Helius Medical Technologies, Inc. Reports Third Quarter 2021 Financial Results

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NEWTOWN, Pa., Nov. 10, 2021 (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 ended September 30, 2021.

Third Quarter and Recent Business Updates

- Received U.S. Food and Drug Administration ("FDA") Breakthrough Designation for Portable Neuromodulation Stimulator ("PoNS®"), a patented treatment combining trigeminal nerve neurostimulation via the tongue with a supervised therapeutic exercise program, for the treatment of dynamic gait and balance deficits resulting from a stroke.
- Launched Therapeutic Experience Program ("TEP") with NYU – Langone Health as its first clinical site.
- Received market authorization from the Australian Therapeutic Goods Administration ("TGA") for the sale of PoNS as a Class IIa medical device for short term use by healthcare professionals as an adjunct to a therapeutic exercise program to improve balance and gait.
- Introduced our U.S. PoNS Treatment website, ponstreatment.com, to expand online resources for U.S.-based clinicians and patients.
- Secured $15 million equity line of credit with Lincoln Park Capital with a 36-month term, ensuring source of equity capital, subject to the terms and conditions therein.
- Developing infrastructure and building inventory in preparation for expected Q1 2022 commercial launch of PoNS for the short-term treatment of gait deficit due to multiple sclerosis ("MS").
- Recently announced pricing of $9.6 million underwritten registered public offering, scheduled to close November 12, subject to customary closing conditions.

Third Quarter 2021 Financial Summary

- Revenue: $109 thousand, vs. $131 thousand in Q3 2020
- Operating loss: $4.4 million vs. $3.7 million in Q3 2020
- Net loss: $4.7 million vs. $3.5 million in Q3 2020
- Cash balance: $4.7 million at September 30, 2021 vs. $3.3 million at December 31, 2020

"We are delighted that our PoNS was granted a second FDA Breakthrough Designation, this time for the treatment of dynamic gait and balance deficits resulting from a stroke," said Dane Andreeff, President and Chief Executive Officer of Helius. "This is a significant milestone for us as we prepare for the U.S. commercialization of the PoNS device for MS in early 2022. We are excited about the recent initiation of our company-sponsored Therapeutic Experience Program, an observational clinical study that will be conducted at 10-12 key neurologist and neurorehabilitation centers throughout the country, with enrollment beginning late in the fourth quarter of 2021. This program will provide us with valuable insight about patients' adherence and compliance to a PoNS therapy program."

"As we ramp up for the U.S. commercial launch for MS and advance our studies of the PoNS device in stroke patients, our goal is to unlock the full potential of neuromodulation, bringing our innovative technology to patients as quickly and efficiently as possible and becoming the standard of care for gait deficit in the U.S. and Canada. We also intend to leverage the recently announced TGA authorization of PoNS in Australia for short term use by healthcare professionals as an adjunct to a therapeutic exercise program to improve balance and gait – a very broad scope – to provide capital to support our U.S. commercial launch efforts," concluded Andreeff.

Third Quarter 2021 Financial Results

Total revenue for the third quarter of 2021 was $109 thousand, compared to $131 thousand in the third quarter of 2020. Product sales were $102 thousand in the third quarter of 2021 compared to $124 thousand in the prior year period. Product sales in both periods were generated through sales of the PoNS device pursuant to supply agreements with PoNS Authorized clinic locations in Canada. License and fee revenue was $7 thousand in each of the third quarters of 2021 and 2020.

Gross profit for the third quarter of 2021 was $23 thousand, compared to gross profit of $109 thousand in the third quarter of 2020.

Operating expenses for the third quarter of 2021 increased $0.6 million to $4.4 million, compared to $3.8 million in the third quarter of 2020. Operating expenses in the third quarter of 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 third quarter of 2021 increased $0.7 million to $4.4 million, compared to $3.7 million in the third quarter of 2020.

Total other expense for the third quarter of 2021 was $314 thousand, compared to total other income of $183 thousand in the third quarter of 2020.

Net loss for the third quarter of 2021 was $4.7 million, or $(2.01) per basic and diluted common share, compared to a net loss of $3.5 million, or $(2.70) per basic and diluted common share, in the third quarter of 2020. Weighted average shares used to compute basic and diluted net loss per common share were 2.3 million and 1.3 million for the third quarter of 2021 and 2020, respectively.

Cash and Liquidity

Cash used in operating activities for the nine months ended September 30, 2021 was $9.9 million and net cash provided by financing activities was $11.4 million for the same period.

On September 1, 2021, we entered into a purchase agreement with Lincoln Park Capital, with a 36-month term, where, subject to terms and conditions therein, we have the right, but not the obligation to sell to Lincoln Park, up to $15.0 million of our common stock. During September 2021, we issued and sold 40,000 shares under the purchase agreement for net proceeds of $0.6 million.

As of September 30, 2021, the Company had cash of $4.7 million, compared to $3.3 million at December 31, 2020.

The Company had no debt outstanding at September 30, 2021.

On November 10, 2021, the Company announced the pricing of a $9.6 million underwritten registered public offering, at a price to the public of $8.00 per share. This financing is scheduled to close on Friday, November 12, 2021, subject to customary closing conditions.

Conference Call

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

Date:	Wednesday, November 10, 2021
Time:	5:00 PM ET
Toll-free (U.S.)	844-348-4652
International	213-358-0895
Conference ID	9388362

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

https://heliusmedical.com/index.php/investor-relations/events/upcoming-events.

