Neuronetics Reports Second Quarter 2022 Financial and Operating Results

August 2, 2022

MALVERN, Pa., Aug. 02, 2022 (GLOBE NEWSWIRE) -- Neuronetics, Inc. (NASDAQ: STIM), a commercial stage medical technology company with a strategic vision of transforming the lives of patients whenever and wherever they need help with the best neurohealth therapies in the world, today announced its financial and operating results for the second quarter of 2022.

Second Quarter 2022 Highlights

- *Exceeded guidance – Second quarter 2022 revenue of $16.3 million, exceeded previously issued guidance of $15.0 million to $16.0 million*
- *Increased NeuroStar System revenue 70% over the second quarter of 2021*
- *Revenue from 59 NeuroStar Systems during the second quarter, an increase of 64% over the second quarter of 2021*
- *Second quarter 2022 system revenue increased 20% sequentially as compared to first quarter 2022*

Recent Operational Highlights

- *Received FDA 510(k) clearance for obsessive-compulsive disorder (OCD)*
- *Received FDA 510(k) clearance for the treatment of anxiety symptoms in patients who suffer from major depressive disorder (MDD), also known as anxious depression*
- *Positive TMS coverage policies to expand patient access to our NeuroStar Advanced Therapy system for both MDD and OCD*
- *Entered into long-term exclusive commercial partnership agreement with Alleviant Health Centers*

Recent Marketing Highlights

- *Achieved over 134,300 global patients treated with more than 4.8 million of our Treatment Sessions and over 5,360 new patient starts in the quarter, a Company record*
- *Data published in Brain Stimulation Journal highlighted breakthrough treatment protocol insights attained from Neuronetics' industry leading TrakStar clinical outcomes database*

"I am very pleased with our performance throughout the second quarter and first half of the year. We successfully worked through macro challenges and have continued to execute, highlighted by very strong capital system sales volumes and improving utilization along with achieving multiple significant milestones, including the FDA approval for OCD and anxious depression, receiving multiple favorable reimbursement decisions, and expanding the number of exclusive commercial partnerships with national accounts," said Keith J. Sullivan, President and Chief Executive Officer of Neuronetics. "For the remainder of the year, we will look to leverage the momentum we have built to continue to accelerate our growth and help more patients suffering from mental health disorders get the relief that deserve."

Second Quarter 2022 Financial and Operating Results for the Three Months Ended June 30, 2022

Revenues by Geography
Three Months Ended June 30,

	2022 Amount	2021 Amount	% Change
	(in thousands, except percentages)		
United States	$ 16,132	$ 13,809	17 %
International	197	394	(50) %
Total revenues	$ 16,329	$ 14,203	15 %

Total revenue for the three months ended June 30, 2022, was $16.3 million, an increase of 15% compared to the three months ended June 30, 2021 revenue of $14.2 million. During the quarter, total U.S. revenue increased by 17% and international revenue decreased by 50% over the prior year quarter. The U.S. revenue growth was primarily driven by an increase in NeuroStar Advanced Therapy System sales and the decline in international revenue was primarily driven by a decrease in international NeuroStar Advanced Therapy Systems sales.

U.S. Revenues by Product Category
Three Months Ended June 30,

2022 Amount	2021 Amount	% Change

	(in thousands, except percentages)		
NeuroStar Advanced Therapy System	$ 4,382	$ 2,577	70 %
Treatment sessions	11,295	10,801	5 %
Other	455	431	6 %
Total U.S. revenues	$ 16,132	$ 13,809	17 %

U.S. NeuroStar Advanced Therapy System revenue for the three months ended June 30, 2022, was $4.4 million, an increase of 70% compared to the three months ended June 30, 2021, revenue of $2.6 million. For the three months ended June 30, 2022 and 2021, the Company sold 58 and 36 systems, respectively, that were recognized as NeuroStar capital revenue during each period. Additionally, for the three months ended June 30, 2022, the Company executed 1 operating lease agreement that contributed to operating lease revenue.

U.S. treatment session revenue for the three months ended June 30, 2022, was $11.3 million, an increase of 5% compared to the three months ended June 30, 2021, revenue of $10.8 million. The revenue growth was primarily driven by an increase in the number of accounts utilizing our PHQ-10 tool. As a result, our treatment session volume in our local per click accounts, those utilizing our PHQ-10 tool, increased 15% compared to the second quarter of 2021.

In the second quarter of 2022, U.S. treatment session revenue per active site was $11,280 as compared to $12,001 during the second quarter of 2021 as a result of an increase in the number of new accounts installing systems in the second quarter of 2022.

