

**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): September 24, 2025



HELIUS MEDICAL TECHNOLOGIES, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)	001-38445 (Commission File Number)	36-4787690 (IRS Employer Identification No.)
642 Newtown Yardley Road, Suite 100 Newtown, PA (Address of principal executive offices)		18940 (Zip Code)

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

N/A

(Former name or former address, if changed since last report)

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))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Class A Common Stock, \$0.001 par value	HSDT	The Nasdaq Stock Market LLC

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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On September 24, 2025, Helius Medical Technologies, Inc. (the “Company”) entered into side letter agreements with Dane C. Andreeff, President and Chief Executive Officer, and Jeffrey S. Mathiesen, Chief Financial Officer, Treasurer and Secretary (together, the “Side Letters”). The Side Letters provide for one-time discretionary cash bonuses paid to Mr. Andreeff and Mr. Mathiesen in amounts equal to \$890,000 and \$610,000, respectively (together, the “Cash Bonuses”). The Cash Bonuses will directly offset any severance, bonus opportunity, equity, retirement or other benefit under any plan or arrangement of the Company to which Mr. Andreeff and Mr. Mathiesen would otherwise be entitled.

In consideration of the payment of the Cash Bonuses, each of Mr. Andreeff and Mr. Mathiesen have agreed that the offerings consummated on September 18, 2025, as previously disclosed in the Company’s Current Report on Form 8-K filed on September 18, 2025, do not constitute a Change in Control (as defined in Mr. Andreeff’s and Mr. Mathiesen’s employment agreements, as applicable (together, the “Employment Agreements”) or give rise to an event constituting Good Reason under the Employment Agreements. To the extent any amounts become due or claimed to be due to Mr. Andreeff or Mr. Mathiesen under the Employment Agreements or otherwise upon or following any termination of Mr. Andreeff’s or Mr. Mathiesen’s employment with the Company, including without limitation any severance, change-in-control severance, pro-rata bonus, continued COBRA subsidies, or other cash amounts, such amount will be offset dollar-for-dollar against the Cash Bonuses, as applicable.

The foregoing description of the Side Letters does not purport to be complete and is qualified in its entirety by the terms and conditions of the Side Letters, which are attached hereto as Exhibits 10.1 and 10.2, respectively, to this Current Report on Form 8-K (this “Report”) and are incorporated herein by reference.

Item 7.01 Regulation FD Disclosure.

On September 25, 2025, the Company issued a press release announced the filing of its U.S. Food and Drug Administration (“FDA”) 510(k) submission for the Portable Neuromodulation Stimulator device label expansion seeking an indication for gait and balance deficit in patients with chronic stroke symptoms. The submission was made with data generated in the Company’s Stroke Registrational Program and was filed under its current FDA Breakthrough Device Designation.

A copy of the press release is furnished as Exhibit 99.1 to this Report and incorporated herein by reference.

Information contained on or accessible through any website reference in the press release is not part of, or incorporated by reference in, this Report, and the inclusion of such website addresses in this Report by incorporation by reference of the press release is as inactive textual references only.

Exhibit 99.1 hereto contains forward-looking statements within the meaning of the federal securities laws. These forward-looking statements are based on current expectations and are not guarantees of future performance. Further, the forward-looking statements are subject to the limitations listed in Exhibit 99.1 and in the other reports of the Company filed with the Securities and Exchange Commission, including that actual events or results may differ materially from those in the forward-looking statements.

The information in this Report, including Exhibit 99.1 hereto, is furnished pursuant to Item 7.01 and shall not be deemed “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, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such

filing. The Company's submission of this Report shall not be deemed an admission as to the materiality of any information required to be disclosed solely to satisfy the requirements of Regulation FD.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
10.1	Side Letter, dated as of September 24, 2025, between the Company and Dane C. Andreeff.
10.2	Side Letter, dated as of September 24, 2025, between the Company and Jeffrey S. Mathiesen.
99.1	Press Release, dated September 25, 2025.
104	Cover Page Interactive Data File (embedded within Inline XBRL document).



