

**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**

**May 14, 2018**

Date of Report (Date of earliest event reported)



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

**WYOMING**  
(State or other jurisdiction of  
incorporation or organization)

**001-38445**  
(Commission  
File Number)

**36-4787690**  
(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

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## Item 8.01 Other Events

Helius Medical Technologies, Inc. (the “Company”) is providing the following information to update and clarify the risk factor related to the Cooperative Research And Development Agreement (“CRADA”) with the U.S. Army Medical Research and Materiel Command (“USAMRC”) included in the Company’s Annual Report on Form 10-K (the “Form 10-K”). The following language replaces and supersedes the risk factor included in the Form 10-K in its entirety:

***If we fail to obtain FDA authorization for commercialization of or otherwise fail to ensure that the PoNS device is available for purchase by the U.S. Government by December 31, 2021, we are subject to significant risk of loss of data and proprietary rights and to certain contractual penalties.***

Under the CRADA, if we fail to obtain FDA marketing authorization of the PoNS device by December 31, 2021 we would be in breach of the CRADA should the army and the Company decide not to extend the CRADA termination date. In addition, if the company fails to ensure commercialization of the PoNS Treatment is available for purchase by the U.S. Government by December 31, 2021, we may forfeit the right to pursue commercialization on our own. Specifically, if we do not commercialize the PoNS by December 31, 2021, we may be required to (i) transfer possession, ownership and sponsorship of any regulatory application, and correspondence supporting the PoNS technology to the USAMRMC and (ii) provide the U.S. Government with a non-exclusive, irrevocable license to any patent, copyright, data rights, proprietary information and regulatory information, in order to permit the U.S. Government to pursue commercialization on its own. Any such loss of our ability to exclusively market and sell the PoNS Treatment would have a material adverse effect on our business.

Additionally, under our Strategic Agreement with A&B (HK) Company Ltd., or A&B, if we fail to obtain FDA marketing authorization for commercialization, or otherwise fail to ensure that the PoNS device is available for purchase by the U.S. Government, by December 31, 2021, we may be required to pay a \$2.0 million contract penalty to A&B.

**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: May 14, 2018

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