Gross margin for the second quarter of 2022 was 75.3%, a decrease of approximately 530 basis points from the second quarter of 2021 gross margin of 80.6%. The decrease was primarily a result of a change in product mix compared to the second quarter of 2021.

Operating expenses during the second quarter of 2022 were $22.1 million, an increase of $4.1 million, or 23%, compared to $18.0 million in the second quarter of 2021. The increase was primarily driven by the implementation of new marketing initiatives and personnel costs related to our sales force compared to the prior year quarter.

Net loss for the second quarter of 2022 was $(10.4) million, or $(0.39) per share, as compared to the second quarter 2021 net loss of $(7.5) million, or $(0.29) per share. Net loss per share was based on 26,786,778 and 25,902,591 weighted-average common shares outstanding for the second quarters of 2022 and 2021, respectively.

EBITDA for the second quarter of 2022 was $(9.1) million as compared to the second quarter of 2021 EBITDA of $(6.3) million. See the accompanying financial table that reconciles EBITDA, which is a non-GAAP financial measure, to net loss.

Cash and cash equivalents were $70.9 million as of June 30, 2022. This compares to cash and cash equivalents of $94.1 million as of December 31, 2021, and $115.8 million as of June 30, 2021.

510(k) Clearance for Treatment of Adult OCD and Anxious Depression

OCD

In May of 2022, the U.S. Food and Drug Administration (FDA) granted clearance for NeuroStar as an adjunct treatment for adult patients suffering from OCD. NeuroStar has initiated a limited, exclusive launch at centers across the United States and expects to begin training the broader installed base in the fourth quarter of 2022. Importantly, this new indication can be remotely activated on the customer's existing NeuroStar hardware enabling NeuroStar to treat even more patients suffering from debilitating mental health disorders. In the United States, over 4 million adults suffer from OCD and approximately half of those patients have serious impairment.

Anxious Depression

NeuroStar has successfully leveraged real-world data from its proprietary database of patient outcomes, TrakStar, to gain clearance for a new indication with the FDA. In July of 2022, the FDA granted a new indication for NeuroStar to treat anxiety symptoms in adults with major depressive disorder (MDD), also known as anxious depression. Our submission utilized data collected from 644 patients treated at 75 centers across the country and showed that 65.5% of patients achieved a clinically meaningful reduction in their anxiety symptoms. This new indication is immediately available to physicians to treat their patients. It does not require new hardware and is reimbursed with current CPT codes under current coverage policies. MDD is a common and serious psychiatric diagnosis among adults with an estimated prevalence of 13.9 million patients under treatment in the United States. Anxiety symptoms are a common co-morbidity in patients with MDD, commonly called anxious depression, with an estimated prevalence of more than 50% of MDD patients, and patients with anxious depression are generally regarded as harder to treat with currently available pharmaceutical options.

Long Term Commercial Partnerships

Alleviant Health Centers

In June of 2022, the Company initiated a commercial partnership with Alleviant Health Centers, an Arkansas-based network of full-service mental health clinics. Under the agreement, Neuronetics will be the exclusive supplier of new TMS equipment to Alleviant and its affiliates. Alleviant had been using a different TMS device prior to our partnership but with plans to expand their footprint across multiple states, they chose NeuroStar because our ongoing support, training and marketing initiatives will be integral to their growth and continued success.

Positive TMS Coverage Policies

In July of 2022, the Company announced a series of healthcare policy updates that increase patient access to NeuroStar Advanced Therapy for TMS. First Coast and Novitas Medicare Administrative Contractors (MACs) have proposed policy updates to local coverage determination (LCD) that would reduce the number of prior medication failures for TMS eligibility from four down to one for people suffering from major depressive disorder (MDD). An additional proposed change would remove the requirement for a previous psychotherapy trial. First Coast coverage area includes two million Medicare beneficiaries, more than 74,000 physicians and 247 hospitals that serve Medicare patients in FL, PR and USVI. Novitas coverage includes over eight million covered lives in CO, NM, TX, OK, AR, LA, MS, PA, NJ, MD, DE, and DC.

Additional positive coverage policies applicable to TMS were recently issued by Highmark BCBS, publishing coverage for obsessive-compulsive disorder (OCD), affecting 6.8 million members in DE, NY, PA, & WV; Select Health, publishing their first TMS policy for MDD, impacting 981,000 members in UT, ID & NV; and Pacific Source removing the MDD pre-authorization requirement for their Medicare Advantage plan members in OR, MT, ID & WA.

Business Outlook

For the full year 2022, the Company now expects total worldwide revenue to be between $60.0 million and $62.0 million.

For the full year 2022, the Company now expects total operating expenses to be between $86.0 million and $88.0 million.

