NeuroSense Investor Relations

NeuroSense Announces Second Quarter 2023 Financial Results and Provides Business Update

- ALS Phase 2b PARADIGM Trial Completed Patient Enrollment
- Topline results expected in Q-4 2023
- Cash runway beyond topline clinical study readouts, into Q-2 2024

CAMBRIDGE, Mass., Aug. 16, 2023 /PRNewswire/ -- NeuroSense Therapeutics Ltd. (NASDAQ: NRSN) ("NeuroSense"), a company developing treatments for severe neurodegenerative diseases, today published its financial results for the quarter ended June 30, 2023 and provided a business update.

"Throughout this quarter NeuroSense achieved multiple milestones, including the completion of patient enrollment of our Phase 2b ALS study. Results observed from several biomarker studies are promising, especially in that they support our clinical strategy. The findings, along with the data we collect from our Phase 2b study, could inform the optimization of a pivotal Phase 3 study of PrimeC in ALS," stated NeuroSense's CEO, Alon Ben-Noon. "We are well positioned to complete our Phase 2b study and report topline results in Q-4 2023."

Business Update

Capital Raise of $4.5 Million

In Q-2 2023, NeuroSense raised $4.5 million in capital and based on our current expense projections is now funded into Q-2 2024, well beyond the expected timing for the release of topline results from the PARADIGM study.

Phase 2b Amyotrophic Lateral Sclerosis (ALS) PARADIGM Trial Completed Patient Enrollment

In Q-2 2023, NeuroSense completed enrollment of its double-blind, placebo-controlled, multi-center Phase 2b clinical trial using a unique upgraded formulation of PrimeC, which is designed to maximize the synergistic effect between the compounds in its combination drug. The clinical trial endpoints include assessment of ALS biomarkers, evaluation of clinical efficacy, and improvement in quality of life to demonstrate an attenuation in disease progression. Elucidation of the mechanism of action of PrimeC utilizing data from the upcoming Phase 2b trial may enable patient stratification and increase the likelihood of success in a pivotal trial. Topline results are expected in Q-4 2023. Significantly, over 96% of participants who completed the trial chose to continue in the study and be treated with PrimeC through a 12-month open-label extension.

Strategic Scientific Agreement with Biogen

In May 2023, NeuroSense announced a collaboration agreement with Biogen to evaluate the impact of PrimeC on neurofilament levels in the plasma of participants in NeuroSense's Phase 2b ALS PARADIGM trial. Biogen will fund this meaningful neurofilament biomarker study and upon receipt of results has the right of first refusal to co-develop and/or commercialize PrimeC for the treatment of ALS for a limited time.

Phase 2 Alzheimer's Disease (AD) Trial Under Preparation

In Q-1 2023, NeuroSense published data from a biomarker study, which revealed elevated levels of novel biomarker TDP-43 in AD as compared to healthy controls. NeuroSense believes these results support the therapeutic potential of its combination drug platform for AD. NeuroSense is preparing to commence a Phase 2 double-blind proof-of-concept clinical study, with regulatory submissions and site readiness ongoing during Q-2 2023 and first patient enrolled expected in the next few weeks.

Parkinson's Disease (PD) Biomarker Study Completed

In Q-2 2023, NeuroSense published data from a biomarker study in Parkinson's disease, which observed a statistically significant decrease in levels of AGO2, a novel PD biomarker, in newly diagnosed PD patients when compared to the healthy control group. The Company is exploring potential co-development for the PD indication.

Key Industry Conferences

In addition, NeuroSense joined EverythingALS in the EverythingALS Digital Biomarkers Summit in July 2023.

Financial Summary

Six Months Ended June 30, 2023

- **Research and development expenses** for the six months ended June 30, 2023 increased to $4.0 million compared to $3.17 million for the six months ended June 30, 2022. This increase was primarily attributable to subcontractors and consultants with respect to our Phase 2b clinical study that started in May 2022. NeuroSense expects research and development expenses to remain steady until the end of 2023, and then slightly decrease as a result of completing the double blind stage of the clinical study.
- **General and administrative expenses** for the six months ended June 30, 2023 decreased to $3.11 million compared to $3.69 million for the six months ended June 30, 2022. This decrease was primarily attributable to lower share-based compensation and insurance expenses. NeuroSense expects that general and administrative expenses will remain at the same level through 2023.
- **Financing expenses** for the six months ended June 30, 2023 and 2022, were $2.2 million and $58,000, respectively. The increase of $2.14 million, or 3,686%, was mainly attributed to liability with respect to warrants and prefunded warrants.
- **Financing income** for the six months ended June 30, 2023 and 2022 were $200,000 and $716,000, respectively. The decrease of $516,000, or 72%, was mainly attributed to change in rate differentials and warrants.
- **Operating expenses** for the six months ended June 30, 2023 were $7.12 million compared to $6.85 million for the six months ended June 30, 2022 due to the reasons described above.

As of June 30, 2023, NeuroSense had cash and short-term deposits of $7.1 million. NeuroSense reported a $1.55 million deficit in shareholder equity as of June 30, 2023, resulting from the required accounting treatment under IFRS related to the pre-funded warrants and warrants that the Company issued as part of the $4.5 million financing completed on June 26, 2023. A summary of the Company's unaudited financial results is included in the tables below.

