
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2025

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission File No. 001-38445

HELIUS MEDICAL TECHNOLOGIES, INC.

(Exact name of Registrant as specified in its charter)

Delaware	36-4787690
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
642 Newtown Yardley Road, Suite 100 Newtown, Pennsylvania	18940
(Address of principal executive offices)	(Zip Code)
(215) 944-6100	
(Registrant's telephone number, including area code)	

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 per share	HSDT	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of April 28, 2025, the registrant had 7,920,928 shares of Class A common stock, \$0.001 par value per share, outstanding.

HELIUS MEDICAL TECHNOLOGIES, INC.
INDEX

<u>Part I.</u>	<u>Financial Information</u>	
<u>Item 1.</u>	<u>Condensed Consolidated Financial Statements</u>	3
	<u>Unaudited Condensed Consolidated Balance Sheets as of March 31, 2025 and December 31, 2024</u>	3
	<u>Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss for the three months ended March 31, 2025 and 2024</u>	4
	<u>Unaudited Condensed Consolidated Statements of Stockholders' Equity for the three months ended March 31, 2025 and 2024</u>	5
	<u>Unaudited Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2025 and 2024</u>	6
	<u>Notes to Unaudited Condensed Consolidated Financial Statements</u>	7
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	16
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	24
<u>Item 4.</u>	<u>Controls and Procedures</u>	24
<u>Part II.</u>	<u>Other Information</u>	25
<u>Item 1.</u>	<u>Legal Proceedings</u>	25
<u>Item 1A.</u>	<u>Risk Factors</u>	25
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	26
<u>Item 3.</u>	<u>Defaults Upon Senior Securities</u>	26
<u>Item 4.</u>	<u>Mine Safety Disclosures</u>	26
<u>Item 5.</u>	<u>Other Information</u>	26
<u>Item 6.</u>	<u>Exhibits</u>	27
	<u>Signatures</u>	28

PART I. FINANCIAL INFORMATION

ITEM 1. Condensed Consolidated Financial Statements

Helius Medical Technologies, Inc.**Unaudited Condensed Consolidated Balance Sheets**

(in thousands, except share data)

	<u>March 31, 2025</u>	<u>December 31, 2024</u>
ASSETS		
Current assets		
Cash and cash equivalents	\$ 1,109	\$ 1,088
Accounts receivable, net	—	70
Other receivables	502	565
Inventory, net	1,113	1,036
Prepaid expenses and other current assets	661	665
Total current assets	3,385	3,424
Property and equipment, net	99	107
Operating lease right-of-use asset, net	—	11
Total assets	<u>\$ 3,484</u>	<u>\$ 3,542</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 1,231	\$ 873
Accrued and other current liabilities	733	1,239
Current portion of operating lease liabilities	—	12
Current portion of deferred revenue	39	39
Total current liabilities	2,003	2,163
Deferred revenue, net of current portion	69	79
Derivative liability	132	241
Total liabilities	<u>2,204</u>	<u>2,483</u>
Commitments and contingencies (Note 9)		
Stockholders' equity		
Class A common stock, \$0.001 par value; 150,000,000 shares authorized; 6,126,778 and 3,728,172 shares issued and outstanding as of March 31, 2025 and December 31, 2024, respectively	6	4
Additional paid-in capital	174,686	172,421
Shares to be issued, 2,678,000 shares of Class A common stock as of March 31, 2025 (Note 6)	1,843	—
Accumulated deficit	(175,537)	(171,699)
Accumulated other comprehensive loss	282	333
Total stockholders' equity	<u>1,280</u>	<u>1,059</u>
Total liabilities and stockholders' equity	<u>\$ 3,484</u>	<u>\$ 3,542</u>

The accompanying notes are an integral part of the unaudited condensed consolidated financial statements.

Helius Medical Technologies, Inc.

Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2025	2024
Revenue		
Product sales, net	\$ 38	\$ 124
Other revenue	11	11
Total revenue	49	135
Cost of revenue	121	123
Gross (loss) profit	(72)	12
Operating expenses		
Selling, general and administrative expenses	2,994	2,633
Research and development expenses	945	788
Amortization expense	—	7
Total operating expenses	3,939	3,428
Loss from operations	(4,011)	(3,416)
Nonoperating income		
Interest expense, net	(6)	(8)
Change in fair value of derivative liability	109	1,142
Foreign exchange gain (loss)	50	(288)
Other income, net	20	54
Nonoperating income, net	173	900
Loss before provision for income taxes	(3,838)	(2,516)
Provision for income taxes	—	—
Net loss	(3,838)	(2,516)
Other comprehensive (loss) income		
Foreign currency translation adjustments	(51)	288
Comprehensive loss	\$ (3,889)	\$ (2,228)
Loss per share		
Basic	\$ (0.51)	\$ (3.08)
Diluted	\$ (0.51)	\$ (3.08)
Weighted average number of common shares outstanding		
Basic	7,556,267	817,327
Diluted	7,556,267	817,327

The accompanying notes are an integral part of the unaudited condensed consolidated financial statements.

Helius Medical Technologies, Inc.
Unaudited Condensed Consolidated Statements of Stockholders' Equity
(in thousands, except share data)

	Class A Common Stock		Additional Paid-In Capital	Shares To Be Issued		Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares	Amount		Shares	Amount			
Balance as of January 1, 2025	3,728,172	\$ 4	\$172,421	—	\$ —	\$(171,699)	\$ 333	\$ 1,059
Issuance of common stock in public offering	93,300	—	77	—	—	—	—	77
Share issuance costs	—	—	(10)	—	—	—	—	(10)
Exercise of warrants, net of issuance costs	2,305,306	2	1,576	2,678,000	1,843	—	—	3,421
Stock-based compensation	—	—	622	—	—	—	—	622
Other comprehensive loss	—	—	—	—	—	—	(51)	(51)
Net loss	—	—	—	—	—	(3,838)	—	(3,838)
Balance as of March 31, 2025	<u>6,126,778</u>	<u>\$ 6</u>	<u>\$174,686</u>	<u>2,678,000</u>	<u>\$1,843</u>	<u>\$(175,537)</u>	<u>\$ 282</u>	<u>\$ 1,280</u>

	Class A Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares	Amount				
Balance as of January 1, 2024	714,590	\$ 1	\$ 162,979	\$(159,957)	\$(673)	\$ 2,350
Issuance of common stock in public offering	148,201	—	1,374	—	—	1,374
Share issuance costs	—	—	(174)	—	—	(174)
Exercise of warrants	23,400	—	263	—	—	263
Settlement of restricted stock units	1,656	—	—	—	—	—
Stock-based compensation	—	—	401	—	—	401
Other comprehensive income	—	—	—	—	288	288
Net loss	—	—	—	(2,516)	—	(2,516)
Balance as of March 31, 2024	<u>887,847</u>	<u>\$ 1</u>	<u>\$ 164,843</u>	<u>\$(162,473)</u>	<u>\$(385)</u>	<u>\$ 1,986</u>

The accompanying notes are an integral part of the unaudited condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2025	2024
Cash flows from operating activities:		
Net loss	\$ (3,838)	\$ (2,516)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of derivative liability	(109)	(1,142)
Stock-based compensation expense	622	401
Foreign exchange (gain) loss	(50)	288
Depreciation expense	8	9
Amortization expense	—	7
Provision for (reversal of) inventory reserve	5	(19)
Non-cash operating lease expense	11	10
Changes in operating assets and liabilities:		
Accounts receivable	70	66
Other receivables	63	6
Inventory	(82)	92
Prepaid expense and other current assets	5	120
Operating lease liabilities	(12)	(11)
Accounts payable	289	284
Accrued and other current liabilities	(508)	(586)
Deferred revenue	(10)	(10)
Net cash used in operating activities	<u>(3,536)</u>	<u>(3,001)</u>
Cash flows from investing activities:		
Purchase of property and equipment	—	(5)
Net cash used in investing activities	<u>—</u>	<u>(5)</u>
Cash flows from financing activities:		
Proceeds from issuance of common stock	77	1,374
Proceeds from exercise of warrants	3,733	162
Payment of deferred offering costs	—	(31)
Share issuance costs	(253)	(42)
Net cash provided by financing activities	<u>3,557</u>	<u>1,463</u>
Effect of currency exchange rate changes on cash and cash equivalents	—	(1)
Net increase (decrease) in cash and cash equivalents	21	(1,544)
Cash and cash equivalents at beginning of period	1,088	5,182
Cash and cash equivalents at end of period	<u>\$ 1,109</u>	<u>\$ 3,638</u>
Supplemental cash flow information		
Non-cash investing and financing transactions:		
Derivative warrant liability reclassified to equity on exercise of warrants	\$ —	\$ 101
Deferred offering costs reclassified to equity upon public offering	\$ 8	\$ 132
Share issuance costs included in accounts payable	\$ 61	\$ —

The accompanying notes are an integral part of the unaudited condensed consolidated financial statements.

