NeuroSense Investor Relations

NeuroSense Announces Year End 2022 Financial Results and Provides Business Update

CAMBRIDGE, Mass., March 22, 2023 /PRNewswire/ -- NeuroSense Therapeutics Ltd. (Nasdaq: NRSN) ("NeuroSense"), a company developing treatments for severe neurodegenerative diseases, announced today that its annual report on Form 20-F, containing audited consolidated financial statements for the year ended December 31, 2022, as filed with the Securities and Exchange Commission, is available through its website (https://www.neurosense-tx.com), and provided a business update.

Shareholders may receive a hard copy of the annual report free of charge upon request. This press release is being issued pursuant to Nasdaq Listing Rule 5250(d)(1)(C).

"During the fourth quarter, we continued to make progress in advancing our lead combination drug candidate PrimeC for the treatment of amyotrophic lateral sclerosis (ALS) in the Phase 2b PARADIGM trial. As over 50% of the patients have been enrolled, we expect to release topline results in the second half of 2023," stated NeuroSense's CEO, Alon Ben-Noon. "We obtained positive results in a biomarker study in Alzheimer's disease and plan to commence a Phase 2 trial for this indication during the first half of this year. The complexity of neurological diseases, including ALS and Alzheimer's, may be more effectively treated with combination therapies, which operate through multiple mechanisms of action. We are targeting multiple value-driving milestones in 2023."

Business Update

- **Phase 2b ALS Trial: Enrollment ongoing in Italy & Israel, and approved to commence in Canada**

  NeuroSense achieved several milestones during Q4 in the clinical development of PrimeC, its lead drug candidate currently being evaluated in PARADIGM, a double-blind, randomized, placebo-controlled, multi-national Phase 2b clinical trial. Over 50% of the patients have been enrolled. At the beginning of 2023, the first patient was enrolled in Italy. Health Canada approved the trial to commence enrollment in Canada, with patients dosing expected to commence in the beginning of Q2 2023.

  NeuroSense withdrew its protocol from its U.S. Food and Drug Administration (FDA) Investigational New Drug (IND) in order to align its clinical strategy with the FDA for its planned pivotal Phase 3 trial and New Drug Application (NDA) submission based on the results of the PARADIGM study and results of additional studies we intend to conduct in the interim. The FDA had requested additional non-clinical data from NeuroSense to support the duration of the PARADIGM trial, as PrimeC is intended for long-term administration in the treatment of ALS. In the interest of treating and completing dosing of people living with ALS in an expedient and safe manner through PARADIGM, NeuroSense has focused its North American recruitment in Canada. The Company plans to open clinical sites in the U.S. in an anticipated Phase 3 pivotal study to address the unmet need of the U.S. ALS community. NeuroSense is on track to complete patient enrollment in H1 2023 and report topline results in H2 2023.

- **Positive Final Results from Alzheimer's Biomarker Study: Phase 2 Trial to Commence H1 2023**

  Shortly after the end of Q4, NeuroSense reported final results from a biomarker study conducted to evaluate the potential of its combination platform therapy for the treatment of Alzheimer's disease (AD). Preliminary results from the study showed that TDP-43, a novel biomarker, was elevated in AD patients compared to a healthy control group. Based on encouraging preliminary results, NeuroSense expanded the study, utilizing a larger healthy control group for further validation. Based on the final results of this biomarker study and the fact that NeuroSense's platform combination therapy has already shown a statistically significant reduction of TDP-43 in a Phase 2a clinical trial in ALS, the Company plans to commence a Phase 2 AD clinical study in H1 2023.

- **Parkinson's disease (PD) biomarker study: results expected in Q2 2023**

  NeuroSense is currently conducting a biomarker study, testing blood samples of PD patients vs control and exploring the difference in several key disease markers as well as markers that are related to NeuroSense's combination therapy platform. Results are expected to be announced in early Q2 2023.

