

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) **January 28, 2021**

NEURONETICS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38546
(Commission
File Number)

33-1051425
(I.R.S. Employer
Identification No.)

3222 Phoenixville Pike, Malvern, PA
(Address of principal executive offices)

19355
(Zip Code)

Registrant's telephone number, including area code (610) 640-4202

(Former name or former address, if changed since last report.) Not applicable.

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol (s)	Name on each exchange on which registered
Common Stock (\$0.01 par value)	STIM	The Nasdaq Global Market

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01 Regulation FD Disclosure.

Neuronetics, Inc. (the “Company”) has provided the following business overview updates:

We are a commercial stage medical technology company focused on designing, developing and marketing products that improve the quality of life for patients who suffer from psychiatric disorders. Our first commercial product, the NeuroStar® Advanced Therapy System, is a non-invasive and non-systemic office-based treatment that uses transcranial magnetic stimulation, or TMS, to create a pulsed, MRI-strength magnetic field that induces electrical currents designed to stimulate specific areas of the brain associated with mood. The system is cleared by the United States Food and Drug Administration, or FDA, to treat adult patients with major depressive disorder, or MDD, that have failed to achieve satisfactory improvement from prior antidepressant medication in the current MDD episode. NeuroStar Advanced Therapy is also available in other parts of the world, including Japan, where it is listed under Japan’s national health insurance. NeuroStar Advanced Therapy is safe, clinically effective, reproducible and precise and we believe is supported by the largest clinical data set of any competing TMS system. We are a market leader in TMS therapy based on our U.S. installed base of 1,143 active NeuroStar Advanced Therapy Systems in approximately 909 psychiatrist offices as of September 30, 2020 and the estimated 94,609 patients treated with approximately 3.4 million of our treatment sessions through such date. We recently added twenty-two new field sales personnel. These individuals have considerable experience in capital sales, though the majority of their experience is outside the mental health field. We are currently training these sales personnel with the expectation that they will be fully productive by the second quarter of 2021; however, our ability to achieve full productivity may be delayed as our sales force develops experience in our field. We generated revenues of \$12.4 million and \$33.7 million for the three and nine months ended September 30, 2020.

Item 8.01 Other Events.

The Company is making available the attached presentation (the “Investor Presentation”) which contains information that the company may use, in whole or in part, in connection with presentations to certain investors.

Cautionary Statement Regarding Forward-Looking Statements

The Investor Presentation includes statements that may be forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The words “believe,” “estimate,” “expect,” “anticipate,” “project,” “forecast” and similar expressions, or the negative thereof, among others, generally identify forward-looking statements. Forward-looking statements used in the Investor Presentation include statements regarding revenue guidance; future revenue and revenue growth; liquidity to fund growth; new product launches and market

opportunity, market share and market share growth; future gross margin. Neuronetics cautions that these forward-looking statements are based on management's current expectations, estimates, forecasts and projections about Neuronetics, and assumptions management believes are reasonable, and are subject to risks and uncertainties that may cause actual results to differ materially from those indicated in the forward-looking statements. Such risks and uncertainties include, but are not limited to, surgeons' willingness to use the Company's existing and newly launched products; the Company's ability to continue to invest in medical education and training, product development, and/or sales and marketing initiatives at levels sufficient to drive future revenue growth; the Company's ability to attract new, high-quality distributors and potential disruption to the Company's existing distribution network; continued pricing pressure, as well as exclusion from major healthcare systems; the risk of supply shortages and the associated, potentially long-term disruption to product sales; unexpected expense and delay; changes to laws and regulations applicable to the Company and the industry in which it competes; and general economic and business conditions in the markets in which the Company does business, both in the U.S. and abroad. Additional information about the factors that may affect the operations of Neuronetics and results is set forth in Neuronetics' annual and quarterly reports filed with the U.S. Securities and Exchange Commission. Forward-looking statements contained in the Investor Presentation are made only as of the first day of the month and year set forth on the cover hereof and Neuronetics undertakes no obligation to release publicly any revisions or updates to forward-looking statements as a result of subsequent events or developments, except as required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Investor Presentation dated January 27, 2021.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

NEURONETICS, INC.

