expenses to subcontractors and consultants as well as salaries and social benefits as a result of the progression of the Phase 2b ALS clinical study, which were fully offset by a decrease in share-based compensation expenses. NeuroSense expects research and development expenses to remain steady through the remainder of 2024 as a result of the open label extension of the Phase 2b ALS clinical study and the ongoing of the Phase 2 AD study.
- **General and administrative expenses** for the three months ended March 31, 2024 and 2023 were \$1.11 and \$1.14 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 increase in professional services. NeuroSense expects general and administrative expenses to remain steady through the remainder of 2024.
- **Operating expenses** for the three months ended March 31, 2024 and 2023 were \$3 million due to the reasons described above.

As of March 31, 2024, NeuroSense had cash of \$0.74 million, which does not include gross proceeds of approximately \$4.5 million from a financing that the Company completed in April 2024. As part of the transaction, the Company entered into a securities purchase agreement, pursuant to which the Company issued in a registered direct offering (i) 1,732,000 ordinary shares; (ii) pre-funded warrants to purchase 1,248,000 ordinary shares at an exercise price of \$0.0001, exercisable at any time upon their issuance until exercised in full and (iii) warrants to purchase 2,980,000 ordinary shares at an exercise price of \$1.50.

Following the end of the first quarter of 2024, the Company determined to change its accounting method from IFRS to U.S. GAAP and accordingly has reissued its audited financial statements for all periods covered by its 2023 financial statements under U.S. GAAP. A copy of the reissued financial statements and accompanying financial data has been filed with the Securities and Exchange Commission on Form 6-K. The Company's unaudited consolidated financial results for the three months ended March 31, 2024 are presented in accordance with US GAAP Reporting Standards.

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

Ben-Noon concluded, "We continue to build strong clinical evidence for PrimeC and are looking forward to upcoming announcements. Concurrently, we are working to safeguard our financial future and ability to continue our clinical activities so as to ensure that there is adequate cash on the balance sheet to complete these milestones. We plan to meet with the FDA in Q3 2024 to discuss the clinical path forward towards an NDA submission, which we believe will be a major inflection point for NeuroSense. The coming months hold tremendous potential, and we are optimistic about the outcomes and the future for NeuroSense Therapeutics."

[1] High-risk patients, defined by the European Network for the Cure of ALS (ENCALS) Risk Factor as those with a higher risk for rapid disease progression, comprise approximately 50% of the total ALS population.

NeuroSense Therapeutics Ltd.

Condensed Interim Balance Sheets

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

	March 31, 2024	December 31, 2023
	<u>Unaudited</u>	
Assets		
Current assets:		
Cash and cash equivalent	735	2,640
Other receivables	421	236
Restricted deposit	36	40
Total current assets	<u>1,192</u>	<u>2,916</u>
Non-current assets:		
Property and equipment, net	88	85
Operating right of use assets	143	162
Restricted deposit	23	22
Total non-current assets	<u>254</u>	<u>269</u>
Total assets	<u>1,446</u>	<u>3,185</u>
Liabilities and Shareholders' Deficit		
Current liabilities:		
Trade payables	2,384	1,459
Other payables	2,151	2,000
Total current liabilities	<u>4,535</u>	<u>3,459</u>
Non-Current liabilities:		
Operating long-term lease liability	55	73
Liability in respect of warrants	3,849	1,412
	<u>3,904</u>	<u>1,485</u>
Total liabilities	<u>8,439</u>	<u>4,944</u>
Shareholders' deficit:		
Authorized: 60,000,000 shares at March 31, 2024 and December 31, 2023; Issued and outstanding: 15,582,042 and 15,379,042 shares at March 31, 2024 and December 31, 2023, respectively.	-	-
Share premium and capital reserve	24,532	24,362
Accumulated deficit	(31,525)	(26,121)
Total Shareholders' deficit	<u>(6,993)</u>	<u>(1,759)</u>
Total liabilities and shareholders' deficit	<u>1,446</u>	<u>3,185</u>

NeuroSense Therapeutics Ltd.

Condensed Interim Statements of Operations and Comprehensive Loss

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

	Three months ended March 31, 2024	Three months ended March 31, 2023	For the year ended December 31, 2023
	Unaudited		
Research and development expenses	(1,882)	(1,852)	(7,274)
General and administrative expenses	(1,112)	(1,139)	(4,775)
Operating loss	(2,994)	(2,991)	(12,049)
Financing income (expenses), net	(2,410)	67	1,942
Net loss and comprehensive loss	(5,404)	(2,924)	(10,107)
Basic and diluted net loss per share	(0.35)	(0.25)	(0.74)
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	15,405,253	11,785,603	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 Shareholders' Equity (Deficit)
	Number	Amount			
Three months ended March 31, 2024:					
Balance as at January 1, 2024	15,379,042	-	24,362	(26,121)	(1,759)
Share based compensation					
Exercise of vested RSUs	203,000	-	170	-	170
Net loss and comprehensive loss	-	-	-	(5,404)	(5,404)
Balance as at March 31, 2024	15,582,042	-	24,532	(31,525)	(6,993)
Three months ended March 31, 2023:					
Balance as at January 1, 2023	11,781,963	-	21,858	(16,014)	5,844
Share based compensation	-	-	406	-	406
Net loss and comprehensive loss	-	-	-	(2,924)	(2,924)
Balance as at March 31, 2023	11,781,963	-	22,264	(18,938)	3,326
For the year ended December 31, 2023:					
Balance as at January 1, 2023	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 compensation	-	-	1,698	-	1,698
Net loss and comprehensive loss	-	-	-	(10,107)	(10,107)

Balance as at December 31, 2023	15,379,042	-	24,362	(26,121)	(1,759)
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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 by 24% by 2040 in the U.S. and EU.

About PARADIGM

PARADIGM is a prospective, multinational, randomized, double-blind, placebo-controlled Phase 2b ([NCT05357950](#)) clinical trial of PrimeC in ALS. The trial included 68 participants living with ALS in Canada, Italy, and Israel. 96% of the trial participants who completed the 6-month double-blind portion of the trial chose to receive treatment with PrimeC through a 12-month open label extension. Furthermore, to date all participants that completed the 18-month trial treatment duration, requested to continue PrimeC, which is provided to them in an Investigator Initiated Trial, not limited with time.

As previously reported, top-line data from the 6-month double-blind segment of the trial showed clinically meaningful signs of efficacy with a 29% difference in ALSFRS-R ($p=0.12$) and a 13% difference in SVC ($p=0.5$), both in favor of PrimeC vs placebo in analysis of the intent to treat (ITT) population. These data include all 68 people living with ALS enrolled in Canada, Italy, and Israel, with the exclusion of one patient who was misdiagnosed. In the PP top-line analysis from PARADIGM, a statistically significant slowing of disease progression was observed with a 37.4% ($p=0.03$) difference in ALSFRS-R in favor of PrimeC vs placebo. 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 our [website](#) and follow us on [LinkedIn](#) and [X](#).

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 top-line results and regulatory meetings and submissions. 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 R&D costs or operating expenses, 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 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.

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/2024-06-24-NeuroSense-Management-Provides-Corporate-Update-and-First-Quarter-2024-Financial-Results>