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

NeuroSense and QuantalX announced, in January, a first-of-its-kind collaboration to improve early diagnosis and treatment of neurodegenerative diseases. QuantalX's breakthrough direct electrophysiology imaging technology (Delphi-MD) is expected to provide multiple clinically objective and accurate measurements of PrimeC's effects on patients' brain function in a planned Phase 3 ALS pivotal trial. Delphi-MD will be one of several measures used to measure PrimeC's efficacy in ALS. Delphi-MD will also be used in NeuroSense's upcoming Phase 2 clinical study in Alzheimer's disease.

- **Key Industry Conferences and Publications**

NeuroSense presented at and participated in several industry conferences during the 4th quarter including:
- 2 poster presentations on PrimeC, PARADIGM, and biomarker research at the 21st Annual NEALS Meeting
- Poster presentation on PrimeC in the treatment of ALS at Neuroscience 2022
- Poster presentation on NeuroSense's current development, clinical, and research plans at the 33rd International Symposium on ALS/MND
- Meetings with prospective partners and interested parties at BIO-Europe

NeuroSense led the Nasdaq Opening Bell Ceremony on October 13, 2022 and hosted the ALS Combination Therapy Summit in New York City, covering 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. Several ALS key opinion leaders participated in the conference.

Financial Summary

- **Research and development expenses** for the years ended December 31, 2022 and 2021 were $6,416 thousand and $3,082 thousand, respectively. The increase of $3,334 thousand, or 108% was mainly attributed to (i) an increase of $765 thousand in salaries and social benefits, mainly due to an increase in the number of employees, (ii) an increase of $2,984 thousand in subcontractor and consulting expenses relating to clinical programs and (iii) a decrease of $377 thousand in share-based compensation expenses to our employees and service providers.
- **General and administrative expenses** for the years ended December 31, 2022 and 2021 were $7,136 thousand and $2,505 thousand, respectively. The increase of $4,631 thousand, or 185% was primarily attributable to (i) a $1,664 thousand increase in share-based compensation expenses due to grants of additional options and RSUs to our employees, directors and service providers, (ii) an increase of $1,106 thousands in insurance costs as a public company, (iii) an increase of $763 thousand in salaries and social benefits, mainly due to additional compensation paid to our executive officers upon our IPO and an increase in the number of employees and (iv) a $713 thousand increase in professional services expenses.
- **Operating expenses** for the years ended December 31, 2022 and 2021 were $13,552 thousands, and $5,587 thousands, respectively. The increase of $7,965 thousands, was due to the reasons described above.

As of December 31, 2022, NeuroSense had cash and short-term deposits of $7.1 million.

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

About NeuroSense Therapeutics

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.

About Alzheimer's Disease

Alzheimer's disease (AD) is the most common form of progressive dementia, affecting 5-10% of the population over 65 years of age, with prevalence estimates increasing exponentially with age (Singh and Fudenberg 1988). Clinically, it is characterized by a progressive deterioration of cognition, predominantly affecting episodic memory, (Chouraki and Seshadri 2014). The global AD treatment market is expected to grow to $5 billion in 2022.

About ALS
Amyotrophic lateral sclerosis (ALS) is an incurable neurodegenerative disease that causes complete paralysis and death within 2-5 years from diagnosis. Every year, more than 5,000 patients are diagnosed with ALS in the

U.S. alone, with an annual disease burden of $1 billion. The number of patients with ALS is expected to grow 24% by 2040 in the U.S. and EU.

About PrimeC

PrimeC, NeuroSense's lead drug candidate, is a novel extended-release oral formulation composed of a unique fixed-dose combination of two FDA-approved drugs: ciprofloxacin and celecoxib. PrimeC is designed to synergistically target several key mechanisms of amyotrophic lateral sclerosis (ALS) that contribute to motor neuron degeneration, inflammation, iron accumulation and impaired RNA regulation to potentially inhibit the progression of ALS. NeuroSense completed a Phase 2a clinical study which successfully met its safety and efficacy endpoints including reducing functional and respiratory deterioration and statistically significant changes in ALS-related biological markers indicating PrimeC's biological activity. PrimeC was granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

About Delphi-MD

The Delphi-MD medical device provides definitive and quantitative, real-time brain function analysis through a first-in-class direct brain network visualization technology. The device magnetically stimulates healthy or symptomatic patients' brain networks in a simple point of care affordable test, to enable early detection and differential diagnosis of brain abnormalities.

