NeuroSense Investor Relations

NeuroSense Announces Third Quarter 2022 Financial Results and Provides Business Update

CAMBRIDGE, Mass., Dec. 1, 2022 /PRNewswire/ -- NeuroSense Therapeutics Ltd. (NASDAQ: NRSN) ("NeuroSense"), a company developing treatments for severe neurodegenerative diseases, today announced its financial results for the quarter ended September 30, 2022 and provided a business update.

"During and immediately following the end of the third quarter, NeuroSense achieved multiple milestones, including FDA acceptance of our IND and approval from the Italian Medicines Agency allowing us to commence patient enrollment in the U.S. and Europe for our Phase 2b ALS study, which we expect to begin in the coming weeks. With over $8.4 million in cash and short-term deposits on our balance sheet at the end of Q3, we believe we are well positioned to complete our Phase 2b study and report topline results during Q3 2023," stated NeuroSense's CEO, Alon Ben-Noon. "In our multi-dose pharmacokinetic study, which highlighted PrimeC's novel formulation and enhanced PK profile, we observed favorable synergism between the compounds, we believe further confirming our Phase 2b study design."

Business Update

- **FDA Acceptance of IND to Commence Patient Enrollment in the U.S. and AIFA Approval to Commence Patient Enrollment in Italy**

NeuroSense achieved several milestones during Q3 in the clinical development plan for PrimeC, currently being evaluated in PARADIGM, a double-blind, placebo-controlled, multi-center Phase 2b clinical trial. Over 40% of the patients necessary to complete the trial have been enrolled. Upon the recent announcement that the U.S. Food and Drug Administration (FDA) has accepted the Company's Investigational New Drug (IND) and the approval received from the Italian Medicines Agency (AIFA), patient enrollment is expected to commence for PARADIGM in the U.S. and Europe in the next few weeks.

- **Synergism Observed in Multi-Dose PK Studies with PrimeC**

In Q3, NeuroSense released results from a multi-dose pharmacokinetic (PK) study (NCT05436678). The PK open-label, randomized, multi-dose, three-treatment, three-period crossover study evaluated the effect of food on the bioavailability of PrimeC as compared to the bioavailability of co-administered ciprofloxacin tablets and celecoxib capsules in adult subjects in the U.S. under an FDA-cleared IND protocol. Based on results, we believe the PK profile of PrimeC supports the formulation's extended-release properties, as the concentrations of the active components have been synchronized, aiming to potentially maximize the synergism between the two compounds.

- **Key Industry Conferences and Publications**

An article authored by NeuroSense's scientific team, along with leading ALS researchers, titled "Combination of ciprofloxacin/celecoxib as a novel therapeutic strategy for ALS," which presented results from NeuroSense's Phase 2a study, was published in the peer-reviewed journal: *Amyotrophic Lateral Sclerosis and Frontotemporal Degeneration*.

NeuroSense strengthened existing connections and explored new scientific collaborations through ALS conferences during and following the end of Q3. NeuroSense's Chief Medical Officer, Ferenc Tracik, MD, and Head of Scientific Program, Shiran Zimri, PhD, presented on the use of biomarkers in ALS clinical trials in the TRICALS Consortium 2022 Masterclass, the largest European research initiative to find a cure for ALS, which took place in the Netherlands.

At U.S.-based ALS ONE's 5th Annual ALS Research Symposium, Dr. Tracik presented NeuroSense's latest clinical updates and findings in his lecture titled: "Shifting the Paradigm- PrimeC: A Potential Disease-Modifying Treatment for ALS Driven by Novel Biomarkers Measuring Mechanism of Action".

NeuroSense's CEO, Alon Ben-Noon, participated as a panelist at "New Treatment Paradigm with More MoAs On the Way?" hosted by Cantor Fitzgerald's Neurology and Psychiatry Conference in San Francisco. Prof. Jeremy Shefner, Chairman of NeuroSense's Scientific Advisory Board, was the Keynote Speaker for the conference's Neurology section.

On October 13, 2022, NeuroSense had the honor of leading the Nasdaq Opening Bell Ceremony. That day, the Company hosted the ALS Combination Therapy Summit, which covered topics including the complexity of CNS indications, novel technologies targeting ALS mechanisms, market potential for an innovative and effective cure, and combination therapies as frontline solutions. Among the participants and presenters were Dr. Charles Duncan, Cantor's Managing Director and central nervous system (CNS) expert analyst, Dr. Jeffrey Rosenfeld, Professor of Neurology and Associate Chairman of Neurology at Loma Linda University School of Medicine, Ms. Indu Navar, CEO and Founder of EverythingALS, a patient-focused non-profit advancing assistive novel measurement tools for ALS biomarkers, Mr. Alon Ben-Noon, NeuroSense's CEO, Dr. Shiran Zimri, NeuroSense's Head of the Scientific Program and others.

NeuroSense's VP of Business Development, Nedira Salzman-Frenkel and VP of Discovery & IP Generator, Dr. Niva Russek-Bloom, participated in the BIO-Europe® Partnering Conference in Lepzing, Germany where 4,650 delegates came together to explore potential collaboration and partnership opportunities.

At the Northeast Amyotrophic Lateral Sclerosis Consortium (NEALS) 21st Annual Meeting, Dr. Tracik and Dr. Zimri each presented posters on PrimeC's clinical development, Phase 2b study design, and biomarker research, developments, and findings.