Helius Medical Technologies, Inc.
Notes to Unaudited Condensed Consolidated Financial Statements

1. BASIS OF PRESENTATION

The accompanying interim unaudited condensed consolidated financial statements of Helius Medical Technologies, Inc. (together with its wholly owned subsidiaries the “Company”) have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (“SEC”) and should be read in conjunction with the audited consolidated financial statements and notes included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2024 that was filed with the Securities and Exchange Commission on March 25, 2025 (“2024 10-K”). Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles in the United States of America (“GAAP”) have been condensed or omitted.

There have been no material changes to the Company's significant accounting policies from those described in the 2024 Form 10-K. Certain prior period amounts have been reclassified to conform to the current period presentation.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements. Actual results could differ from those estimates.

In the opinion of management, the unaudited condensed consolidated financial statements reflect all adjustments necessary for a fair statement of the results for the interim periods presented. All such adjustments, unless otherwise noted herein, are of a normal, recurring nature. The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the full year.

Going Concern Uncertainty

As of March 31, 2025, the Company had cash and cash equivalents of \$1.1 million. For the three months ended March 31, 2025, the Company had an operating loss of \$4.0 million, and as of March 31, 2025, its accumulated deficit was \$175.5 million. For the three months ended March 31, 2025, the Company had \$38 thousand of net revenue from the commercial sale of products. The Company expects to continue to incur operating losses and net cash outflows until such time as it generates a level of revenue to support its cost structure. There is no assurance that the Company will achieve profitable operations, and, if achieved, whether it will be sustained on a continued basis. These factors indicate substantial doubt about the Company’s ability to continue as a going concern within one year after the date the unaudited condensed consolidated financial statements are filed. The Company’s unaudited condensed consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and satisfaction of liabilities in the ordinary course of business; no adjustments have been made relating to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company not continue as a going concern.

The Company intends to fund ongoing activities by utilizing its current cash and cash equivalents on hand, cash received from the sale of its PoNS device in the U.S. and Canada and by raising additional capital through equity or debt financings. There can be no assurance that we will be successful in raising additional capital or that such capital, if available, will be on terms that are acceptable to us. If we are unable to raise sufficient additional capital, we may be compelled to reduce the scope of our operations and planned capital expenditures or sell certain assets, including intellectual property, and we may be forced to cease or wind down operations, seek protection under the provisions of the U.S. Bankruptcy Code, or liquidate and dissolve our company.

Global Economic Conditions

Generally, worldwide economic conditions remain uncertain, particularly due to the conflict between Russia and Ukraine, as well as in the Middle East between Israel and Hamas, disruptions in the banking system and financial markets, increased inflation, sustained high interest rates and unpredictable trade policies, including tariffs, customs regulations and other trade restrictions. The general economic and capital market conditions both in the United States and worldwide, have been volatile in the past and at times have adversely affected the Company’s access to capital and

increased the cost of capital. The capital and credit markets may not be available to support future capital raising activity on favorable terms. If economic conditions decline, the Company's future cost of equity or debt capital and access to the capital markets could be adversely affected.

Changes in economic conditions, trade restrictions, high interest rates, supply chain constraints, logistics challenges, labor shortages, the effects of conflicts in Ukraine and the Middle East, disruptions in the banking system and financial markets, high levels of inflation and an increase in interest rates have increased costs and have had and may continue to have a negative impact on the Company's business. Although the Company has taken and may continue to take measures to mitigate these impacts, if these measures are not effective, the Company's business, financial condition, results of operations, and liquidity could be materially adversely affected.