(Registrant)

Date: January 28, 2021

By: /s/ Stephen Furlong

Name: Stephen Furlong

Title: VP, Finance and Chief Financial Officer

(Principal Financial and Accounting Officer)



Neuronetics, Inc.

NASDAQ: STIM

Company Presentation

January 2021



Disclaimers

This presentation has been prepared solely for use at this meeting. The material is given in conjunction with an oral presentation and should not be taken out of context. Unless the context requires otherwise, references to "Neuronetics" "the company," "we," "us" and "our," refer to Neuronetics, Inc.

This presentation includes statements that may be forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The words "believe," "estimate," "expect," "anticipate," "project," "forecast" and similar expressions, or the negative thereof, among others, generally identify forward-looking statements. Forward-looking statements used in this presentation include statements regarding revenue guidance; future revenue and revenue growth; liquidity to fund growth; new product launches and market opportunity, market share and market share growth; future gross margin. Neuronetics cautions that these forward-looking statements are based on management's current expectations, estimates, forecasts and projections about Neuronetics, and assumptions management believes are reasonable, and are subject to risks and uncertainties that may cause actual results to differ materially from those indicated in the forward-looking statements. Such risks and uncertainties include, but are not limited to, surgeons' willingness to use the Company's existing and newly launched products; the Company's ability to continue to invest in medical education and training, product development, and/or sales and marketing initiatives at levels sufficient to drive future revenue growth; the Company's ability to attract new, high-quality distributors and potential disruption to the Company's existing distribution network; continued pricing pressure, as well as exclusion from major healthcare systems; the risk of supply shortages and the associated, potentially long-term disruption to product sales; unexpected expense and delay; changes to laws and regulations applicable to the Company and the industry in which it competes; and general economic and business conditions in the markets in which the Company does business, both in the U.S. and abroad. Additional information about the factors that may affect the operations of Neuronetics and results is set forth in Neuronetics' annual and quarterly reports filed with the U.S. Securities and Exchange Commission. Forward-looking statements contained in this presentation are made only as of the first day of the month and year set forth on the cover hereof and Neuronetics undertakes no obligation to release publicly any revisions or updates to forward-looking statements as a result of subsequent events or developments, except as required by law.



Presenters



Keith Sullivan

President & CEO

30 years of experience:



Steve Furlong

Vice President &
Chief Financial Officer

33 years of experience:



Neuronetics Snapshot

- **NeuroStar Advanced Therapy** — Transcranial Magnetic Stimulation (TMS)
 - Focused on psychiatric indications
 - Current Indication: Major Depressive Disorder (MDD) in adults failed to receive satisfactory improvement from prior antidepressant medication in the current episode
 - Safe, effective and non-invasive office-based treatment
 - FDA cleared 2008
 - CE mark (2012) and approved in Japan in September 2017. Reimbursement in Japan acquired in June 2019



Investment Highlights



- Clinically Relevant Outcomes for Patients with MDD
- Significant Clinical Study Compendium
- Large Direct Sales and Customer Support Team — Difficult to Replicate
- Broad US Reimbursement
- Favorable Psychiatrist Economics
- \$9.6B Targeted Annual TAM Among Psychiatrist Practices
- Potential New Indication Opportunities and Geographic Expansion for Growth
- Financial Profile:** FY 2019 Revenue \$62.7M 2019 year over year growth of 19% versus 2018. Q3 2020 Revenue \$12.4M versus \$16.0M in 2019. Q3 2020 Ending Cash Balance, \$50.7M.