A poster presentation on NeuroSense's current clinical development and research plans was delivered at the Society for Neurosciences' (SfN) NeuroScience 2022 by Dr. Zimri.

Financial Summary

Nine Months Ended September 30, 2022

- **Research and development expenses** for the nine months ended September 30, 2022 increased to $4.87 million compared to $3.04 million for the nine months ended September 30, 2021. This increase was primarily attributable to an increase in expenses to subcontractors and consultants as a result of the commencement of a Phase IIb 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 2022, as a result of the ongoing Phase IIb ALS clinical study.
- **General and administrative expenses** for the nine months ended September 30, 2022 increased to $5.30 million compared to $0.91 million for the nine months ended September 30, 2021. This increase was primarily attributable to an increase in professional services, directors and officers insurance expenses, salaries and share-based compensation related to the costs of being a public company. NeuroSense expects that general and administrative expenses will remain steady through 2022.
- **Operating expenses** for the nine months ended September 30, 2022 were $10.17 million compared to $3.94 million for the nine months ended September 30, 2021 due to the reasons described above.

As of September 30, 2022, NeuroSense had cash and short-term deposits of $8.44 million. Based on NeuroSense's current expected level of operating expenditures, NeuroSense believes that its cash resources will be sufficient to continue the development of the Company's product into the fourth quarter of 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	**September 30, 2022**	**December 31, 2021**
Assets		
Current assets:		
Cash	**4,411**	11,063
Short term deposits (*)	**4,033**	-
Other receivables	**425**	310
Restricted deposits	**23**	39
Total current assets	**8,892**	11,412
Non-current assets:		
Right of use assets	**249**	-
Non-current restricted deposit	**34**	-
Property, plant and equipment, net	**55**	19
Total non-current assets	**338**	19
Total assets	**9,230**	11,431
Liabilities and Equity		
Current liabilities:		
Trade payables	**206**	39
Other payables	**605**	558
Total current liabilities	**811**	597
Non Current liabilities:		
Long term lease liability	**173**	-
Liability in respect of warrants	**400**	1,828
	573	1,828
Total liabilities	**1,384**	2,425
Shareholders' equity:		
Ordinary shares	**-**	-
Share premium and capital reserve	**25,482**	17,452
Accumulated deficit	**(17,636)**	(8,446)
Total Shareholders' equity	**7,846**	9,006
Total liabilities and shareholders' equity	**9,230**	11,431

(*) Short term bank deposits for periods of 3-12 months with annual interest rate of 1.15%-3.89%.

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

	Nine months ended September 30, 2022	Nine months ended September 30, 2021	For the year ended December 31, 2021
Research and development expenses	**(4,872)**	(3,036)	(3,082)
General and administrative expenses	**(5,301)**	(906)	(2,505)
Operating loss	**(10,173)**	(3,942)	(5,587)
Financing income	**1,051**	3	2,732
Financing expenses	**(68)**	(1)	(1,186)
Financing income, net	**983**	2	1,546
Net loss and comprehensive loss	**(9,190)**	(3,940)	(4,041)
Basic and diluted net loss per share	**(0.80)**	(0.69)	(0.65)
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	**11,394,085**	5,716,157	6,243,411

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

	Ordinary Shares	Share Premium And Capital Reserve	Accumulated deficit	Total Equity
Nine months ended September 30, 2022:				
Balance as of January 1, 2022	-	17,452	(8,446)	9,006
Share-based compensation	**-**	3,812	-	3,812
Net loss and comprehensive loss	**-**	-	(9,190)	(9,190)
Cancelation of options	**-**	(96)	-	(96)
Exercise of warrants	**-**	4,314	-	4,314
Balance as of September 30, 2022	**-**	**25,482**	**(17,636)**	**7,846**
Nine months ended September 30, 2021:				
Balance as of January 1, 2021	-	5,064	(4,405)	659
Share-based compensation	**-**	3,161	-	3,161
Net loss and comprehensive loss	**-**	-	(3,940)	(3,940)
Exercise of warrants	-	844	-	844
Issuance of SAFE instruments	-	800	-	800
Balance as of September 30, 2021	-	9,869	(8,345)	1,524
For the year ended December 31, 2021:				
Balance as of January 1, 2021	-	5,064	(4,405)	659
Issuance of SAFE instruments	-	800	-	800
Exercise of warrants and options	-	1,311	-	1,311
Share-based compensation	-	4,716	-	4,716
Issuance of ordinary shares, net upon IPO	-	5,561	-	5,561
Net loss and comprehensive loss	-	-	(4,041)	(4,041)
Balance as of December 31, 2021	-	17,452	(8,446)	9,006

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 company's PrimeC and CogniC development programs; the timing of completion of the Company's Phase 2b study and report of topline results; 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 the company and further updates with respect thereto; and the development and commercial potential of any product candidates of the company. Such risks and uncertainties include the risk that there will a delay in the timing of completion of the Company's Phase 2b study and the report of topline results, that expenses for the remainder of 2022 will be higher than expected and other risks and uncertainties set forth in the Company's filings with the Securities and Exchange Commission (SEC), including the Company's Annual Report on Form 20-F filed with the SEC on April 14, 2022. Further, certain forward-looking statements are based on assumptions as to future events that may not prove to be accurate. 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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