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 9388362. 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 promote neuroplasticity, aiming to improve the lives of people needing to improve their balance and gait. 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. It is authorized for sale in Canada for two indications: (i) PoNS is authorized 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) PoNS is authorized 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.

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 pre-commercial activities for the PoNS device,

the Company's future liquidity, expected time to begin 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. and Canada, expectations for the Therapeutic Experience Program, the Company's intention to leverage the recently announced TGA authorization of PoNS to provide capital to support US commercial launch efforts and the anticipated closing of the public offering.

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 the Company's ability to full access its equity line with Lincoln Park, 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 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.
Unaudited Consolidated Balance Sheets
(Except for share data, amounts in thousands)

	September 30, 2021	December 31, 2020
ASSETS		
Current assets		
Cash	$ 4,700	$ 3,331
Accounts receivable, net	23	74
Other receivables	175	156
Inventory, net	538	389
Prepaid expenses	802	735
Total current assets	6,238	4,685
Property and equipment, net	451	486
Other assets		
Goodwill	762	759
Intangible assets, net	381	527
Operating lease right-of-use asset, net	47	90
Total other assets	1,190	1,376
TOTAL ASSETS	**$ 7,879**	**$ 6,547**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,067	$ 747
Accrued liabilities	1,276	1,337
Operating lease liability	47	59
Deferred revenue	252	281
Total current liabilities	2,642	2,424
Non-current liabilities		
Operating lease liability	—	32
Deferred revenue	200	220
TOTAL LIABILITIES	**2,842**	**2,676**
STOCKHOLDERS' EQUITY		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding as of September 30, 2021 and December 31, 2020	—	—
Class A Common stock, $0.001 par value; 150,000,000 shares authorized; 2,392,130 and 1,484,362 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	2	1

Additional paid-in capital	139,093	123,872
Accumulated other comprehensive loss	(1,125)	(1,099)
Accumulated deficit	(132,933)	(118,903)
TOTAL STOCKHOLDERS' EQUITY	**5,037**	**3,871**
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 7,879**	**$ 6,547**

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Revenue:				
Product sales	$ 102	$ 124	$ 242	$ 441
Fee revenue	—	—	—	9
License revenue	7	7	22	20
Total operating revenue	**109**	**131**	**264**	**470**
Cost of sales:				
Cost of product sales	86	22	169	187
Gross profit	**23**	**109**	**95**	**283**
Operating expenses:				
Research and development	1,489	1,327	4,182	3,755
Selling, general and administrative	2,859	2,370	9,800	7,625
Amortization expense	48	72	153	287
Total operating expenses	**4,396**	**3,769**	**14,135**	**11,667**
Operating loss	**(4,373)**	**(3,660)**	**(14,040)**	**(11,384)**
Other (expense) income:				
Other income	—	—	—	63
Change in fair value of derivative financial instruments	—	1	—	4
Foreign exchange (loss) gain	(314)	182	10	(278)
Total other (expense) income	**(314)**	**183**	**10**	**(211)**
Net loss	**(4,687)**	**(3,477)**	**(14,030)**	**(11,595)**
Other comprehensive income (loss):				
Foreign currency translation adjustments	287	(172)	(26)	208
Comprehensive loss	**$ (4,400)**	**$ (3,649)**	**$ (14,056)**	**$ (11,387)**
Net loss per share				
Basic	**$ (2.01)**	**$ (2.70)**	**$ (6.29)**	**$ (10.36)**
Diluted	**$ (2.01)**	**$ (2.70)**	**$ (6.29)**	**$ (10.36)**
Weighted average shares outstanding				
Basic	**2,326,893**	**1,289,657**	**2,229,422**	**1,119,639**
Diluted	**2,326,893**	**1,289,657**	**2,229,422**	**1,119,639**

Helius Medical Technologies, Inc.
Unaudited Condensed Consolidated Statements of Cash Flows
(Amounts in thousands)

	Nine Months Ended September 30,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (14,030)	$ (11,595)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of derivative financial instruments	—	(4)
Stock-based compensation expense	3,896	2,021
Unrealized foreign exchange (gain) loss	(26)	245
Depreciation expense	84	92
Amortization expense	153	287
(Recovery of) provision for doubtful accounts	(19)	160
Non-cash lease expense	46	209

Intangible asset impairment	—	182
Loss from disposal of property and equipment	—	110
Gain from lease modification	—	(56)
Changes in operating assets and liabilities:		
Accounts receivable	70	(30)
Other receivables	(19)	226
Inventory	(149)	26
Prepaid expenses	(67)	(56)
Operating lease liability	(47)	(189)
Accounts payable	270	(956)
Accrued liabilities	(38)	(120)
Deferred revenue	(49)	(119)
Net cash used in operating activities	**(9,925)**	**(9,567)**
Cash flows from investing activities:		
Purchase of property and equipment	(49)	(14)
Proceeds from sale of property and equipment	—	61
Internally developed software	(2)	(7)
Net cash (used in) provided by investing activities	**(51)**	**40**
Cash flows from financing activities:		
Proceeds from the issuance of common stock and accompanying warrants	11,614	7,233
Share issuance costs	(1,581)	(506)
Proceeds from the exercise of warrants	1,320	—
Proceeds from Paycheck Protection Program Loan	—	323
Repayment of Paycheck Protection Program Loan	—	(323)
Net cash provided by financing activities	**11,353**	**6,727**
Effect of foreign exchange rate changes on cash	(8)	21
Net increase (decrease) in cash	1,369	(2,779)
Cash at beginning of year	3,331	5,459
Cash at end of year	**$ 4,700**	**$ 2,680**