NeuroSense Investor Relations

NeuroSense Announces Year End 2023 Financial Results and Provides Business Update

CAMBRIDGE, Mass., April 5, 2024 /PRNewswire/ -- NeuroSense Therapeutics Ltd. (NASDAQ: NRSN) ("NeuroSense"), a company developing novel treatments for severe neurodegenerative diseases, today reported its financial results for the year ended December 31, 2023 and provides a business update.

Corporate Highlights from Q4 and To Date

- Topline clinical results from the Phase 2b PARADIGM ALS trial demonstrated a statistically significant, 37.4% difference (P=0.03), slowing of disease progression in ALSFRS-R in patients treated with PrimeC compared to placebo, in the pre-specified Per Protocol (PP) analysis
- Subsequent analyses of quality of life and complication-free survival demonstrated positive results as well as positive trends of key biomarker outcome of neurofilament light chain (NfL) levels, in patients participating in NeuroSense's Phase 2b PARADIGM study
- These data will be presented at an upcoming medical conference and submitted for publication in a peer-reviewed journal

"During the fourth quarter, we reported significant clinical results from our Phase 2b ALS study, followed by further encouraging results on additional pre-specified clinical parameters relating to quality of life and complication-free survival. This is perhaps one of the most significant outcomes seen to date. We are thankful for the study participants, their families and caregivers, principal investigators, study coordinators, and our supportive scientific advisory board and ALS community," stated NeuroSense's CEO, Alon Ben-Noon.

Financial Results

Research and development expenses for the years ended December 31, 2023 and 2022 were $7,588 thousand and $6,416 thousand, respectively. The increase of $1,172 thousand, or 18%, was mainly attributed to (i) an increase of $693 thousand in salaries and social benefits, mainly due to an increase in the number of employees, (ii) an increase of $1,181 thousand, or 33%, in subcontractor and consulting expenses relating to clinical programs and (iii) a decrease of $703 thousand, or 44%, in share-based compensation expenses to our employees and service providers.

General and administrative expenses for the years ended December 31, 2023 and 2022 were $5,714 thousand and $7,136 thousand, respectively. The decrease of $1,422 thousand, or 20%, was primarily attributable to (i) a $1,604 thousand, or 45%, decrease in share-based compensation expenses due to less grants of options and RSUs to our employees, directors and service providers, (ii) a decrease of $663 thousand, or 56%, in insurance costs as a public company, (iii) an increase of $174 thousand, or 21%, in salaries and social benefits, mainly due to additional compensation paid to our executive officers and an increase in the number of employees and (iv) a $401 thousand, or 37%, increase in professional services expenses.

Operating expenses for the years ended December 31, 2023 and 2022 were $13,302 thousand and $13,552 thousand, respectively. The decrease of $250 thousand, or 2%, was primarily due to the reasons described above.

As of December 31, 2023, NeuroSense had cash of approximately $2.6 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, 2023 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/. The Company will deliver a hard copy of its annual report, including its complete audited consolidated financial statements, free of charge, to its shareholders upon request at info@neurosense-tx.com.

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 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 the 6-month double blind portion of PARADIGM, a prospective, multinational, randomized, double-blind, placebo-controlled Phase 2b ALS (**NCT05357950**) clinical trial, which met its safety and tolerability endpoints, also showing a statistically significant slowing of disease progression in the pre-specified Per Protocol (PP) population. 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.

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 PrimeC as a potential treatment for people with ALS and the timing for release of additional results from PARADIGM clinical trial. 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, a delay in patient enrollment in the planned Phase 3 pivotal ALS trial of PrimeC; 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 the company; the ability to regain compliance with Nasdaq's continued listing standards; 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 April 3, 2024. 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.
Consolidated Statements of Financial Position
(U.S. dollars in thousands)

	As of December 31,	
	2023	**2022**
Assets		
Current assets:		
Cash and cash equivalent	**$ 2,640**	$ 3,543
Short term deposits	**-**	3,547
Other receivables	**236**	255
Restricted deposits	**40**	36
Total current assets	**2,916**	7,381

Non-current assets:		
Property, plant and equipment, net	**85**	77
Right of use assets	**153**	229
Restricted deposit	**22**	23
Total non-current assets	**260**	329
Total assets	**$ 3,176**	$ 7,710
Liabilities shareholders' and equity		
Current liabilities:		
Trade payables	**$ 1,459**	$ 498
Other payables	**2,000**	1,228
Total current liabilities	**3,459**	1,726
Non Current liabilities:		
Long term lease liability	**73**	147
Liability in respect of warrants	**1,518**	218
	1,591	365
Total liabilities	**5,050**	2,091
Shareholders' equity:		
Ordinary shares	**—**	—
Share premium and capital reserve	**30,192**	26,405
Accumulated deficit	**(32,066)**	(20,786)
Total shareholders' equity (deficit)	**(1,874)**	5,619
Total liabilities and shareholders' equity	**$ 3,176**	$ 7,710

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		
	2023	**2022**	**2021**
Research and development expenses	**$ (7,588)**	$ (6,416)	$ (3,082)
General and administrative expenses	**(5,714)**	(7,136)	(2,505)
Operating loss	**(13,302)**	(13,552)	(5,587)
Financing expenses	**(2,209)**	(45)	(1,186)
Financing income	**4,231**	1,257	2,732
Total financing income, net	**2,022**	1,212	1,546
Net loss and comprehensive loss	**$ (11,280)**	$ (12,340)	$ (4,041)
Basic and diluted net loss per share	**$ (0.83)**	$ (1.07)	$ (0.65)

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

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For further information: For further information: Email: info@neurosense-tx.com | Tel: +972 (0)9 799 6183

Additional assets available online: Photos (1)

https://neurosense.investorroom.com/2024-04-05-NeuroSense-Announces-Year-End-2023-Financial-Results-and-Provides-Business-Update