Major Depressive Disorder



Disease Overview

- Characterized by depressed mood or loss of interest in pleasure for at least two weeks
- Periods of remission and relapse over a lifetime
- 300 million people worldwide living with depression
 - 13 million adults with MDD in the US
 - 3.0% global incidence rate

Disease Burden

- Economic burden in US estimated to be \$210 billion in 2010

Medical Management

- First line treatment is antidepressants with or without psychotherapy
 - Care by PCP, followed by referral to psychiatrist after failed treatment attempt



Transcranial Magnetic Stimulation

- TMS uses pulsed, MRI-strength magnetic field
- Induces electrical currents to stimulate specific areas of brain associated with mood
- Stimulation triggers a cascading electro-chemical effect
- Changes connections in brain structures to improve neuronal circuit activity and mood

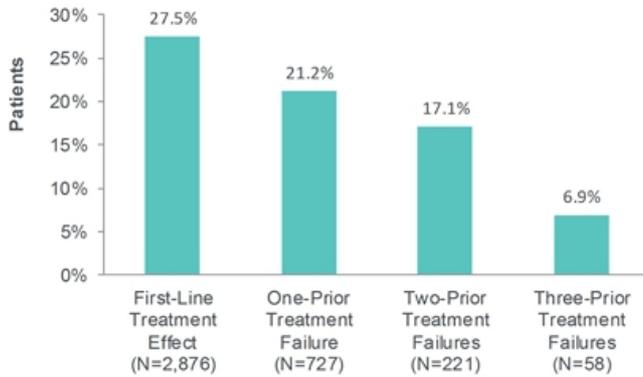


Effectiveness of TMS therapy depends on precise and targeted stimulation that is consistent and repeatable over treatment sessions

Limitations of Antidepressant Medications

Limited Effectiveness

STAR*D Study¹
Achieving Remission (HAMD 17)



- Approximately 28% and 21% of patients achieved remission in their first and second medication attempts, respectively
- Likelihood of remission was limited and declined with each new medication attempt

Treatment-Emergent Side Effects

STAR*D Study¹
Discontinuation Due to Side Effects

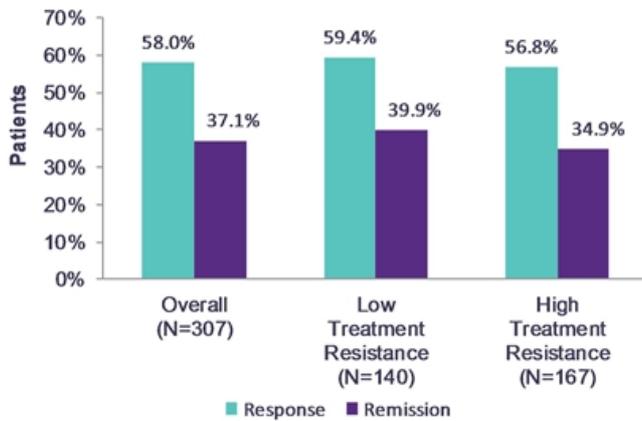


- Likelihood of discontinuing treatment increased with each new medication attempt
- In the fourth treatment attempt, likelihood of dropping out of treatment had more than quadrupled
- Adverse events discontinuation rate in monotherapy 9% to 41%

Clinically Proven Solution

Acute Phase in Real-World Clinical Settings Study¹

CGI-S Outcomes



- 1 in 2 patients respond
- 1 in 3 patients achieve remission

Long-term Durability in Real-World Clinical Settings Study²

CGI-S Outcomes



- Long-term durability has been demonstrated with response and remission rates among users

Outcomes Registry

- World's largest registry of treatment resistant depression with over 10,000 enrolled patients, of those >5,800 evaluable patients, across >100 treatment facilities
- Remission rate of 33% and response rate of 62% for over 5,800 self-evaluating patients
- Remission rate of 52% and response rate of 73% for 1,900+ patients evaluated by clinician rating scale