2. RECENT ACCOUNTING PRONOUNCEMENTS

In November 2024, the FASB issued ASU 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses. ASU 2024-03 requires interim and annual tabular disclosure of disaggregated information for certain income statement expense captions. Specific expense categories required to be disclosed quantitatively include inventory purchases, employee compensation, depreciation, and intangible asset amortization, as well as other specified expense categories currently disclosed under existing disclosure requirements. Additionally, any remaining amounts that are not separately disaggregated are required to be described qualitatively. ASU 2024-03 also requires separate disclosure of total selling expenses incurred each reporting period, with annual disclosure of the entity's definition of selling expenses. The annual disclosures required by ASU 2024-03 are effective for the Company beginning in its fiscal year ending December 31, 2027, with interim disclosures effective beginning in its fiscal year ending December 31, 2028. The provisions of ASU 2024-03 are to be applied prospectively, although retrospective application is permitted. Early adoption is also permitted. The Company is currently evaluating the ASU to determine its impact on the Company's disclosures.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. The guidance requires expanded annual disclosures including the standardization and disaggregation of income tax rate reconciliation categories and the amount of income taxes paid by jurisdiction. The guidance is effective for the Company beginning in its fiscal year ending December 31, 2025. The Company is currently evaluating the ASU to determine its impact on the Company's disclosures.

In March 2024, the SEC adopted rules under SEC Release No. 33-11275, The Enhancement and Standardization of Climate-Related Disclosures for Investors, which requires the disclosure of material Scope 1 and Scope 2 greenhouse gas emissions and other climate-related topics in annual reports and registration statements. For non-accelerated filers and smaller reporting companies, disclosure requirements will begin phasing in for fiscal years beginning on or after January 1, 2027, subject to legal challenges and the SEC's voluntary stay of the disclosure requirements. The Company is currently evaluating the impact these rules will have on its consolidated financial statements and related disclosures.

3. SUPPLEMENTAL BALANCE SHEET DISCLOSURES

Components of selected captions in the unaudited condensed consolidated balance sheets consisted of the following:

Accounts receivable, net

Accounts receivable from product sales are net of allowance for credit losses. The allowance for credit losses was \$0 as of both March 31, 2025 and December 31, 2024.

Inventory, net (in thousands)

	March 31, 2025	December 31, 2024
Raw materials	\$ 575	\$ 576
Work-in-process	391	402
Finished goods	239	145
Inventory, gross	1,205	1,123
Inventory reserve	(92)	(87)
Inventory, net	<u>\$ 1,113</u>	<u>\$ 1,036</u>

During the three months ended March 31, 2025, no inventory was written off to the inventory reserve.

Prepaid expenses and other current assets (in thousands)

	March 31, 2025	December 31, 2024
Prepaid expenses	\$ 632	\$ 603
Inventory related	20	55
Deferred offering costs	9	7
Total prepaid expenses and other current assets	<u>\$ 661</u>	<u>\$ 665</u>

Accrued and other current liabilities (in thousands)

	March 31, 2025	December 31, 2024
Insurance payable	\$ 224	\$ 356
Employees benefits	404	759
Professional services	34	24
Franchise tax	50	—
Other	21	100
Total accrued and other current liabilities	<u>\$ 733</u>	<u>\$ 1,239</u>

Deferred revenue

Exclusive Distribution Agreement

Pursuant to an Exclusive Distribution Agreement with Health Tech Connex Inc. (“HTC”) (“Exclusivity Agreement”) entered into on March 3, 2023, subject to certain terms and conditions, the Company granted to HTC the exclusive right to provide PoNS Therapy in the Fraser Valley and Vancouver metro regions of British Columbia. HTC will purchase the PoNS devices for use in these regions exclusively from the Company and on terms no less favorable than the then-current standard terms and conditions. This Exclusivity Agreement replaced the previous Clinical Research and Co-Promotion Agreement (“Co-Promotion Agreement”) between the parties entered into in October 2019 that included a similar exclusive right provision. The exclusive right under the Exclusivity Agreement was granted for a value of CAD\$273 thousand, which is represented by the unamortized up-front payment under the former Co-Promotion Agreement. The initial term of the Exclusivity Agreement expires on December 31, 2027, and is renewable by HTC for one additional five-year term upon sixty days’ written notice to the Company.

