Helius Medical Technologies, Inc. Reports Fourth Quarter and Full Year 2021 Financial Results

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NEWTOWN, Pa., March 14, 2022 (GLOBE NEWSWIRE) -- Helius Medical Technologies, Inc. (Nasdaq:HSDT) ("Helius" or the "Company"), a neurotech company focused on neurological wellness, today reported financial results for the quarter and full year ended December 31, 2021.

Fourth Quarter and Recent Business Updates

- U.S. commercial launch of PoNS® for multiple sclerosis ("MS") progressed with first prescriptions received this month.
- Received marketing authorization in Australia for sale of PoNS as a Class IIa medical device to improve balance and gait.
- Launched partnership with Medical University of South Carolina for collaborative clinical trial on stroke, allowing for observation of PoNS therapy in a real-world clinical setting.
- Partnered with NYU Langone Health as the first clinical trial site for the Company-sponsored Therapeutic Experience Program ("TEP"), an open label observational interventional trial designed to evaluate the impact of subjects' adherence to PoNS Therapy in patients with MS.
- Closed public offering of common stock with $11.1 million in gross proceeds.
- Q4 2021 revenue increased by 35% to $258 thousand compared to $191 thousand in Q4 2020 and full year 2021 revenue was $522 thousand vs. $661 thousand in 2020.

"The fourth quarter was an exciting and noteworthy time for the Company. While preparing for the U.S. commercial launch of PoNS for multiple sclerosis, we also received market authorization in Australia for use of PoNS to improve balance and gait, launched our Therapeutic Experience Program with NYU Langone, announced a collaborative clinical trial in stroke with the Medical University of South Carolina, and grew to 37 clinic locations in Canada," stated Dane Andreeff, President and Chief Executive Officer of Helius. "In the U.S., the first PoNS prescriptions were received this month, and with the planned finalization of our pivotal stroke trial design and further expansion of TEP expected by the end of the second quarter, 2022 should be another eventful year for Helius, and we look forward to providing updates as our activities progress."

Fourth Quarter 2021 Financial Results

Total revenue for the fourth quarter of 2021 increased to $258 thousand, a 35% increase compared to $191 thousand in the fourth quarter of 2020, and was comprised primarily of product sales in both periods.

Gross profit for the fourth quarter of 2021 was $129 thousand, compared to gross loss of $10 thousand in the fourth quarter of 2020.

Operating expenses for the fourth quarter of 2021 increased to $4.2 million, compared to $3.0 million in the fourth quarter of 2020, an increase of $1.2 million. The planned increase primarily resulted from increased clinical and development activities preparing for the U.S. commercial launch of PoNS.

Operating loss for the fourth quarter of 2021 increased $1.1 million to $4.1 million, compared to $3.0 million in the fourth quarter of 2020.

Net loss was $4.1 million for the fourth quarter of 2021, compared to $2.5 million in the corresponding prior year period. The basic and diluted net loss per share for the fourth quarter was $1.31 per share, compared to $1.77 per share, for the fourth quarter of 2020.

Full Year 2021 Financial Results

Total revenue for the full year 2021 was $522 thousand, compared to $661 thousand for the full year 2020, and was comprised primarily of product sales for both periods.

Gross profit for the full year 2021 was $224 thousand, compared to gross profit of $273 thousand for the full year 2020.

Operating expenses for the full year 2021 increased $3.7 million to $18.4 million, compared to $14.7 million for the full year 2020. In addition to planned increases resulting from infrastructure and product development activities preparing for the commercial launch of PoNS in the U.S., operating expenses for the full year 2021 included non-recurring severance expenses related to the departure of our former chief operating officer of $0.4 million cash expense and $0.5 million non-cash stock-based compensation expense.

Operating loss for the full year 2021 increased $3.7 million to $18.1 million, compared to $14.4 million for the full year 2020.

Net loss for the full year 2021 was $18.1 million, compared to $14.1 million for the full year 2020. The basic and diluted net loss per share for the full year 2021 was $7.38 per share, compared to $11.80 per share, for the full year 2020.

Cash and Liquidity

Cash used in operating activities for the twelve months ended December 31, 2021 was $13.4 million compared to $11.7 million in the prior year.

As of December 31, 2021, the Company had cash of $11.0 million, compared to $3.3 million at December 31, 2020.

The Company had no debt outstanding at December 31, 2021.