Clinically Proven Solution

Two Randomized Controlled Trials

- Sponsored largest RCT, sham-controlled TMS trial ever conducted
 - Enrolled 325 adult patients with treatment resistant MDD
 - **Primary Efficacy Endpoint:** MADRS at 4 weeks (P=0.057); not achieved but clinically meaningful improvement demonstrated
 - **Secondary Efficacy Endpoints Included:** HAMD 17 at 4 and 6 weeks (P=0.006 and P=0.005, respectively); HAMD 24 at 4 and 6 weeks (P=0.012 and P=0.015, respectively)
 - Basis of initial 510(k) clearance in 2008 — failed one prior antidepressant medication¹
 - All patients who failed one prior research-grade Rx (N=164; MADRS, P=0.0006)
- Second, industry-independent RCT, sham-controlled trial funded by the NIMH
 - Enrolled 199 adult patients with treatment resistant MDD
 - **Primary Efficacy Endpoint:** Remission measured using HAMD 24 at up to 6 weeks (P=0.02)
 - Basis of expanded labeling in 2014 — failed one or more prior antidepressants²

Unmatched Body of TMS Clinical Data



Safety Record

- > 3.4 million treatment sessions delivered globally
- > 94,600 patients treated
- Adverse events discontinuation rate ~5%³

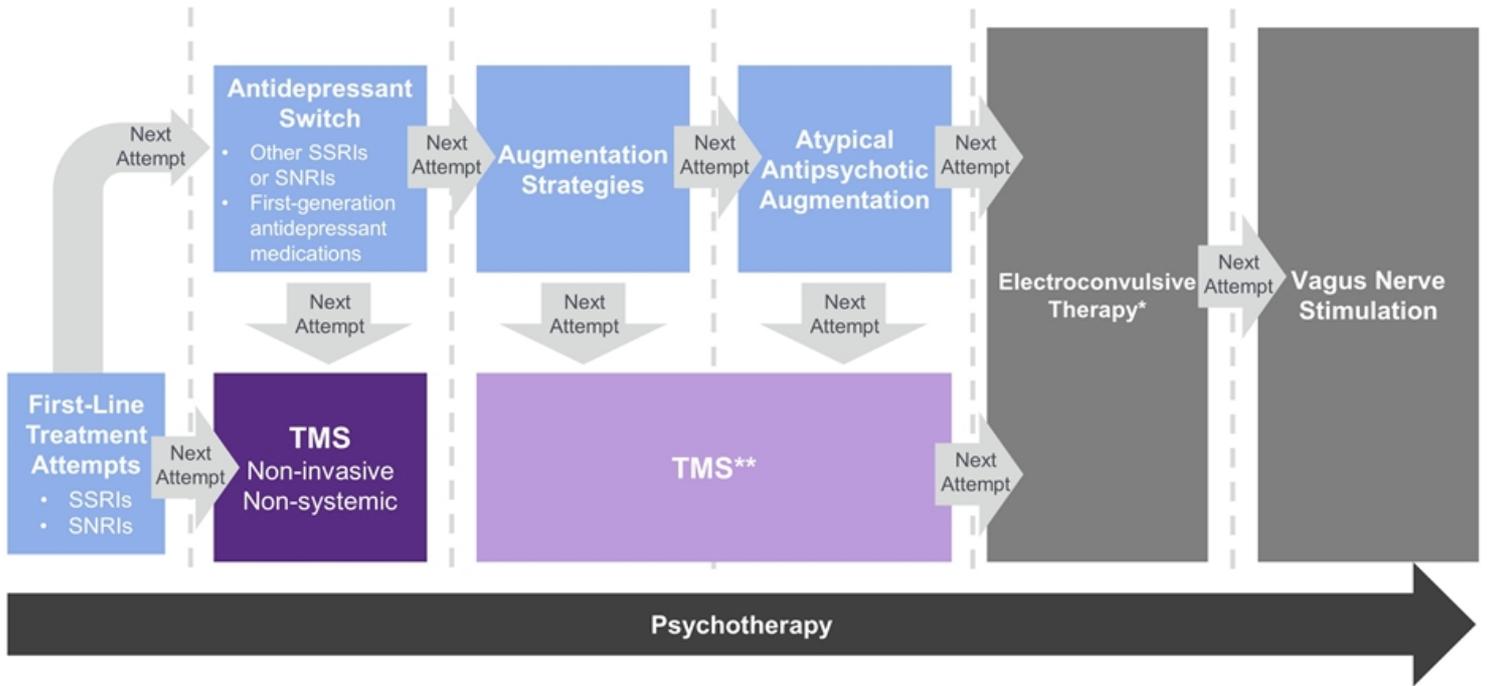
1. O'Reardon, J.P., et al. (2007) *Biological Psychiatry*, 62(11):1208–1216