For the third quarter of 2022, the Company expects to report total worldwide revenue of between $14.5 million and $15.5 million.

Webcast and Conference Call Information

Neuronetics' management team will host a conference call on August 2, 2022, beginning at 8:30 a.m. Eastern Time.

To listen to the conference call on your telephone, participants may register for the call via this link **https://register.vevent.com/register/BI4b00043a886241ebb671ea828194825d**. To access the live audio webcast or subsequent archived recording, visit the Investor Relations section of Neuronetics' website at ir.neuronetics.com. The replay will be available on the Company's website.

About Neuronetics

Neuronetics, Inc. believes that mental health is as important as physical health. As a global leader in neuroscience and the largest transcranial magnetic stimulation ("TMS") company in the industry, Neuronetics is redefining patient and physician expectations by designing and developing products that improve the quality of life for people suffering from neurohealth conditions. An FDA-cleared, non-drug, noninvasive treatment for people with depression, Neuronetics' NeuroStar® Advanced Therapy system is the leading TMS treatment for major depressive disorder ("MDD") in adults with over 4.8 million treatments delivered. NeuroStar is widely researched and backed by the largest clinical data set of any TMS system for depression, including the world's largest depression Outcomes Registry. Our NeuroStar® Advanced Therapy system is also FDA-cleared to treat people suffering from obsessive-compulsive disorder, as well as for the treatment of comorbid anxiety symptoms ("anxious depression") for adults with MDD suffering from anxiety symptoms. Neuronetics is committed to transforming lives by offering an exceptional treatment option that aims to produce extraordinary results. For safety information and indications for use, visit NeuroStar.com.

"Safe harbor" statement under the Private Securities Litigation Reform Act of 1995:

Statements in the press release regarding Neuronetics, Inc. (the "Company") that are not historical facts constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements may be identified by terms such as "outlook," "potential," "believe," "expect," "plan," "anticipate," "predict," "may," "will," "could," "would" and "should" as well as the negative of these terms and similar expressions. These statements include those relating to the Company's business outlook and current expectations for upcoming quarter and fiscal year 2022, including with respect to revenue, operating expense, growth, and any statements of assumptions underlying any of the foregoing items. These statements are subject to significant risks and uncertainties and actual results could differ materially from those projected. The Company cautions investors not to place undue reliance on the forward-looking statements contained in this release. These risks and uncertainties include, without limitation, risks and uncertainties related to: the impact of COVID 19 on the Company's operational and budget plans as well as general political and economic conditions, including as a result of efforts by governmental authorities to mitigate COVID 19, such as travel restrictions and third-party business closures and the related impact on resource allocations, manufacturing and supply chains and patient access to commercial products; the Company's ability to execute its business continuity; the Company's ability to achieve or sustain profitable operations due to its history of losses; the Company's reliance on the sale and usage of its NeuroStar Advanced Therapy for Mental Health System to generate revenues; the scale and efficacy of the Company's salesforce as well as the Company's ability to retain talent; availability of coverage and reimbursement from third-party payors for treatments using the Company's products; physician and patient demand for treatments using the Company's products; developments in respect of competing technologies and therapies for the indications that the Company's products treat; product defects; the Company's ability to obtain and maintain intellectual property protection for its technology; developments in clinical trials or regulatory review of NeuroStar Advanced Therapy for Mental Health System for additional indications; and developments in regulation in the United States and other applicable jurisdictions. For a discussion of these and other related risks, please refer to the Company's recent SEC filings which are available on the SEC's website at www.sec.gov. These forward-looking statements are based on the Company's expectations and assumptions as of the date of this press release. Except as required by law, the Company undertakes no duty or obligation to update any forward-looking statements contained in this press release as a result of new information, future events, or changes in the Company's expectations.

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NEURONETICS, INC.
Statements of Operations
(In thousands, except per share data)

	Three Months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Revenues	$ 16,329	$ 14,203	$ 30,510	$ 26,491
Cost of revenues	4,039	2,750	7,524	4,971
Gross Profit	12,290	11,453	22,986	21,520
Operating expenses:				
Sales and marketing	13,685	9,042	26,334	17,604
General and administrative	6,356	6,681	12,734	12,785
Research and development	2,045	2,294	3,849	4,604
Total operating expenses	22,086	18,017	42,917	34,993
Loss from Operations	(9,796)	(6,564)	(19,931)	(13,473)
Other (income) expense:				
Interest expense	1,000	977	1,978	1,962
Other income, net	(374)	(16)	(649)	(29)
Net Loss	$ (10,422)	$ (7,525)	$ (21,260)	$ (15,406)
Net loss per share of common stock outstanding, basic and diluted	$ (0.39)	$ (0.29)	$ (0.80)	$ (0.63)
Weighted-average common shares outstanding, basic and diluted	26,787	25,903	26,692	24,608

