NeuroSense Investor Relations

NeuroSense Reports First Quarter 2023 Financial Results & Provides Business Update: Phase 2b ALS Trial Completes Enrollment, Topline Data Expected Q4 2023

CAMBRIDGE, Mass., June 1, 2023 /PRNewswire/ -- NeuroSense Therapeutics Ltd. (Nasdaq: NRSN) ("NeuroSense"), a company developing treatments for severe neurodegenerative diseases, today announced financial results for the quarter ended March 31, 2023 and provided a business update.

"Having completed patient enrollment in our Phase 2b amyotrophic lateral sclerosis (ALS) trial, we are optimistic that topline results may offer new hope for people living with ALS and may generate a major inflection point for NeuroSense as we advance our combination therapy, PrimeC, toward market," stated NeuroSense's CEO, Alon Ben-Noon. "As we witness the trend of successful combination therapy strategies for neurodegenerative diseases, PrimeC has the added advantage of offering both a synergistic mechanism of action and an improved pharmacokinetic profile to enhance efficacy. We see the fact that nearly all PARADIGM participants who have completed the 6-month trial to date have chosen to continue receiving PrimeC for 12 more months as a positive signal."

Business Update

- **Completed Patient Enrollment in Phase 2b ALS PARADIGM Trial; 96% of Participants Who Completed the Trial Chose to Continue with PrimeC for 12-month OLE**

In May 2023, NeuroSense announced the completion of enrollment in PARADIGM, (NCT05357950), a multinational, randomized, double-blind, placebo-controlled Phase 2b clinical trial of PrimeC in people living with ALS. The clinical trial is evaluating PrimeC's efficacy, as well as safety and tolerability. Study participants are dosed for six months after being randomized 2:1 to receive PrimeC or placebo, respectively. Participants who complete the 6-month study have the option to be treated with PrimeC during a 12-month open label extension (OLE) phase. 96% of participants who completed the 6-month portion of the trial have opted to continue with the OLE. Topline results for the six month study are expected in Q4 2023.

- **Phase 2 Alzheimer's Disease (AD) Trial Under Preparation; Patient Enrollment to Commence Q3 2023**

Data from an AD biomarker study completed in Q1 2023 demonstrated the therapeutic potential of NeuroSense's combination drug platform for AD. The study revealed elevated levels of the novel biomarker TDP-43 in AD as compared to the healthy control group. NeruoSense's platform has already shown a statistically significant reduction of TDP-43 in a prior Phase 2a clinical trial biomarker study in ALS. A Phase 2 double-blind proof-of-concept clinical study is now under preparation, with regulatory submissions and site readiness set for the end of Q2 2023. The first patient is expected to be enrolled in Q3 2023. NeuroSense is collaborating with QuantalX, using direct electrophysiology imaging technology (Delphi-MD) to provide multiple clinically objective and accurate measurements in the Phase 2 AD study.

- **Positive Results from Parkinson's Disease (PD) Biomarker Study**

In May 2023, NeuroSense reported results from a biomarker study conducted to evaluate the potential of its combination platform therapy for the treatment of PD. NeuroSense observed a statistically significant (p= 0.002) decrease in levels of AGO2, a novel PD biomarker, in newly diagnosed PD patients (n=15) when compared to the healthy control group. There were no significant changes observed in AGO2 levels of more advanced stage PD patients, indicating that this trend could be related to disease onset. NeuroSense's platform combination therapy technology has already shown a statistically significant increase of AGO2 in a Phase 2a clinical trial biomarker study in ALS. These results strengthen the scientific rationale to develop NeuroSense's platform technology for PD. NeuroSense is now exploring potential co-development for this asset with collaborators that have a core focus in PD.

- **Established Collaboration with Massachusetts General Hospital's NeuroEpigenetics Lab**

NeuroSense's collaboration with Dr. Ghazaleh Sadri-Vakili, MS, PhD and Massachusetts General Hospital's NeuroEpigenetics Lab explores the neurotherapeutic effects of PrimeC by utilizing a novel in vitro model generated from post-mortem ALS brain tissue (synaptoneurosomes (SNs) system). The objective of the collaborative studies is to expand the understanding of PrimeC's mechanism of action in attenuating ALS-related pathology, specifically TDP-43 accumulation, autophagy defects, mitochondrial dysfunction, and oxidative stress.

- **Established Collaboration with QuantalX to Improve Early Detection and Treatment of Neurodegenerative Diseases**

In addition to QuantalX's Delphi-MD providing multiple clinically objective measurements in NeuroSense's upcoming Phase 2 AD trial, the companies agreed that Delphi-MD will be used for early diagnosis and ongoing monitoring of trial participants in NeuroSense's planned future pivotal Phase 3 ALS trial, pending the successful conclusion of PARADIGM.

Financial Summary

- **Research and development expenses** for the three months ended March 31, 2023 increased to $2.09 million compared to $1.30 million for the three months ended March 31, 2022. This increase was primarily attributable to an increase in expenses to subcontractors and consultants as well as salaries and social benefits as a result of the commencement of a Phase 2b ALS clinical study in the second quarter of 2022, which were offset by a decrease in share-based compensation expenses. NeuroSense expects research and development expenses will remain steady through 2023 as a result of the ongoing Phase 2b ALS clinical study and the start of the Phase 2 AD study.
- **General and administrative expenses** for the three months ended March 31, 2023 decreased to $1.54 million compared to $1.97 million for the three months ended March 31, 2022. This decrease was primarily attributable to a decrease in directors and officers insurance expenses and share-based compensation. NeuroSense expects that general and administrative expenses will remain steady through 2023.
- **Operating expenses** for the three months ended March 31, 2023 were $3.64 million compared to $3.26 million for the three months ended March 31, 2022 due to the reasons described above.