2. George, M.S., et al. (2010) *Archives of General Psychiatry*, now published as *JAMA Psychiatry*, 67(5):507–516

3. In sham-controlled studies



MDD Patient Continuum of Care



NeuroStar Advanced Therapy is indicated for treatment of MDD in adult patients who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode

* ECT may be used earlier in the patient continuum of care in patients experiencing catatonia, acute suicidal behaviors or psychotic symptoms

** TMS may be used at any point along the continuum of care following one or more failed treatment attempts



Our Solution: NeuroStar Advanced Therapy

NeuroStar Advanced Therapy System



Efficient

- Non-invasive and no anesthesia
- MT Assist
- Treatment time as low as 19 minutes
- TrakStar stores patient's treatment data

Therapy

- Psychiatrist establishes treatment dose and positioning in first session
- Five days a week for up to six weeks
- Trained member of office staff may administer subsequent treatment sessions under psychiatrist supervision

Precise

- Proprietary SenStar Connect contact sensing
- SenStar magnetic field detector
- Proprietary, laser-aligned, six-point coordinate system



Payors and Reimbursement

Payor Coverage

- Estimated to cover 95% of total private payor covered lives in the US
- 65+ major US private insurers provide coverage policies
 - The top 25 US private insurers, including **United/OPTUM**, **Anthem**, **Aetna**, **Cigna**, **HCSC**, **TRICARE** and **Humana**, represent 205 million covered lives¹ in excess of 200 million²
- 100% Medicare Coverage
 - 59.7 million covered lives²

Reimbursement

- Covers MT assist and treatment sessions

CPT Code	Reimbursement
90867	MT Assist and Treatment Session
90868	Treatment Session
90869	Subsequent MT Assist and Treatment Session

1. As of March 15, 2018
2. As of April 1, 2019



Barriers to Entry



Japan Growth Opportunity

- Primary international focus is on Japan
- Third largest healthcare spend globally
- Single payor healthcare system
- Shonin Approval: September 2017
- Exclusive distribution agreement with Teijin Pharma signed October 2017
 - Teijin to promote sales of systems and treatment sessions
 - Minimum purchase requirements
 - Milestone payments received in 2017, \$2.8M
- Reimbursement listing effective June 2019
 - 2nd Milestone payment received in 2019, \$0.7M
 - 158 hospitals qualified
 - Approved reimbursement amount is ¥12,000



Estimated TAM in Japan for Treatment Sessions¹



Japan represents a large market opportunity



Intellectual Property

Patent Portfolio

- Issued or allowed patents:
39 US / 52 OUS
- Pending patent applications:
6 US / 9 OUS

Key Portfolio Coverage Areas

- **Contact Sensing**
 - Multiple, US patent expires 2024-2027
- **MT Assist**
 - US patent expires 2024
- **Iron Core Magnet**
 - Multiple, US patents expire 2025–2027



Significant IP portfolio intended to protect our technical advantage and ensure freedom to operate globally



Management and Board of Directors

Management

Keith Sullivan	President and CEO
Janie Bates	VP, Marketing
Steve Furlong	VP, CFO
Sara Grubbs	VP, Sales
Greg Harper	VP, Product Development & Operations
Andrew Macan	SVP, General Counsel, Chief Compliance Officer, and Corporate Secretary
Anthony Pui	VP, International Commercial Development
Kara Thornton	Senior Director, Head of Human Resources

Board of Directors

John Bakewell	Former EVP and CFO, Wright Medical Group
Sheryl L. Conley	Former Global President and Chief Marketing Officer, Zimmer Holdings
Brian Farley	Chairman; Former CEO and Chairman, Entellus Medical
Wilfred Jaeger	Three Arch Partners
Glenn Muir	Former CFO, Hologic
Bruce J. Shook	Director, President and CEO, Intact Vascular and Vesper Medical
Keith Sullivan	President and CEO, Neuronetics, Inc.