Condensed Interim Unaudited Statements of Financial Position
U.S. dollars in thousands

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash	**7,089**	3,543
Short term deposits	**-**	3,547
Other receivables	**434**	255
Restricted deposit	**38**	36
Total current assets	**7,561**	7,381
Non-current assets:		
Property, plant and equipment, net	**93**	77
Right of use assets	**191**	229
Non-current restricted deposit	**23**	23
Total non-current assets	**307**	329
Total assets	**7,868**	7,710
Liabilities and Equity		
Current liabilities:		
Trade payables	**1,090**	498
Other payables	**1,915**	1,228
Total current liabilities	**3,005**	1,726
Non Current liabilities:		
Long term lease liability	**104**	147
Liability in respect of warrants and pre-funded warrants	**6,304**	218
	6,408	365
Total liabilities	**9,413**	2,091

Shareholders' equity:		
Ordinary shares	**-**	-
Share premium and capital reserve	**28,355**	26,405
Accumulated deficit	**(29,900)**	(20,786)
Total Shareholders' equity (deficit)	**(1,545)**	5,619
Total liabilities and shareholders' equity (deficit)	**7,868**	7,710

Condensed Interim Unaudited Statements of Income and Comprehensive Loss
U.S. dollars in thousands except share and per share data

	Six months ended June 30, 2023	Six months ended June 30, 2022	For the year ended December 31, 2022
Research and development expenses	**(4,005)**	(3,166)	(6,416)
General and administrative expenses	**(3,113)**	(3,688)	(7,136)
Operating loss	**(7,118)**	(6,854)	(13,552)
Financing expenses	**(2,196)**	(58)	(45)
Financing income	**200**	716	1,257
Financing income (expenses), net	**(1,996)**	658	1,212
Net loss and comprehensive loss	**(9,114)**	(6,196)	(12,340)
Basic and diluted net loss per share	**(0.77)**	(0.55)	(1.07)
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	**13,623,042**	11,294,701	11,504,521

Condensed Interim Unaudited Statements of Changes in Equity
U.S. dollars in thousands

	Ordinary Shares	Share Premium And Capital Reserve	Accumulated Deficit	Total Equity (Deficit)
Six months ended June 30, 2023:				
Balance as at January 1, 2023	-	26,405	(20,786)	5,619
Share-based compensation	**-**	**1,945**	**-**	**1,945**

Exercise of options	**-**	**5**	**-**	**5**
Net loss and comprehensive loss	**-**	**-**	**(9,114)**	**(9,114)**
Balance as at June 30, 2023	**-**	**28,355**	**(29,900)**	**(1,545)**
Six months ended June 30, 2022:				
Balance as at January 1, 2022	-	17,452	(8,446)	9,006
Share-based compensation	**-**	2,808	-	2,808
Net loss and comprehensive loss	**-**	-	(6,196)	(6,196)
Cancelation of options		(96)	-	(96)
Exercise of warrants	**-**	4,314	-	4,314
Balance as at June 30, 2022	-	24,478	(14,642)	9,836
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

Condensed Interim Unaudited Statements of Cash Flows
U.S. dollars in thousands

	Six months ended June 30, 2023	**Six months ended June 30, 2022**	**For the year ended December 31, 2022**
Cash flows from operating activities			
Net loss for the period	**(9,114)**	(6,196)	(12,340)
Adjustments:			
Depreciation and Amortization	**47**	41	89
Share-based compensation	**1,784**	2,808	5,105
Revaluation of liability in respect to warrants and pre-funded warrants	**(73)**	(693)	(1,166)
Loss from financial instruments issuance as of the date of issuance	**1,659**		
Finance expenses (income), net	**365**	65	(24)
Changes in assets and liabilities:			
Decrease (increase) in other receivables	**(179)**	(397)	55
Increase in trade payables	**592**	81	459
Increase in other payables	**841**	5	236
Net cash used in operating activities	**(4,078)**	(4,286)	(7,586)

Cash flows from investing activities			
Interest received	**47**	-	49
Change in short term deposit	**3,500**	(6,000)	(3,500)
Investment in restricted deposit	**(2)**	(19)	(20)
Purchase of property, plant and equipment	**(25)**	(30)	(70)
Net cash provided by (used in) investing activities	**3,520**	(6,049)	(3,541)
Cash flows from financing activities			
Payment in respect of cancellation of options	**-**	(96)	(96)
Exercise of warrants and options	**5**	3,870	3,870
Issuance of shares, warrants and pre-funded warrants, net	**4,142**	-	-
Repayment of lease liability	**(44)**	(67)	(79)
Net cash provided by financing activities	**4,103**	3,707	3,695
Effects of exchange rate changes on cash and cash equivalents	**1**	(86)	(88)
Net increase (decrease) in cash and cash equivalents	**3,546**	(6,714)	(7,520)
Cash and cash equivalents at beginning of the period	**3,543**	11,063	11,063
Cash and cash equivalents at end of the period	**7,089**	4,349	3,543

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 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 of, and the results of, the PARADIGM clinical trial, cash runway estimate and the timing of patient enrollment in our Alzheimer's Disease (AD) clinical trial. 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 and a delay in patient enrollment in our AZ clinical trial; greater than anticipated costs and expenses; 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; the nature, strategy and focus of the company and further updates with respect thereto; the development and commercial potential of any product candidates of the company; 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 Therapeutics Ltd. undertakes no duty to update such information except as required under applicable law.

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

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