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

October 22, 2018
Date of Report (Date of earliest event reported)

HELIUS MEDICAL TECHNOLOGIES, INC.
(Exact name of registrant as specified in its charter)

DELAWARE	**001-38445**	**36-4787690**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

(Exact name of registrant as specified in charter)

642 Newtown Yardley Road, Suite 100
Newtown, Pennsylvania, 18940
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (215) 944-6100

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 14a12 under the Exchange Act (17 CFR 240.14a12)
☐ Precommencement communications pursuant to Rule 14d2(b) under the Exchange Act (17 CFR 240.14d2(b))
☐ Precommencement communications pursuant to Rule 13e4(c) under the Exchange Act (17 CFR 240.13e4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).
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

On October 22, 2018, Helius Medical Technologies, Inc. (the "Company") issued a press release announcing the receipt of medical device license clearance from Health Canada for its Portable Neuromodulation Stimulator (PoNS) device. A copy of the press release is furnished herewith as Exhibit 99.1.

The information set forth in this Item 7.01 and in the press release attached hereto as Exhibit 99.1, is deemed to be "furnished" and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section. The information set forth in this Item 7.01, including Exhibit 99.1, shall not be deemed incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933, as amended, except to the extent that the Company specifically incorporates it by reference.

Item 8.01 Other Events.

On October 22, 2018, the Company announced that its wholly owned subsidiary, NeuroHabilitation Corporation, received authorization from Health Canada to market its Portable Neuromodulation Stimulator (PoNS), a class II medical device in Canada. The Health Canada Medical Device License certifies the PoNS device meets all Canadian safety, effectiveness, and quality requirements.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press release dated October 22, 2018

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.

HELIUS MEDICAL TECHNOLOGIES, INC.

Dated: October 22, 2018

By: /s/ Joyce LaViscount
Joyce LaViscount, Chief Financial Officer

Ex. 99.1

Helius Medical Technologies Receives Medical Device License Clearance from Health Canada for PoNS™ Device

NEWTOWN, PA., October 22, 2018 - (GLOBE NEWSWIRE) -- Helius Medical Technologies, Inc. (NASDAQ:HSDT) (TSX:HSM) ("Helius" or the "Company"), a neurotech company focused on neurological wellness, today announced its wholly owned subsidiary, NeuroHabilitation Corporation, received authorization from Health Canada to market its Portable Neuromodulation Stimulator (PoNS™), a class II medical device in Canada. The Health Canada Medical Device License certifies the PoNS Device meets all Canadian safety, effectiveness, and quality requirements. The Canadian Medical Device License approval was preceded by the Company's achievement of ISO 13485 Certification, the international standard for medical device quality management systems.

"The Company is thrilled to have received Canadian regulatory clearance to market our PoNS Treatment as an adjunct to physical therapy for chronic balance deficit in patients with mild-to-moderate traumatic brain injury (TBI)," said Philippe Deschamps, Helius' President, CEO and Chairman. "Canada is one of the most respected healthcare markets in the world and was therefore well represented in our successful TBI clinical trial. We are excited to have this first regulatory confirmation on the benefits of our breakthrough PoNS Treatment. We thank Health Canada for its rapid review and clearance of our application. We look forward to providing our innovative treatment for this very high unmet medical need to Canadians suffering from the chronic effects of TBI.

Mr. Deschamps continued: "Earlier this month, we announced the creation of Heuro Canada, a new operating entity formed as part of our strategic alliance with HealthTech Connex (HTC) to distribute PoNS Treatment in Canada, once clearance was obtained. Through Heuro Canada, we are working expeditiously to build the requisite commercial and operating infrastructure to begin treating patients now that we have received regulatory clearance for the PoNS Treatment. We have already established the first two Heuro Canada neuroplasticity clinics which we expect to be operational in the fourth quarter of 2018 and we expect to begin treating patients in Canada in the first quarter of 2019."

About Helius Medical Technologies, Inc.

Helius Medical Technologies is a neurotech company focused on neurological wellness. The Company's purpose is to develop, license and acquire unique and non-invasive platform technologies that amplify the brain's ability to heal itself. The Company's first product in development is the Portable Neuromodulation Stimulator (PoNS). For more information, visit www.heliusmedical.com.

About the PoNS Device and PoNS Treatment

The Portable Neuromodulation Stimulator (PoNS) is a Class II Medical Device cleared for commercial distribution in Canada and an investigational, non-invasive, medical device currently under review by the United States Food and Drug Administration for clearance to improve balance in patients following a mild-to-moderate traumatic brain injury (mTBI) when combined with targeted physical therapy. PoNS Treatment is the first and only tongue-delivered neuromodulation treatment being developed to combine stimulation of cranial nerves with physical and cognitive therapy to restore lost neurological function. The Company's trials investigating the PoNS in traumatic brain injury are more fully discussed in the Company's disclosure materials, including its Annual Report on Form 10-K and other filings with the United States Securities and Exchange Commission.

Cautionary Disclaimer 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. Such forward-looking statements include, among others, statements concerning the expected timing for the Company's Heuro Canada neuroplasticity clinics becoming operational and the initiation of treatment of patients in Canada.

Forward-looking statements are often identified by terms such as "believe", "will", "may", "should", "anticipate", "expects", "estimate", "intend" and similar expressions.

There can be no assurance that such statements will prove to be accurate and actual results and future events could differ materially from those anticipated in such statements. Important factors that could cause actual results to differ materially from the Company's expectations include the possibility that Heuro clinics take longer to set up and patient recruitment takes longer than projected, the possibility that the manufacturing of commercial PoNS devices takes longer than projected, the implementation of the distribution infrastructure takes longer than expected, the Company's need to raise additional capital to achieve its business objectives and other risks detailed from time to time in the filings made by the Company with securities regulators.

The reader is cautioned that assumptions used in the preparation of any forward-looking statements may prove to be incorrect. Events or circumstances may cause actual results to differ materially from those predicted, as a result of numerous known and unknown risks, uncertainties, and other factors, many of which are beyond the control of the Company. The reader is cautioned not to place undue reliance on any forward-looking statement. Such information, although considered reasonable by management at the time of preparation, may prove to be incorrect and actual results may differ materially from those anticipated. Forward-looking statements contained in this news release are expressly qualified by this cautionary statement. Risks and uncertainties about the Company's business are more fully discussed in the Company's disclosure materials, including its Annual Report on Form 10-K for the year ended December 31, 2017, its Quarterly Reports on Form 10-Q for the quarters ended March 31, 2018 and June 30, 2018 and its other filings with the United States Securities and Exchange Commission and the Canadian securities regulators and which can be obtained from either at www.sec.gov or www.sedar.com.

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.

The Toronto Stock Exchange has not reviewed and does not accept responsibility for the adequacy or accuracy of the content of this news release.

About HealthTech Connex, Inc.

HealthTech Connex, Inc. is a health technology company working to revolutionize the practice of clinical neuroscience through advanced technologies based on the highest quality science and innovation. Located

in Surrey, British Columbia, Canada, it is one of the first companies to emerge from the city's Innovation Boulevard, an agile partnership of health, business, higher education and government creating new health technologies to improve peoples' lives. www.HealthTechConnex.com

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Westwicke Partners on behalf of Helius Medical Technologies, Inc.

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