Financial Overview

Expected Preliminary Estimated Q4 and Full Year 2020 Results (Unaudited)

(1)

Unaudited financials	Q4 2020	FY 2020
Revenue	~\$15.0 – 15.5 million Sequential increase of between 21% and 25% compared to Q3 2020	~\$48.7 – \$49.2 million

(1) These preliminary, unaudited financial results are subject to the close of the quarter and year, completion of our quarter-end and year-end closing procedures and further financial review. See "Forward-Looking Statements & Disclaimer."



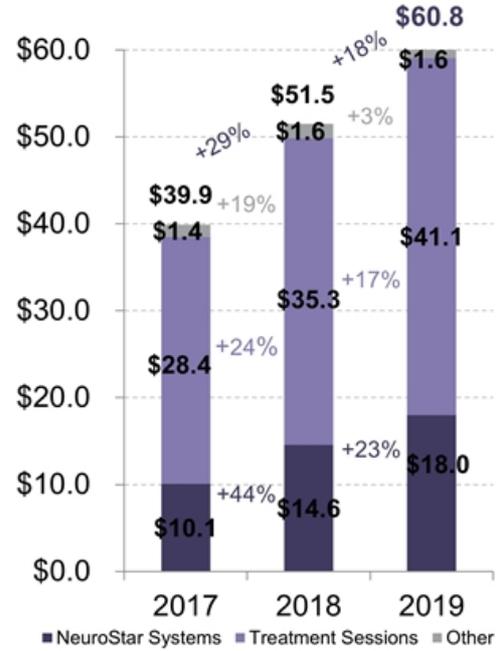
Annual Revenue

(\$ in millions)

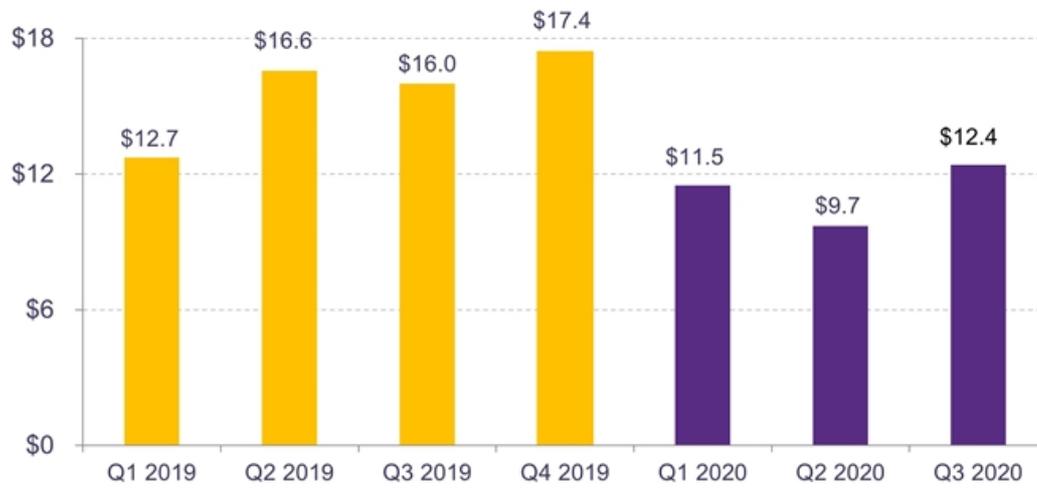
Annual Revenue by Geography



Annual Product Revenue (US)



Worldwide Quarterly Revenue (\$ in millions)



