NeuroSense Investor Relations

NeuroSense Announces Second Quarter 2022 Financial Results and Provides Business Update

CAMBRIDGE, Mass., Aug. 31, 2022 /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, 2022 and provided a business update.

"Throughout this quarter NeuroSense achieved multiple milestones, including the initiation of our Phase IIb ALS study. As an integral part of our clinical program, NeuroSense is pioneering the identification and use of novel biomarkers in neurodegenerative diseases. Results observed from the biomarker studies are promising, especially in that they support our clinical strategy. These findings, along with the data we collect from our Phase IIb study, could inform the optimization of a pivotal Phase III study of PrimeC in ALS," stated NeuroSense's CEO, Alon Ben-Noon. "With over $10 million in cash and equivalents on our balance sheet at the end of Q2, we are well positioned to complete our Phase IIb study and report topline results in Q2 2023."

Business Update

- **Commenced ALS Phase IIb PARADIGM Clinical Trial with PrimeC**

In Q2 2022, NeuroSense commenced its double-blind, placebo-controlled, multi-center Phase IIb 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 amyotrophic lateral sclerosis (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 IIb trial may enable patient stratification and increase the likelihood of success in a pivotal trial.

- **PrimeC and CogniC observed to Target ALS and Alzheimer's Disease in Successfully Completed Biomarker Studies**

During Q2 2022, the 3rd stage of the Company's ALS biomarker study was completed. The study revealed that levels of disease-related biomarkers remained unchanged in people living with ALS who were treated with standard of care, in contrast to the statistically significant decline observed in these biomarkers in patients treated with PrimeC in NeuroSense's Phase IIa study.

Furthermore, a new study on Alzheimer's disease (AD) biomarkers was also completed. The study identified several biomarkers associated with AD, which the Company believes indicate NeuroSense's combination drug CogniC, for the treatment of AD, may be effective in targeting the pathways involved in the disease.

- **Completed Single and Multi-Dose PK Studies of PrimeC for ALS and GLP Toxicology Study**

In April 2022, NeuroSense initiated a pharmacokinetic (PK) study (NCT05232461) of PrimeC. The PK open-label, randomized, single-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 preliminary results, the PK profile of PrimeC supports the formulation's extended-release properties as the active components are released simultaneously.

In August 2022, NeuroSense completed enrollment and dosing of all subjects in a multi-dose PK study (NCT05436678), with results expected in September 2022.

In addition, NeuroSense reported the successful completion of the "in-life" phase of its 90-day GLP Toxicology study. In this study, the components of PrimeC, celecoxib and ciprofloxacin, were administered to rodents at doses 4x the maximal clinical dose. All animals appeared normal, with no significant findings observed. The Company intends to present the data from this study to the FDA as part of PrimeC's drug development plan.

- **Expanded IP Portfolio**

The Canadian Intellectual Property Office granted NeuroSense a key patent titled "Compositions comprising an anti-inflammatory drug and DICER activator for treatment of neuronal diseases" for its lead drug candidate PrimeC. This patent has already been issued to the Company in the U.S. and Australia.

- **Key Industry Collaborations and Conferences**

During Q2 2022, NeuroSense strengthened existing connections and explored new scientific collaborations through ALS

conferences. NeuroSense's Chief Medical Officer, Dr. Ferenc Tracik, MD, presented at the *ALS Drug Development Summit in Boston*, "From Monotherapy to Combination Therapy: Considering a Paradigm Shift to Target Complexity of ALS." The Company also participated in Maxim Group's panel discussion on *Innovations in ALS: Exploring New Treatments In Development*. Following the end of the second quarter, at the *World Orphan Drug Congress in Boston*, NeuroSense's Head of Scientific Program, Dr. Shiran Zimri, presented "PrimeC Significantly Alters Key ALS Biomarkers."

In July, NeuroSense announced a collaboration agreement with NeuraLight Ltd. to advance the science of oculometric digital biomarkers in the detection and monitoring of neurological diseases including ALS through the use of computer vision, artificial intelligence (AI), deep learning algorithms, and machine learning (ML). The NeuroSense-NeuraLight collaboration entails sharing and tracking patient data to advance the identification and use of ALS digital biomarkers.