642 Newtown Yardley Road, Suite 100
Newtown, PA 18940
215.944.6100
<https://heliusmedical.com/>

September 24, 2025

Personal and Confidential

Dane C. Andreeff
140 East St. Lucia Lane
Santa Rosa Beach, Florida 32459

Re: *Project Sumtera*

Dear Mr. Andreeff:

This Letter Agreement (this "**Letter Agreement**") is entered into by and between Helius Medical Technologies, Inc., a Delaware corporation (the "**Company**") and you, Dane Andreeff (the "**Executive**"), effective as of September 24, 2025. Reference is made to that certain Employment Agreement dated June 14, 2021 entered into by and between the Company and the Executive (as amended, the "**Employment Agreement**"). Capitalized terms used but not defined in this Letter Agreement have the meanings given in the Employment Agreement.

1. TRANSACTION BONUS. In consideration of the agreements in this Letter Agreement, the Company hereby agrees to pay you a one-time discretionary cash bonus in the gross amount of \$890,000.00 (the "**Bonus**"), less required withholdings, payable on within 6 business days following the closing of the Transaction, provided you remain employed by the Company through such payment date (unless otherwise agreed in writing). The Bonus is a special, discretionary payment, will directly offset any severance, bonus opportunity, equity, retirement or other benefit under any plan or arrangement of the Company unless required by law, and is not intended to create any ongoing or recurring entitlement. For purposes of this Letter Agreement, "**Transaction**" means the transaction whereby the Company entered into those certain securities purchase agreements dated September 15, 2025 with certain accredited investors pursuant to which the Company agreed to sell and issue to such investors in a private placement (i) shares of the Company's common stock; (ii) pre-funded warrants to purchase shares of common stock and (iii) stapled warrants to purchase shares of common stock, together with any related agreements, transactions or understandings entered into by the Company ancillary thereto.

2. WAIVER; NO CHANGE IN CONTROL OR GOOD REASON. In consideration of the payment of the Bonus and the agreements set forth in this Letter Agreement, the Executive acknowledges and agrees that the Transaction and any actions taken in connection therewith (including changes as they may relate to the Executive in reporting lines, organizational structure or equity terms related to the Transaction) do not, and will not, constitute a Change in Control or give rise to an event constituting Good Reason under the Employment Agreement. In addition, upon receipt of the Bonus, the Executive irrevocably waives and releases any right to assert that the Transaction constitutes a Change in Control. For the avoidance of doubt, this waiver is limited to the Transaction and actions reasonably related thereto and does not waive Good Reason rights arising from events unrelated to the Transaction that occur after the closing date of the Transaction, subject to the Employment Agreement's notice and cure provisions.

3. OFFSET; CREDIT; REPAYMENT. Both the Company and the Executive hereby agree that the Bonus will be offset dollar-for-dollar against, and the Company may set off or recoup the Bonus from, any and all amounts that may become due or claimed to be due to the Executive under the Employment Agreement or otherwise upon or following any termination of the Executive's employment with the Company, including without limitation any severance, change-in-control severance, pro-rata bonus, continued COBRA subsidies, or other cash amounts (collectively, the "**Termination Amounts**"). If and to the extent any setoff or recoupment described above is not permitted by applicable law or would result in noncompliance with Section 409A of the Internal Revenue Code ("**Section 409A**"), the Executive agrees to promptly repay to the Company, upon written demand and in no event later than thirty (30) days thereafter, an amount equal to the lesser of (i) the Bonus (net of taxes previously withheld) and (ii) the aggregate cash value of the Termination Amounts (net of taxes withheld) actually paid to the Executive, until the Bonus has been fully recovered. The parties will cooperate in good faith to implement any lawful alternative that

achieves the economic effect of this Section 3 while complying with applicable law and Section 409A. Nothing herein permits any deduction from wages where prohibited by law; this Section 3 will be applied to non-wage amounts first and otherwise to the maximum extent permitted by law.

4. SECTION 409A. This Letter Agreement is intended to be administered and interpreted to comply with, or be exempt from, Section 409A. Any right of setoff, recoupment, or repayment will be effected only to the extent permitted under Section 409A. Each payment hereunder is a separate payment for Section 409A purposes.

5. NO OTHER AMENDMENTS; CLAWBACK. Except as expressly set forth herein, the Employment Agreement and the Executive's equity and benefit arrangements remain in full force and effect. This Letter Agreement does not constitute a general release of claims. The Bonus is subject to the Company's clawback, recoupment, and compensation recovery policies as in effect from time to time and to applicable law and Nasdaq listing standards.