Deferred revenue as of both March 31, 2025 and December 31, 2024 is comprised of the remaining unamortized amount under the Exclusivity Agreement. Revenue recognized is included in Other revenue in the unaudited condensed consolidated statements of operations and comprehensive loss.

4. LEASES

On January 16, 2025, the Company entered into an agreement to extend the operating lease for the Company's headquarters through March 31, 2026, at a rate of \$4 thousand per month effective April 1, 2025. The lease does not contain any options to extend. Operating lease costs for the three months ended March 31, 2025 and 2024 were \$11 thousand and \$10 thousand, respectively.

Expected operating lease costs as of March 31, 2025 were as follows (in thousands):

2025 (remaining)	\$	37
2026		12
Total lease payments		49

5. FAIR VALUE MEASUREMENTS

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. Fair value of an asset or liability considers assumptions that market participants would use in pricing the asset or liability, including consideration of non-performance risk. The inputs used to determine fair values are categorized in one of the following three levels of the fair value hierarchy:

Level 1 – Quoted market prices in active markets for identical assets or liabilities.

Level 2 – Inputs, other than quoted prices in active markets, that are observable, either directly or indirectly.

Level 3 – Unobservable inputs that are not corroborated by market data.

The unaudited condensed consolidated financial statements include financial instruments for which the fair market value of such instruments may differ from amounts reflected on a historical cost basis. As of March 31, 2025 and December 31, 2024, financial instruments of the Company consist of cash equivalents, which were comprised of deposits of excess cash in an unrestricted money market savings account and a money market mutual fund. The carrying value of cash equivalents generally approximates fair value due to their short-term nature.

The Company's derivative liability as of March 31, 2025 and December 31, 2024 is comprised of warrants issued in connection with the registered public offering completed in August 2022, discussed in more detail in Note 8 to our unaudited condensed consolidated financial statements. The derivative liability is classified as Level 3 within the fair value hierarchy and is required to be recorded at fair value on a recurring basis. See Note 6 for further information on the fair value of the derivative liability.

The majority of the Company's non-financial instruments, which include intangible assets, lease assets, inventories and property and equipment, are not required to be carried at fair value on a recurring basis. However, if certain triggering events occur (or at least annually for indefinite-lived intangible assets), a non-financial instrument is required to be evaluated for impairment. If the Company determines that the non-financial instrument is impaired, the Company would be required to write down the non-financial instrument to its fair value.

6. COMMON STOCK, PREFERRED STOCK AND WARRANTS

Public Offering

On May 9, 2024, the Company closed on a registered public offering consisting of 704,999 shares of Common Stock (the "2024 Public Offering"), pre-funded warrants to purchase 2,147,222 shares of Common Stock (the "Pre-funded Warrants") and accompanying Series A Warrants to purchase up to 2,852,221 shares of its Common Stock ("Series A Warrants") and Series B Warrants to purchase up to 2,852,221 shares of its Common Stock ("Series B Warrants", and together with the Series A Warrants, the "2024 Public Warrants"). The 2024 Public Offering price per share of Common Stock and

accompanying Series A Warrants and Series B Warrants was \$2.25, the public offering price per Pre-funded Warrant and accompanying Series A and Series B warrant was \$2.249.

The Pre-funded Warrants have an exercise price of \$0.001 per share and 1,076,445 were exercised on the closing date. Net proceeds from the 2024 Public Offering, after deducting placement agent fees and expenses and other offering costs, were approximately \$5.5 million.

The 2024 Public Warrants have an exercise price of \$2.25 per share and are exercisable upon issuance. The Series A Warrants will expire five years following the date of issuance and the Series B Warrants will expire twelve months following the date of issuance. The Pre-funded Warrants are exercisable upon issuance and may be exercised at any time until the Pre-funded Warrants are exercised in full.