In addition, NeuroSense joined the EverythingALS Open Innovation Consortium. NeuroSense will support the patient-focused non-profit with ground-breaking patient research in a joint effort to develop treatments. This collaboration will provide insight into patients' needs and allow the company to better serve the ALS community. NeuroSense's CEO, Alon Ben-Noon presented at EverythingALS's Expert Talk Series on August 3, 2022.

Financial Summary

Six Months Ended June 30, 2022

- **Research and development expenses** for the six months ended June 30, 2022 increased to $3.17 million (of which $2.31 million was in cash) compared to $2.52 million for the six months ended June 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 Q2 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 clinical study.
- **General and administrative expenses** for the six months ended June 30, 2022 increased to $3.69 million (of which $1.74 million in cash) compared to $0.55 million for the six months ended June 30, 2021. This increase was primarily attributable to an increase in salaries and professional services, directors and officers insurance expenses, and share-based compensation related to the costs of being a public company. NeuroSense expects that general and administrative expenses will remain at the same level through 2022.
- **Operating expenses** for the six months ended June 30, 2022 were $6.85 million (of which $4.05 million in cash) compared to $3.06 million for the six months ended June 30, 2021 due to the reasons described above.

As of June 30, 2022, NeuroSense had cash and short-term deposits of $10.37 million.
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, 2022	December 31, 2021
Assets		
Current assets:		
Cash	**4,349**	11,063
Short term deposits (*)	**6,025**	-
Other receivables	**707**	310
Restricted deposits	**23**	39
Total current assets	**11,104**	11,412
Non-current assets:		
Right of use assets	**268**	-
Non-current restricted deposit	**35**	-
Property, plant and equipment, net	**46**	19
Total non-current assets	**349**	19
Total assets	**11,453**	11,431
Liabilities and Equity		
Current liabilities:		
Trade payables	**120**	39

Other payables	**616**	558
Total current liabilities	**736**	597
Non-Current liabilities:		
Long term lease liability	190	-
Liability in respect of warrants	691	1,828
	881	1,828
Total liabilities	**1,617**	2,425
Shareholders' equity:		
Ordinary shares	**-**	-
Share premium and capital reserve	**24,478**	17,452
Accumulated deficit	**(14,642)**	(8,446)
Total Shareholders' equity	**9,836**	9,006
Total liabilities and shareholders' equity	**11,453**	11,431

(*) Short term bank deposits for periods of 5-12 months with annual interest rate of 0.91%-2.3%.

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

	Note	Six months ended June 30, 2022	Six months ended June 30, 2022	For the year ended December 31, 2021
Research and development expenses	**7**	**(3,166)**	(2,517)	(3,082)
General and administrative expenses	**8**	**(3,688)**	(545)	(2,505)
Operating loss		**(6,854)**	(3,062)	(5,587)
Financing income		**716**	11	2,732
Financing expenses		**(58)**	(1)	(1,186)
Financing income, net		**658**	10	1,546
Net loss and comprehensive loss		**(6,196)**	(3,052)	(4,041)
Basic and diluted net loss per share		**(0.55)**	(1.62)	(0.65)
Weighted average number of shares outstanding used in computing basic and diluted net loss per share		**11,294,701**	1,887,196	6,243,411

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

	Ordinary Share	Share Premium And Capital Reserve	Accumulated deficit	Total Equity
Six months ended June 30, 2022:				
Balance as of 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 of June 30, 2022	**-**	**24,478**	**(14,642)**	**9,836**
Six months ended June 30, 2021:				
Balance as of January 1, 2021	-	5,064	(4,405)	659
Share-based compensation	-	2,630	-	2,630
Net loss and comprehensive loss	-	-	(3,052)	(3,052)
Issuance of SAFE instruments	-	700	-	700
Balance as of June 30, 2021	-	8,394	(7,457)	937
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 ourwebsite 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 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; and the development and commercial potential of any product candidates of the company. 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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