About QuantalX

QuantalX Neuroscience, Ltd. is dedicated to tackling current brain health challenges leading to late diagnosis and misdiagnosis of neurodegenerative diseases. Delphi-MD's breakthrough technology supports clinicians' neurodiagnostic gaps at the point of care through real-time monitoring of brain functionality; resulting in improved patient care and reduction of associated financial burden. For more information visit https://quantalx.com/ and follow QuantalX on LinkedIn.

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 Alzheimer's 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, including future phase 3, timing for reporting data; 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 QuantalX's Delphi-MD will not successfully provide clinically objective and accurate measurements of NeuroSense's AD Phase 2 clinical trial, there will a delay in the timing of commencement of the Company's AD Phase 2 clinical trial and the delay of report of topline results of the Phase 2b PARADIGM trial, 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.

For additional information, we invite you to visit our website and follow us on LinkedIn and Twitter.

NeuroSense Therapeutics Ltd.
Consolidated Statements of Financial Position
(U.S. dollars in thousands)

		As of December 31,	
	Note	2022	2021

Assets			
Current assets:			
Cash and cash equivalent	4	$ 3,543	$ 11,063
Short term deposits	16	3,547	—
Other receivables	5	255	310
Restricted deposits		36	39
Total current assets		7,381	11,412
Non-current assets:			
Property, plant and equipment, net	6	77	19
Right of use assets	7	229	—
Non-current restricted deposit		23	—
Total non-current assets		329	19
Total assets		$ 7,710	$ 11,431
Liabilities shareholders' and equity			
Current liabilities:			
Trade payables		$ 498	$ 39
Other payables	8	1,228	558
Total current liabilities		1,726	597
Non Current liabilities:			
Long term lease liability		147	—
Liability in respect of warrants	16	218	1,828
		365	1,828
Total liabilities		2,091	2,425
Shareholders' equity:	9,10		
Ordinary shares		—	—
Share premium and capital reserve		26,405	17,452
Accumulated deficit		(20,786)	(8,446)
Total shareholders' equity		5,619	9,006
Total liabilities and shareholders' equity		$ 7,710	$ 11,431

NeuroSense Therapeutics Ltd.
Consolidated Statements of Income and Comprehensive Loss
(U.S. dollars in thousands, except share and per share data)

		For the year ended December 31		
	Note	**2022**	**2021**	**2020**
Research and development expenses	11	$ (6,416)	$ (3,082)	$ (2,495)
General and administrative expenses	12	(7,136)	(2,505)	(393)
Operating loss		(13,552)	(5,587)	(2,888)
Financing expenses	13	(45)	(1,186)	(1)
Financing income	13	1,257	2,732	61
Total financing income, net		1,212	1,546	60
Net loss and comprehensive loss		$ (12,340)	$ (4,041)	$ (2,828)

Basic and diluted net loss per share	15	$ (1.07)	$ (0.65)	$ (0.51)

NeuroSense Therapeutics Ltd.
Consolidated Statements of Changes in Equity
(U.S. dollars in thousands)

	Ordinary Shares	Share Premium and Capital Reserve	Accumulated Deficit	Total Equity
Balance as of January 1, 2020	$ —	$ 2,495	$ (1,577)	$ 918
Share based compensation	—	2,061	—	2,061
Net loss and comprehensive loss	—		(2,828)	(2,828)
Issuance of ordinary shares and warrants, net	—	508	—	508
Balance as of December 31, 2020	$ —	$ 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
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 of December 31, 2022	$ —	$ 26,405	$ (20,786)	$ 5,619

SOURCE NeuroSense

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

Additional assets available online: Photos (1)

https://neurosense.investorroom.com/2023-03-22-NeuroSense-Announces-Year-End-2022-Financial-Results-and-Provides-Business-Update