Warrant inducement

On January 21, 2025, the Company entered into warrant exercise inducement offer letters (the “Inducement Letters”) with certain holders (the “Holders”) of its existing 2024 Public Warrants to purchase shares of the Company’s Class A common stock (the “Existing Warrants”), pursuant to which the Holders agreed to exercise for cash their Existing Warrants to purchase an aggregate of 4,971,110 shares of the Company’s common stock, in the aggregate, at a reduced exercise price of \$0.751 per share, in exchange for the Company’s agreement to issue new Series C Warrants and Series D Warrants (the “Inducement Warrants”) on substantially the same terms as the Existing Warrants described below, to purchase up to 6,213,888 shares of the Company’s common stock (the “Inducement Warrant Shares”). The Company received aggregate gross proceeds of approximately \$3.7 million from the exercise of the Existing Warrants by the Holders. The Company engaged Roth Capital Partners, LLC (“Roth”) to act as its financial advisor with the transactions summarized above and has paid Roth \$0.2 million for its services, in addition to reimbursement for certain expenses along with other legal and regulatory expenses of \$0.1 million resulting in net proceeds of \$3.4 million and non-cash share issuance costs of \$1.0 million and \$3.1 million related to the modification of the Existing Warrants and issuance of the Inducement Warrants, respectively. As of March 31, 2025, 2,678,000 shares (the “Abeyance Shares”) from the exercised Existing Warrants are held in abeyance to be issued at the direction of the Holders due to the ownership limitations from the warrant agreements. On April 15, 2025, 474,000 shares previously held in abeyance were issued to the Holders.

The Company has filed a registration statement on Form S-3 and S-3/A covering the resale of the Inducement Warrant Shares issued or issuable upon the exercise of the Inducement Warrants, which was effective March 27, 2025. In the Inducement Letters, the Company agreed not to issue any shares of common stock or common stock equivalents or to file any other registration statement with the SEC (in each case, subject to certain exceptions) for sixty (60) calendar days. The Company also has agreed not to effect or agree to effect any variable rate transaction (as defined in the Inducement Letters) for seventy-five (75) calendar days from the date of the Inducement Letters.

On April 21, 2025, stockholder approval was obtained for the issuance of the Inducement Warrants at the Company’s annual meeting of stockholders.

At-The-Market Offering

On June 23, 2023, the Company entered into a Sales Agreement (the “Sales Agreement”) with Roth to create an at-the-market offering program (“ATM”) under which the Company may offer and sell shares with an aggregate offering price of up to \$2.0 million. Roth is entitled to a fixed commission rate equal to up to 3% of the gross proceeds pursuant to the Sales Agreement. 93,300 and 148,201 shares have been sold under the ATM generating net proceeds of \$0.1 million and \$1.3 million in 2025 and 2024, respectively.

Warrants

August 2022 Warrants

In connection with the Company's registered public offering that closed on August 9, 2022, the Company issued warrants to purchase an aggregate of 720,000 shares of common stock ("2022 Public Warrants"). The Company performed an analysis of the provisions of the 2022 Public Warrants and concluded that the 2022 Public Warrants did not meet the guidance for being classified as an equity instrument due to a potential price reset prompted by a change in an unrelated instrument's conversion rate or, in the event of a fundamental transaction, settlement rights that differ from those of the underlying common stockholders.

The fair value of the 2022 Warrants as of March 31, 2025 and December 31, 2024 was determined using both a Monte Carlo simulation model, which uses multiple input variables to determine the probability of the occurrence of a price reset or a fundamental transaction and the Black-Scholes option pricing model. The following table includes the share price and the inputs used to estimate the fair value of the warrants:

	March 31, 2025	December 31, 2024
Stock price	\$ 0.40	\$ 0.67
Warrant term (in years)	2.36	2.61
Expected volatility	88.76 %	98.92 %
Risk-free interest rate	3.89 %	4.26 %
Dividend rate	0.00 %	0.00 %

The fair value of the derivative liability associated with the 2022 Warrants as of March 31, 2025 and December 31, 2024 was \$0.1 million and \$0.2 million, respectively. The change in the fair value of the derivative liability was recognized as a component of nonoperating income (expense) in the Company's unaudited condensed consolidated statements of operations and comprehensive loss. No 2022 Warrants were exercised or cancelled during the three months ended March 31, 2025. The remaining outstanding 2022 Warrants to purchase 603,690 shares of Common Stock are classified as a derivative liability as of March 31, 2025, were exercisable upon issuance and will expire five years following the date of issuance.