2022 Guidance

The Company currently expects first quarter revenue to range from $150 thousand to $170 thousand and quarterly revenue to increase sequentially each quarter throughout the year as the U.S. commercialization of PoNS develops.

Conference Call

As previously announced, management will host a conference call as follows:

Date:	Monday, March 14, 2022
Time:	5:00 PM ET
Toll-free (U.S.)	844-348-4652
International	213-358-0895
Conference ID	2995141

A live webcast of the call will also be provided on the Events section of the Company's investor relations website at:

https://edge.media-server.com/mmc/p/mtbio3ko.

A replay of the call will be available for one week at 855-859-2056 (U.S.) or 404-537-3406 (international). The conference ID for the replay is 2995141. The webcast will be archived on the Events section of the Company's investor relations website.

About Helius Medical Technologies, Inc.

Helius Medical Technologies is a leading neurotech company in the medical device field focused on neurologic deficits using non-implantable platform technologies that amplify the brain's ability to compensate and promotes neuroplasticity, aiming to improve the lives of people dealing with neurologic diseases. The Company's first commercial product is the Portable Neuromodulation Stimulator (PoNS). For more information, visit www.heliusmedical.com.

About the PoNS Device and PoNS Therapy

The Portable Neuromodulation Stimulator (PoNS) is an innovative non-surgical medical device, inclusive of a controller and mouthpiece, which delivers electrical stimulation to the surface of the tongue to improve balance and gait. The PoNS device is indicated for use in the United States as a short-term treatment of gait deficit due to mild-to-moderate symptoms from multiple sclerosis ("MS") and is to be used as an adjunct to a supervised therapeutic exercise program in patients 22 years of age and over by prescription only. Helius is advancing PoNS post-approval research in MS through a recently launched Therapeutic Experience Program (TEP) designed to partner with neurologists and neurorehabilitation therapists at 10-12 US centers of excellence, who express an interest in becoming "early adopters" of PoNS therapy.

PoNS is also authorized for sale in Canada for two indications: (i) for use as a short-term treatment (14 weeks) of chronic balance deficit due to mild-to-moderate traumatic brain injury ("mmTBI") and is to be used in conjunction with physical therapy; and (ii) for use as a short term treatment (14 weeks) of gait deficit due to mild and moderate symptoms from MS and is to be used in conjunction with physical therapy. PoNS is also authorized for sale in Australia for short term use by healthcare professionals as an adjunct to a therapeutic exercise program to improve balance and gait.

Cautionary Disclaimer Statement:

This press release does not and shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or other jurisdiction. Any offer, if at all, will be made only by means of a prospectus, including a prospectus supplement, forming a part of the effective registration statement.

Certain statements in this news release are not based on historical facts and constitute forward-looking statements or forward-looking information within the meaning of the U.S. Private Securities Litigation Reform Act of 1995 and Canadian securities laws. All statements other than statements of historical fact included in this news release are forward-looking statements that involve risks and uncertainties. Forward-looking statements are often identified by terms such as "believe," "continue," "expect," "will," "goal," "aim to" and similar expressions. Such forward-looking statements include, among others, statements regarding the Company's future growth and operational progress, including commercial activities for the PoNS device, our revenue from sales of our products, receipt of prescriptions and progress of commercialization of the PoNS device in the U.S., the ability of the PoNS device to become the standard of care for gait deficit in the U.S., Canada and Australia, expectations for the Therapeutic Experience Program, expectations for the clinical trial in stroke, leveraging the approval of PoNS in Australia, clinical development plans, product development activities, plans for U.S. Food and Drug Administration, or FDA, filings and their subsequent approvals and our future expenses and cash flow.

There can be no assurance that such statements will prove to be accurate and actual results and future events could differ materially from those expressed or implied by such statements. Important factors that could cause actual results to differ materially from the Company's expectations include uncertainties associated with the Company's capital requirements to achieve its business objectives, availability of funds, including that funding from our purchase agreement with Lincoln Park Capital Fund, LLC may be limited or be insufficient to fund our operations, the ability to find additional sources of funding, the impact of the COVID-19 pandemic, manufacturing, labor shortage and supply chain risks, the Company's ability to train physical therapists in the supervision of the use of the PoNS treatment, the Company's ability to secure contracts with rehabilitation clinics, the Company's ability to obtain national Medicare coverage and to obtain a reimbursement code so that the PoNS device is covered by Medicare and Medicaid, the Company's ability to build internal commercial infrastructure, secure state distribution licenses, build a commercial team and build relationships with Key Opinion Leaders, neurology experts and neurorehabilitation centers, market awareness of the PoNS device, future clinical trials and the clinical development process, the product development process and FDA regulatory submission review and approval process, other development activities, ongoing government regulation and other factors, and other risks detailed from time to time in the "Risk Factors" section of the