6. GOVERNING LAW; ENTIRE AGREEMENT; COUNTERPARTS. This Letter Agreement will be governed by and construed in accordance with the laws of the State of Delaware, without regard to its conflict of laws rules. This Letter Agreement, together with the Employment Agreement, constitutes the entire agreement of the parties with respect to the subject matter hereof and supersedes any prior discussions on such subject. This Letter Agreement may be executed in counterparts (including by electronic signature or PDF), each of which will be deemed an original and together constitute one agreement.

IN WITNESS WHEREOF, the Company and the Executive have caused this Letter Agreement have caused their signatures to this Letter Agreement to be duly executed as of the date first written above.

THE COMPANY:

THE EXECUTIVE:

HELIUS MEDICAL TECHNOLOGIES, INC.

By: /s/ Jeffrey S. Mathiesen
Name: Jeffrey S. Mathiesen
Title: Chief Financial Officer, Treasurer and
Secretary

/s/ Dane Andreeff
DANE ANDREEFF



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Newtown, PA 18940
215.944.6100
<https://heliusmedical.com/>

September 24, 2025

Personal and Confidential

Jeffrey S. Mathiesen
12784 Kinross Lane
Naples, Florida 34120

Re: *Project Sumtera*

Dear Mr. Mathiesen:

This Letter Agreement (this "***Letter Agreement***") is entered into by and between Helius Medical Technologies, Inc., a Delaware corporation (the "***Company***") and you, Jeffrey S. Mathiesen (the "***Executive***"), effective as of September 24, 2025. Reference is made to that certain Employment Agreement dated June 14, 2021 entered into by and between the Company and the Executive (as amended, the "***Employment Agreement***").

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THE COMPANY:

THE EXECUTIVE:

HELIUS MEDICAL TECHNOLOGIES, INC.

By: /s/ Dane C. Andreeff
Name: Dane C. Andreeff
Title: President and Chief Executive Officer

/s/ Jeffrey S. Mathiesen
JEFFREY S. MATHIESEN

Helius Announces FDA 510(k) Submission for PoNS® Device Label Expansion in Stroke

Seeking an indication for gait and balance deficit in patients with chronic symptoms of stroke under its Breakthrough Device Designation

NEWTOWN, Pa., Sept 25, 2025 (GLOBE NEWSWIRE) -- Helius Medical Technologies, Inc. (NASDAQ: HSDT), today announced the filing of its U.S. Food and Drug Administration (FDA) 510(k) submission for the PoNS (Portable Neuromodulation Stimulator) device label expansion seeking an indication for gait and balance deficit in patients with chronic stroke symptoms. The submission was made with data generated in its Stroke Registrational Program (SRP) and was filed under its current FDA Breakthrough Device Designation.

All statistical analyses for the Functional Gait Assessment (FGA) primary endpoint demonstrated PoNS superior effectiveness in improving gait deficit by achieving a clinically meaningful mean improvement of more than 5 points, which was statistically significant across all studies ($p < 0.05$) and was maintained for at least 12 weeks after completion of the therapy. Conversely the control group achieved, across all trials, a mean FGA improvement of less than 4 points, which fell below the 4.2-point Minimal Detectable Change (MDC) that reflects clinical meaningfulness of the therapeutic intervention.

“Substantial evidence across the SRP trials supports the superiority of active PoNS Therapy® as compared to physical therapy alone, when applied in standard clinical settings for stroke rehabilitation,” said Antonella Favit-Van Pelt, M.D., Ph.D., Helius’ Chief Medical Officer. “The totality of data in stroke survivors with gait deficits confirms the broader evidence of PoNS therapeutic effect in improving walking disability by enhancing and potentiating the benefit of physical therapy. Consistent with the existing body of clinical evidence, PoNS also confirms to be a safe and well tolerated therapy.”

PoNS efficacy and safety was clinically established from three clinical trials across 10 sites and 159 enrolled chronic stroke survivors with gait deficit due to stroke. The studies were structured to assess the effectiveness and safety of the PoNS device in conjunction with routine physical rehabilitation therapy over a 12-week treatment period. Participants were also followed for 12 weeks after completion of treatment to assess durability of treatment effect. Primary efficacy endpoints for gait (by FGA) and balance (by the Berg Balance Score), as well as key secondary endpoints including risk of falling (determined by FGA < 23) and durability of effect (established at $< 30\%$ reduction of FGA improvement 12 week after completion of study treatment) were analyzed, across the two pivotal studies, using a propensity score design methodology adjusted for multiplicity control. Study success was achieved by demonstrating superiority, using the Hochberg method, for either primary endpoint, which, then, allowed for analysis of the key secondary endpoints with the same methodology.