Equity-classified Warrants

The Company has outstanding equity-classified warrants to purchase 7,097,858 shares of Common Stock at a weighted average exercise price of \$1.87, with expiration dates ranging from February 2026 to May 2029. During the three months ended March 31, 2025, 4,983,306 equity-classified warrants, including 12,222 Pre-funded Warrants and 4,971,110 Exiting Warrants, were exercised for 2,305,306 common shares as the result of the cashless exercise provision for the Pre-Funded Warrants and 2,678,000 Existing Warrants held in abeyance as shares to be issued in connection with the warrant inducement discussed above.

7. STOCK-BASED COMPENSATION

The Company may issue stock-based compensation awards under the Heliuss Medical Technologies, Inc. 2022 Equity Incentive Plan (as amended, the "2022 Plan") or the Heliuss Medical Technologies, Inc. 2021 Inducement Plan (as amended, the "Inducement Plan"), as described more fully in the 2024 10-K. On January 1, 2023, pursuant to the automatic increase provision of the 2022 Plan, the number of shares authorized for issuance increased from 264,319 to 319,941. On May 30, 2024, the Board adopted a First Amendment (the "Amendment") to the 2022 Plan. On June 27, 2024, at the annual meeting of stockholders, the stockholders of the Company approved the Amendment. Pursuant to the terms and conditions of the Amendment, the 2022 Plan was amended to increase the aggregate number of shares of Common Stock that may be issued under the 2022 Plan to 2,089,000 new shares with an automatic increase on January 1st of each year by an amount equal to 5% of the Fully Diluted Shares (as defined in the 2022 Plan) as of the last day of the preceding calendar year. On July 2, 2024, the Company approved an amendment to the Inducement Plan pursuant to which, the Inducement Plan was amended to increase the aggregate number of shares of Common Stock that may be

issued under the Inducement Plan to 150,000 new shares. As of March 31, 2025, the remaining shares available for grant were 9 under the 2022 Plan and 123,910 under the Inducement Plan.

During the three months ended March 31, 2025, the Company granted 637,228 stock options out of the 2022 Plan and no stock options out of the Inducement Plan at a weighted average exercise price of \$0.73 per share. The options vest over one to four years and expire ten years after the grant date.

The grant date fair values of the stock options were estimated using the Black-Scholes option pricing model using the following weighted average assumptions:

	<u>Three Months Ended March 31,</u>	
	<u>2025</u>	
Risk-free interest rate		4.44 %
Expected volatility		125.37 %
Expected term (years)		5.38
Expected dividend yield		0.00 %
Fair value, per share	\$	0.63

There were no restricted stock units granted during the three months ended March 31, 2025.

As of March 31, 2025, there were an aggregate of 2,729,689 stock options outstanding with a weighted average exercise price of \$7.30 per share and no unvested restricted stock units outstanding.

Total stock-based compensation expense was as follows (in thousands):

	<u>Three Months Ended</u>			
	<u>March 31,</u>			
	<u>2025</u>		<u>2024</u>	
Cost of sales	\$	6	\$	4
Selling, general and administrative		509		331
Research and development		107		66
Total stock-based compensation expense	\$	<u>622</u>	\$	<u>401</u>

As of March 31, 2025, the total remaining unrecognized compensation expense related to nonvested stock options and restricted stock units was \$1.3 million which will be amortized over the weighted-average remaining requisite service period of 0.8 years.

8. BASIC AND DILUTED LOSS PER SHARE

The table below presents the computation of basic and diluted loss per share (in thousands, except share and per share information):

	Three Months Ended March 31,	
	2025	2024
Basic:		
Net loss available to common stockholders — basic	\$ (3,838)	\$ (2,516)
Weighted average common shares outstanding — basic ⁽¹⁾⁽³⁾	7,556,267	817,327
Loss per share - basic	\$ (0.51)	\$ (3.08)
Diluted:		
Net loss available to common stockholders — diluted ⁽²⁾	\$ (3,838)	\$ (2,516)
Weighted average common shares outstanding — diluted ⁽¹⁾⁽³⁾	7,556,267	817,327
Loss per share — diluted	\$ (0.51)	\$ (3.08)

