NeuroSense Announces First Quarter 2022 Financial Results and Provides Business Update

CAMBRIDGE, Mass., May 31, 2022 /PRNewswire/ -- NeuroSense Therapeutics Ltd. (NASDAQ: NRSN) ("NeuroSense"), a company developing treatments for severe neurodegenerative diseases, today reported its financial results for the quarter ended March 31, 2022 and provided a business update.

Business Update

Initiated Biomarker Studies for ALS and Alzheimer's disease

Throughout Q1 2022, NeuroSense has been working vigorously to meet key drug development milestones. As an integral part of its clinical program, NeuroSense is pioneering the identification and use of novel disease related biomarkers in neurodegenerative diseases. During Q1 2022, the 3rd stage of the Company's amyotrophic lateral sclerosis (ALS) biomarker study was initiated in collaboration with Massachusetts General Hospital (MGH) in Boston, and a new study on Alzheimer's disease (AD) biomarkers also commenced. Results from both studies are expected in Q2 2022.

Received FDA Clearance of IND for PrimeC in Treatment of ALS

NeuroSense continues to advance its regulatory strategy via the U.S. Food and Drug Administration (FDA). In Q1 2022, the FDA cleared NeuroSense's Investigational New Drug (IND) application to initiate a pharmacokinetic (PK) study of PrimeC, its lead combination drug candidate developed for the treatment of ALS. In addition, a Fast Track application was submitted to the FDA and not granted at this time. The Company is planning to resubmit the application upon further generation of data. PrimeC was previously granted Orphan Drug Designation by the FDA and EMA.

Commenced Enrollment and Dosing in U.S. PK Study of PrimeC for ALS

In April 2022, NeuroSense enrolled and dosed the first healthy volunteer in its PK study (NCT05232461) of PrimeC. The PK open-label, randomized, single-dose, three-treatment, three-period crossover study is evaluating the effect of food on the bioavailability of PrimeC as compared to the bioavailability of co-administered ciprofloxacin tablets and celecoxib capsules in 12 healthy adult subjects in the U.S. under an FDA cleared IND protocol. Data are expected in Q3 2022. The combined data from both this PK study and the Company's upcoming Phase IIb ALS study will assist in designing a pivotal Phase III trial of PrimeC for the treatment of ALS in alignment with FDA requirements.

On Track to Initiate Phase IIb PrimeC Study for ALS

In Q2 2022, NeuroSense expects to commence its double blind, placebo controlled, multicenter Phase IIb clinical trial using a unique upgraded formulation of PrimeC which maximizes 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 statistically significant biomarker data from the upcoming Phase IIb trial may enable patient stratification and increased likelihood of success in a pivotal trial.

Patents Granted for PrimeC in Australia and Canada

NeuroSense continues to bolster its intellectual property estate, with patents granted for PrimeC, during Q1 2022 in Australia and Canada. The same patent, titled "Compositions comprising an anti-inflammatory drug and DICER activator for treatment of neuronal diseases" was previously granted in the U.S.

Collaborations & Strategic Partnerships

In expanding its business development objectives, NeuroSense is discussing potential partnerships with pharmaceutical companies devoted to rare and central nervous system diseases. NeuroSense is currently establishing new scientific collaborations, as well as strengthening existing connections.

"The upcoming initiation of our Phase IIb ALS study is a major milestone for NeuroSense. We move forward in a strong financial position, poised to execute our clinical development plans for the benefit of patients and shareholders. With our current cash position, we expect to complete preclinical studies for Alzheimer's and Parkinson's diseases and, most importantly complete our ALS Phase IIb study, leading to a potential inflection

point in value for our Company," stated NeuroSense's CEO, Alon Ben-Noon.

Financial Summary

As of March 31, 2022, NeuroSense had cash and short-term deposits in a total amount of $13.74 million, compared to $11.06 million as of December 31, 2021. The increase was due to proceeds received from the exercise of warrants in the amount of $3.87 million, partly offset by ongoing expenses.