Q3 2020 Revenue \$12.4M versus \$16.0M in Q3 2019



Results of Operations

	Three Months Ended September 30,		Nine Months Ended September 30,	
(\$ in thousands)	2019	2020	2019	2020
Revenues	\$16,000	\$12,448	\$45,300	\$33,665
<i>YOY Growth</i>		-22%		-26%
Gross Profit	11,808	9,791	34,130	25,874
<i>Gross Margin</i>	74%	79%	75%	77%
Operating Expenses:				
Sales and Marketing <i>% of Revenues</i>	10,362 65%	6,053 49%	31,477 69%	24,927 74%
General and Administrative <i>% of Revenues</i>	4,285 27%	4,210 34%	13,145 29%	13,508 40%
Research and Development <i>% of Revenues</i>	3,489 22%	1,952 16%	9,499 21%	7,089 21%
Total Operating Expenses	18,136	12,215	54,121	45,524
Loss from Operations	(\$6,328)	(\$2,424)	(\$19,991)	(\$19,650)
<i>% of Revenues</i>	-40%	-19%	-44%	-58%



Financial Position

<i>(\$ in thousands)</i>	As of September 30, 2020
Cash and Cash Equivalents	\$50,719
Other Balance Sheet Assets	\$27,620
Total Assets	\$78,339
Current Debt, net	\$34,542
Convertible Preferred Stock Warrant Liability	\$0
Convertible Preferred Stock	\$0
Accumulated Deficit	(\$273,883)
Total Stockholders' Equity	\$27,478





Supplemental Information

NeuroStar Unit Sales and Installed Base

	2019				2020		
	Q1-19	Q2-19	Q3-19	Q4-19	Q1-20	Q2-20	Q3-20
Unit Sales							
Total NeuroStar Units (Capital Sales, Sales Type Leases, Operating Leases) (1)	43	61	68	78	38	35	39
YoY Δ	43%	30%	42%	20%	-12%	-43%	-43%
Beginning Active Installed Base	907	931	976	1,032	1,085	1,119	1,122
Ending Active Installed Base	931	976	1,032	1,085	1,119	1,122	1,143
YoY Δ	19%	20%	20%	25%	20%	15%	11%
Net Active Installed Base Change	24	45	56	53	34	3	21
YoY Δ	-17%	29%	33%	8%	42%	-93%	-63%
Inactive Systems (Calculation) (2)	-19	-16	-12	-25	-4	-32	-18
Inactive System Churn% (Calculation) (3)	-2.1%	-1.7%	-1.2%	-2.4%	-0.4%	-2.9%	-1.6%

(1) = Includes all active systems placed during the period. In 2018, this included 15 operating leases: Q1-6, Q2- 4, Q3-1, Q4-4.

(2) = Calculation: (Ending Installed Base - Beginning Installed Base) - Total NeuroStar Units

(3) = Calculation: Inactive Systems / Ending of Prior Period Installed Base



NeuroStar Revenue

NeuroStar Revenue	
Total U.S. NeuroStar Revenue (\$000s)	YoY ↓
U.S. NeuroStar Capital Revenue (\$000s) (4)	YoY ↓
U.S. NeuroStar Operating Lease Revenue (\$000s) (5)	YoY ↓
U.S. NeuroStar Other (\$000s) (6)	YoY ↓

	2019				2020		
	Q1-19	Q2-19	Q3-19	Q4-19	Q1-20	Q2-20	Q3-20
Total U.S. NeuroStar Revenue (\$000s)	\$3,350	\$4,628	\$4,616	\$5,413	\$2,594	\$2,338	\$2,541
YoY ↓	41%	30%	18%	14%	-23%	-49%	-45%
U.S. NeuroStar Capital Revenue (\$000s) (4)	\$2,939	\$4,034	\$4,264	\$4,959	\$2,410	\$2,224	\$2,438
YoY ↓	54%	23%	24%	14%	-18%	-45%	-43%
U.S. NeuroStar Operating Lease Revenue (\$000s) (5)	\$182	\$187	\$184	\$177	\$155	\$114	\$88
YoY ↓	-29%	3%	-31%	-24%	-15%	-39%	-52%
U.S. NeuroStar Other (\$000s) (6)	\$229	\$407	\$167	\$278	\$29	\$0	\$15
YoY ↓	11%	239%	-21%	50%	-87%	-100%	-91%

- (4) = Revenue includes NeuroStar System Capital Sales and Sales Type Leases
- (5) = Revenue derived from Operating Lease revenue amortization during the period
- (6) = Revenue derived from Treatment Coils in U.S.