Overall, the primary endpoint was met and statistically significant for the FGA primary endpoint. In the primary analysis of the pooled pivotal randomized controlled and single-arm studies, treatment with active PoNS plus physical therapy (PT) led to an adjusted mean change in FGA of 5.37 points (95% CI: 4.23 to 6.52) at Week 12 as compared to a change of 3.31 points (95% CI 1.96 to 4.76) in the control group (sham PoNS plus PT). The treatment group difference by propensity adjustment was 2.06 (95% CI 0.29 to 3.84) with a 2-sided p-value of 0.0233 that met the Hochberg requirement for multiplicity (< 0.025) and, therefore, demonstrated statistical superiority. Durability of active PoNS therapeutic effect achieved at Week 12 was also demonstrated, with a mean percentage reduction in FGA ranging between -

4.71% and -4.97% and with 89.7% (95% CI 81.8% to 97.5%) of subjects meeting the durability performance goal. Improvement from baseline to Week 12 was also demonstrated for BBS in the active PoNS group although it did not reach statistically significant between-group separation. Similarly, risk of falling was resolved in 17.4% of subjects in the active PoNS group as compared to 8.9% in the control subjects, albeit not statistically significant. Treatment with PoNS was confirmed to be safe and well-tolerated with no incidence of treatment-related SAEs, across the SRP trials and existing RWE data, and adverse events (ranging between 0.0% and 14.8%) that were unrelated to the PoNS device.

"Submitting our 510(k) application to the FDA brings the benefits on gait from PoNS Therapy one step closer to stroke patients," said Dane Andreeff, CEO of Helius. "I'm incredibly proud of our team and thankful to the clinicians who facilitated this trial as we work together to increase patient access to this powerful therapy. We're optimistic about a positive FDA outcome and the opportunity to support those living with the effects of stroke."

About the PoNS Device and PoNS Therapy

The Portable Neuromodulation Stimulator ("PoNS") is an innovative, non-implantable, orally applied therapy that delivers neurostimulation through a mouthpiece connected to a controller and it's used, primarily at home, with physical rehabilitation exercise, to improve balance and gait. The PoNS device, which delivers mild electrical impulses to the tongue, is indicated for use in the United States as a short-term treatment of gait deficit due to mild-to-moderate symptoms from 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.

PoNS has shown effectiveness in treating gait or balance and a significant reduction in the risk of falling in stroke patients in Canada, where it received authorization for sale in three indications: (i) for use as a short-term treatment (14 weeks) of gait deficit due to mild and moderate symptoms from stroke and is to be used in conjunction with physical therapy; (ii) for use as a short-term treatment (14 weeks) of chronic balance deficit due to mild-to-moderate traumatic brain injury ("mTBI") and is to be used in conjunction with physical therapy; and (iii) 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. For more information visit www.ponstherapy.com.

About Helius Medical Technologies, Inc.

Helius Medical Technologies is a leading neurotech company in the medical device field focused on neurologic deficits using orally applied technology platform that amplifies the brain's ability to engage physiologic compensatory mechanisms and promote neuroplasticity, improving the lives of people dealing with neurologic diseases. The Company's first commercial product is the Portable Neuromodulation Stimulator. For more information about the PoNS or Helius Medical Technologies, visit www.heliusmedical.com.

The Company has adopted a digital asset treasury strategy focused on accumulating SOL, the native digital asset of the Solana blockchain, leveraging capital markets raises that produce consistent on-chain yield generation. Helius will provide access to the Solana network.

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. Forward-looking statements are often identified by terms such as “believe,” “expect,” “continue,” “will,” “goal,” “aim” and similar expressions. Such forward-looking statements include, among others, statements regarding future presentation and uses of the SRP study results, successful outcome of the FDA submission, the availability of commercial reimbursement and the uses and effectiveness of PoNS and PoNS Therapy.

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, the Company’s ability to find additional sources of funding, manufacturing, labor shortage and supply chain risks, including risks related to manufacturing delays, the Company’s ability to obtain national Medicare insurance coverage and to obtain a reimbursement code, the Company’s ability to continue to build internal commercial infrastructure, secure state distribution licenses, market awareness of the PoNS device, future clinical trials and the clinical development process, the product development process and the 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, 2023, 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.

Investor Relations Contact

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