Research and development expenses for the three months ended March 31, 2022 were $1.29 million, a decrease of $0.73 million, or 36.14%, compared to $2.02 million for the three months ended March 31, 2021. The decrease is primarily due to the reduction in share-based compensation expenses, offset by an increase in expenses to subcontractors and consultants as a result of preparations to commence a Phase IIb ALS clinical study in Q2 2022. NeuroSense expects research and development expenses will continue to increase through 2022 and beyond.

General and administrative expenses for the three months ended March 31, 2022 were $1.97 million an increase of $1.88 million, or 2,089%, compared to $0.09 million for the three months ended March 31, 2021. This increase is primarily due to the increase in salaries and professional services, director's and officer's 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.

Financing expenses for the three months ended March 31, 2022 were $23,000 an increase of $10,000, or 77%, compared to $13,000 for the three months ended March 31, 2021. The increase was mainly due to higher exchange rate expenses.

Financing income for the three months ended March 31, 2022 was $0.57 million an increase of $0.57 million, compared to $0 for the three months ended March 31, 2021. The increase in financing income was mainly due to the devaluation of the Company's liability with respect to warrants which were issued at the end of 2021 as part of NeuroSense's initial public offering.

Net loss for the three months ended March 31, 2022 was $2.71 million an increase of $0.59 million, compared with a net loss of $2.12 million for the three months ended March 31, 2021. The increase was primarily due to an increase in general and administrative expenses, partly offset by a decrease in research and development expenses and an increase in financing income.

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

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

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash	**8,735**	11,063
Short term deposits	**5,004**	-
Other receivables	**225**	310
Restricted deposits	**64**	39
Total current assets	**14,028**	11,412
Non-current assets:		
Right of use assets	**287**	-
Property, plant and equipment, net	**42**	19
Total non-current assets	**329**	19
Total assets	**14,357**	11,431
Liabilities and Equity		
Current liabilities:		
Trade payables	**180**	39
Other payables	**1,048**	558

Total current liabilities	**1,228**	597
Non-current liabilities:		
Long term lease liability	**207**	-
Liability in respect of warrants	**816**	1,828
	1,023	1,828
Total liabilities	**2,251**	2,425
Shareholders' equity:		
Ordinary shares	**-**	-
Share premium and capital reserve	**23,267**	17,452
Accumulated deficit	**(11,161)**	(8,446)
Total Shareholders' equity	**12,106**	9,006
Total liabilities and shareholders' equity	**14,357**	11,431

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

	Note	Three months ended March 31, 2022	Three months ended March 31, 2021	For the year ended December 31, 2021
Research and development expenses	**5**	**(1,296)**	(2,019)	(3,082)
General and administrative expenses	**6**	**(1,968)**	(92)	(2,505)
Operating loss		**(3,264)**	(2,111)	(5,587)
Financing expenses		**(23)**	(13)	(1,186)
Financing income		**572**	-	2,732
Financing income (expenses), net		**549**	(13)	1,546
Net loss and comprehensive loss		**(2,715)**	(2,124)	(4,041)
Basic and diluted net loss per share		**(0.24)**	(0.38)	(0.65)
Weighted average number of shares outstanding used in computing basic and diluted net loss per share		**10,994,264**	5,582,922	6,243,411

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

	Share Premium

	Ordinary Shares	And Capital Reserve	Accumulated deficit	Total Equity
Three months ended March 31, 2022:				
Balance as of 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 of March 31, 2022	**-**	**23,267**	**(11,161)**	**12,106**
Three months ended March 31, 2021:				
Balance as of January 1, 2021	-	5,064	(4,405)	659
Share-based compensation	-	1,975	-	1,975
Net loss and comprehensive loss	-	**-**	(2,124)	(2,124)
Issuance of SAFE instrument	-	100	-	100
Balance as of March 31, 2021	-	7,139	**(6,529)**	**610**
For the year ended December 31, 2021:				
Balance as of January 1, 2021	**-**	5,064	(4,405)	659
Issuance of SAFE instrument	-	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 patent applications; the company's PrimeC development program; the potential for PrimeC to safely and effectively target ALS; preclinical and clinical data for PrimeC; the timing of current and future clinical trials; 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

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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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