NeuroStar Treatment Sessions

Treatment Session Sales

Total Treatment Session Revenues (\$000s)

YoY Δ

Active Installed Base (Ending of Prior Quarter)

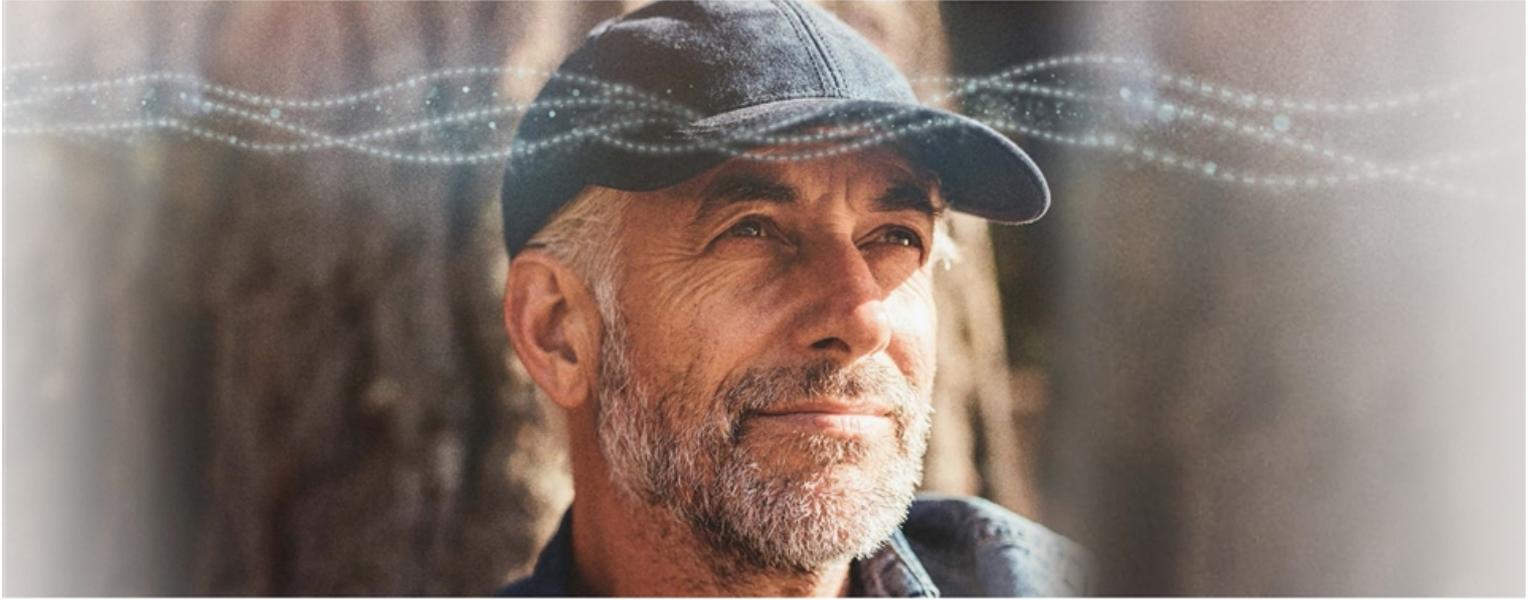
Avg. Revenue per Active System (\$000s) (8)

YoY Δ

2019				2020		
Q1-19	Q2-19	Q3-19	Q4-19	Q1-20	Q2-20	Q3-20
\$8,778	\$10,847	\$10,252	\$11,243	\$8,193	\$6,547	\$9,083
21%	22%	11%	13%	-7%	-40%	-11%
907	981	976	1,082	1,085	1,119	1,122
\$9.7	\$11.7	\$10.5	\$10.9	\$7.6	\$5.9	\$8.1
1%	2%	-7%	-6%	-22%	-50%	-23%

(8) = Total Treatment Session Revenue / Active Installed Base (Ending of Prior Quarter)





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