As of March 31, 2023, NeuroSense had cash and short-term deposits of $4.41 million.

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

NeuroSense Therapeutics Ltd.

Condensed Interim Unaudited Consolidated Statements of Financial Position As Of:

U.S. dollars in thousands	**March 31, 2023**	**December 31, 2022**
Assets		
Current assets:		
Cash	**1,359**	3,543
Short term deposits	**3,053**	3,547
Other receivables	**567**	255
Restricted deposits	**39**	36
Total current assets	**5,018**	7,381
Non-current assets:		
Property, plant and equipment, net	**84**	77
Right of use assets	**210**	229
Non-current restricted deposit	**23**	23
Total non-current assets	**317**	329
Total assets	**5,335**	7,710
Liabilities and Equity		
Current liabilities:		
Trade payables	**419**	498
Other payables	**1,374**	1,228
Total current liabilities	**1,793**	1,726
Non Current liabilities:		
Long term lease liability	**126**	147

Liability in respect of warrants	**527**	218
	653	365
Total liabilities	**2,446**	2,091
Shareholders' equity:		
Share premium and capital reserve	**27,564**	26,405
Accumulated deficit	**(24,675)**	(20,786)
Total Shareholders' equity	**2,889**	5,619
Total liabilities and shareholders' equity	**5,335**	7,710

NeuroSense Therapeutics Ltd.

Condensed Interim Unaudited Consolidated Statements of Income and Comprehensive Loss

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

	Three months ended March 31, 2023	**Three months ended March 31, 2022**	**For the year ended December 31, 2022**
Research and development expenses	**(2,098)**	(1,296)	(6,416)
General and administrative expenses	**(1,543)**	(1,968)	(7,136)
Operating loss	**(3,641)**	(3,264)	(13,552)
Financing expenses	**(310)**	(23)	(45)
Financing income	**62**	572	1,257
Financing income (expenses), net	**(248)**	549	1,212
Net loss and comprehensive loss	**(3,889)**	(2,715)	(12,340)
Basic and diluted net loss per share	**(0.33)**	(0.24)	(1.07)

NeuroSense Therapeutics Ltd.

Condensed Interim Unaudited Consolidated Statements of C hanges in Equity

U.S. dollars in thousands

	Ordinary Shares	**Share Premium And Capital Reserve**	**Accumulated Deficit**	**Total Equity**
Three months ended March 31, 2023:				
Balance as at January 1, 2023	-	26,405	(20,786)	5,619

Share-based compensation	-	1,159	-	1,159
Net loss and comprehensive loss	-	-	(3,889)	(3,889)
Balance as at March 31, 2023	**-**	**27,564**	**(24,675)**	**2,889**
Three months ended March 31, 2022:				
Balance as at January 1, 2022	-	17,452	(8,446)	9,006
Share-based compensation	-	1,597	-	1,597
Net loss and comprehensive loss	-	-	(2,715)	(2,715)
Cancelation of options	-	(96)	-	(96)
Exercise of warrants	-	4,314	-	4,314
Balance as at March 31, 2022	-	23,267	(11,161)	12,106
For the year ended December 31, 2022:				
Balance as at January 1, 2022	-	17,452	(8,446)	9,006
Share-based compensation	-	4,735	-	4,735
Net loss and comprehensive loss	-	-	(12,340)	(12,340
Cancelation of options	-	(96)	-	(96)
Exercise of warrants	-	4,314	-	4,314
Balance as at December 31, 2022	-	26,405	(20,786)	5,619

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 Twitter.

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's 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 of, and the results of, the PARADIGM clinical trial and statements regarding the co-development of our PD assets with collaborators with a core focus on PD. Further, forward-looking statements are subject to a number of risks and uncertainties as a result of which actual results could differ materially and adversely from those anticipated or implied in the forward looking statements. These risks include a delay in the reporting of top-line results from PARADIGM clinical trial; the risk that the results of the trial will not be as anticipated; a delay in commencement of our Phase 2 study in AD; the risk that the final results of PD Biomarker Study will not be consistent with the preliminary results; the risk that we will not be successful in signing co-development agreement or other agreements with collaborators with a core focus on PD risks relating to NeuroSense's PrimeC development programs; the potential for PrimeC to safely and effectively target ALS; the potential for PrimeC to safely and effectively target ALS; preclinical and clinical data for PrimeC; the timing of current and future clinical trials, timing for reporting data; cash runway estimates; the nature, strategy and focus of NeuroSense and further updates with respect thereto; the development and commercial potential of any product candidates of NeuroSense; and that expenses for the remainder of 2023 will be higher than expected and other risks and uncertainties set forth in NeuroSense's filings with the Securities and Exchange Commission (SEC), including

NeuroSense's Annual Report on Form 20-F filed with the SEC on March 22, 2023. 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/2023-06-01-NeuroSense-Reports-First-Quarter-2023-Financial-Results-Provides-Business-Update-Phase-2b-ALS-Trial-Completes-Enrollment,-Topline-Data-Expected-Q4-2023