Company's Annual Report on Form 10-K for the year ended December 31, 2020, its Quarterly Report on Form 10-Q for the quarter ended September 30, 2021 and its other filings with the United States Securities and Exchange Commission and the Canadian securities regulators, which can be obtained from either at www.sec.gov or www.sedar.com.

The reader is cautioned not to place undue reliance on any forward-looking statement. The forward-looking statements contained in this news release are made as of the date of this news release and the Company assumes no obligation to update any forward-looking statement or to update the reasons why actual results could differ from such statements except to the extent required by law.

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Helius Medical Technologies, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(Amounts in thousands except share and per share data)

	Unaudited			
	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Revenue:				
Product sales	$ 251	$ 184	$ 493	$ 625
Fee revenue	—	—	—	9
License revenue	7	7	29	27
Total operating revenue	**258**	**191**	**522**	**661**
Cost of sales:				
Cost of product sales	129	201	298	388
Gross profit	**129**	**(10)**	**224**	**273**
Operating expenses:				
Research and development	1,808	827	5,990	4,582
Selling, general and administrative	2,376	2,089	12,176	9,714
Amortization expense	47	76	200	363
Total operating expenses	**4,231**	**2,992**	**18,366**	**14,659**
Operating loss	**(4,102)**	**(3,002)**	**(18,142)**	**(14,386)**
Other income:				
Other income	—	—	—	63
Change in fair value of derivative financial instruments	—	—	—	4
Foreign exchange gain	—	468	10	189
Total other income	**—**	**468**	**10**	**256**
Net loss	**(4,102)**	**(2,534)**	**(18,132)**	**(14,130)**
Other comprehensive loss:				
Foreign currency translation adjustments	—	(406)	(26)	(197)
Comprehensive loss	**$ (4,102)**	**$ (2,940)**	**$ (18,158)**	**$ (14,327)**
Net loss per share				
Basic	**$ (1.31)**	**$ (1.77)**	**$ (7.38)**	**$ (11.80)**
Diluted	**$ (1.31)**	**$ (1.77)**	**$ (7.38)**	**$ (11.80)**
Weighted average shares outstanding				
Basic	**3,131,448**	**1,430,504**	**2,456,782**	**1,197,774**
Diluted	**3,131,448**	**1,430,504**	**2,456,782**	**1,197,774**

Helius Medical Technologies, Inc.
Consolidated Balance Sheets
(Except for share data, amounts in thousands)

	December 31, 2021	December 31, 2020
ASSETS		
Current assets		
Cash	$ 11,005	$ 3,331
Accounts receivable, net	66	74
Other receivables	185	156
Inventory, net	476	389

Prepaid expenses	862	735
Total current assets	12,594	4,685
Property and equipment, net	409	486
Other assets		
Goodwill	763	759
Intangible assets, net	333	527
Operating lease right-of-use asset, net	3	90
Total other assets	1,099	1,376
TOTAL ASSETS	**$ 14,102**	**$ 6,547**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,069	$ 747
Accrued liabilities	1,433	1,337
Operating lease liability	3	59
Deferred revenue	148	281
Total current liabilities	2,653	2,424
Non-current liabilities		
Operating lease liability	—	32
Deferred revenue	193	220
TOTAL LIABILITIES	**2,846**	**2,676**
STOCKHOLDERS' EQUITY		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding as of December 31, 2021 and December 31, 2020	—	—
Class A Common stock, $0.001 par value; 150,000,000 shares authorized; 3,780,674 and 1,484,362 shares issued and outstanding as of December 31, 2021 and December 31, 2020, respectively	4	1
Additional paid-in capital	149,412	123,872
Accumulated deficit	(137,035)	(118,903)
Accumulated other comprehensive loss	(1,125)	(1,099)
TOTAL STOCKHOLDERS' EQUITY	**11,256**	**3,871**
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 14,102**	**$ 6,547**