NEURONETICS, INC.
Balance Sheets
(In thousands, except per share data)

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 70,931	$ 94,141
Accounts receivable, net	11,391	7,706
Inventory	7,185	6,563
Current portion of net investments in sales-type leases	2,096	2,198
Current portion of prepaid commission expense	1,768	1,559
Current portion of note receivables	95	74
Prepaid expenses and other current assets	1,618	3,090
Total current assets	95,084	115,331
Property and equipment, net	2,067	1,220
Operating lease right-of-use assets	3,614	3,884
Net investments in sales-type leases	1,682	1,697
Prepaid commission expense	7,163	6,763
Long-term note receivable	10,089	10,110
Other assets	3,254	2,218
Total Assets	$ 122,953	$ 141,223
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,350	$ 4,299
Accrued expenses	9,684	8,233
Deferred revenue	1,748	2,501
Current portion of operating lease liabilities	780	670
Current portion of long-term debt, net	4,375	—
Total current liabilities	18,937	15,703
Long-term debt, net	31,210	35,335
Deferred revenue	1,129	1,471
Operating lease liabilities	3,255	3,539
Total Liabilities	54,531	56,048
Commitments and contingencies (Note 17)	—	—
Stockholders' Equity:		
Preferred stock, $0.01 par value: 10,000 shares authorized; no shares issued or outstanding on June 30, 2022, and December 31, 2021	—	—
Common stock, $0.01 par value: 200,000 shares authorized; 26,856 and 26,395		

shares issued and outstanding on June 30, 2022, and December 31, 2021, respectively	268	264
Additional paid-in capital	398,147	393,644
Accumulated deficit	(329,993)	(308,733)
Total Stockholders' Equity	68,422	85,175
Total Liabilities and Stockholders' Equity	$ 122,953	$ 141,223

NEURONETICS, INC.
Statements of Cash Flows
(In thousands)

	Six months ended June 30,	
	2022	**2021**
Cash Flows from Operating Activities:		
Net loss	$ (21,260)	$ (15,406)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	657	552
Share-based compensation	4,455	4,205
Non-cash interest expense	340	324
Cost of rental units purchased by customers	92	137
Changes in certain assets and liabilities:		
Accounts receivable, net	(3,685)	(1,835)
Inventory	(840)	(1,673)
Net investment in sales-type leases	102	330
Prepaid commission expense	(610)	(278)
Prepaid expenses and other assets	1,517	1,120
Accounts payable	(2,256)	(1,365)
Accrued expenses	1,451	(715)
Deferred revenue	(1,095)	(336)
Net Cash Used in Operating Activities	(21,132)	(14,940)
Cash Flows from Investing Activities:		
Purchases of property and equipment and capitalized software	(2,040)	(1,108)
Net Cash Used in Investing Activities	(2,040)	(1,108)
Cash Flows from Financing Activities:		
Payments of debt issuance costs	(90)	—
Proceeds from exercises of stock options	52	2,303
Proceeds from common stock offering	—	80,972
Payments of common stock offering issuance costs	—	(401)
Net Cash (Used) Provided by Financing Activities	(38)	82,874
Net (Decrease) Increase in Cash and Cash Equivalents	(23,210)	66,826
Cash and Cash Equivalents, Beginning of Period	94,141	48,957
Cash and Cash Equivalents, End of Period	$ 70,931	$ 115,783

Non-GAAP Financial Measures (Unaudited)

EBITDA is not a measure of financial performance under generally accepted accounting principles in the United States, or GAAP, and should not be construed as a substitute for, or superior to, GAAP net loss. However, management uses both the GAAP and non-GAAP financial measures internally to evaluate and manage the Company's operations and to better understand its business. Further, management believes the addition of the non-GAAP financial measure provides meaningful supplementary information to, and facilitates analysis by, investors in evaluating the Company's financial performance, results of operations and trends. The Company's calculation of EBITDA may not be comparable to similarly designated measures reported by other companies, because companies and investors may differ as to what type of events warrant adjustment.

The following table reconciles reported net loss to EBITDA:

	Three Months ended June 30,		Six months ended June 30,	
	2022	**2021**	**2022**	**2021**
	(in thousands)		**(in thousands)**	
Net loss	$ (10,422)	$ (7,525)	$ (21,260)	$ (15,406)

Interest expense	1,000	977	1,978	1,962
Income taxes	—	—	—	—
Depreciation and amortization	338	271	657	552
EBITDA	$ (9,084)	$ (6,277)	$ (18,625)	$ (12,892)

Source: Neuronetics