- ⁽¹⁾ In May 2024, in connection with the 2024 Public Offering, the Company issued and sold Pre-funded Warrants exercisable for an aggregate of 2,147,222 shares of Common Stock. The total price of the Pre-funded Warrants is \$2.25 per share, \$2.249 of which was pre-funded and paid to the Company upon issuance of the Pre-funded Warrants. The exercise price of the Pre-funded Warrants is \$0.001 per share. The Pre-funded Warrants are immediately exercisable and do not expire. During the three months ended March 31, 2025, 12,222 Pre-funded Warrants were exercised for 12,196 common shares, leaving no Pre-funded Warrants outstanding. Refer to Note 6 for additional information about the 2024 Public Offering and the Pre-funded Warrants.
- ⁽²⁾ For the three months ended March 31, 2025 and 2024, no adjustment was made to the numerator.
- ⁽³⁾ The weighted average number of common shares outstanding as of March 31, 2025 includes the Abeyance Shares from the exercise of the Existing Warrants, the exercise of which was fully paid by the Holders and requires no further consideration for the delivery of the shares of common stock. Therefore, the Abeyance Shares are included in the computation of basic and diluted loss per share.

The following outstanding securities, presented based on amounts outstanding as of the end of each period, were not included in the computation of diluted net loss per share for the periods indicated, as they would have been anti-dilutive due to the net loss in each period.

	Three Months Ended March 31,	
	2025	2024
Stock options	2,729,689	245,830
Restricted stock units	—	572
Warrants ⁽¹⁾	7,701,548	613,659

- ⁽¹⁾ Anti-dilutive warrants include the 2022 Warrants, Series C Warrants, Series D Warrants and other equity classified warrants that are out-of-the-money.

9. COMMITMENTS AND CONTINGENCIES

The Company is obligated under a license agreement with Advanced NeuroRehabilitation, LLC to pay a 4% royalty on net revenue collected from the sale of devices covered by the patent-pending technology. During the three months ended March 31, 2025 and 2024, the Company recorded royalty expense from the sale of devices of approximately \$2 thousand and \$5 thousand, respectively, in its unaudited condensed consolidated statements of operations and comprehensive loss.

10. SEGMENT AND GEOGRAPHIC INFORMATION

Segment Information

Operating segments are components of an enterprise for which separate financial information is available and are evaluated regularly by the Company's chief operating decision maker ("CODM") in deciding how to allocate resources and assessing performance. The Company's CODM is its Chief Executive Officer. The Company's Chief Executive Officer views the Company's operations and manages its business in one operating segment, which is the business of development and commercialization of products related to PoNS® devices. The Company has a single reporting segment and the determination of the single segment is consistent with the information provided to the CODM. The CODM evaluates performance and allocates resources based on the Company's consolidated financial results.

Geographic Information

The following table presents the Company's revenue disaggregated by geographic area (in thousands):

	Three Months Ended	
	2025	2024
Product sales, net:		
United States	\$ 19	\$ 79
Canada	19	45
Total product sales, net	38	124
Other revenue	11	11
Total revenue	<u>\$ 49</u>	<u>\$ 135</u>

Four customers accounted for 99% of net product sales for the three months ended March 31, 2025 and two customers accounted for 94% of net product sales for the three months ended March 31, 2024. Two customers accounted for 100% of accounts receivable, net as of December 31, 2024.

11. SUBSEQUENT EVENTS

On April 24, 2025, the Company entered into a securities purchase agreement (the "Purchase Agreement") with certain investors (the "Purchasers") pursuant to which the Company sold, in a private placement (the "2025 Private Placement"), unsecured 20% original issue discount promissory notes with an aggregate principal amount of \$1,560,000 (the "Notes") with a maturity date of the earlier of a) July 24, 2025, b) the closing date of the Company's next registered offering of securities on Form S-1. The Purchase Agreement also provides for the issuance of an aggregate of 1,320,150 shares of common stock of the Company, par value \$0.001 per share (the "Private Placement Shares") to the Purchasers. The transaction closed on April 25, 2025.

The aggregate gross proceeds to the Company were \$1,300,000, before deducting placement agent fees and expenses of \$0.1 million. The Company intends to use the net proceeds from the 2025 Private placement for working capital and other general corporate purposes.

Maxim Group LLC served as the placement agent in the 2025 Private Placement, pursuant to the terms of a placement agency agreement and received 7% of the gross proceeds of the Offering and reimbursement of the legal fees of its counsel of up to \$15,000.

ITEM 2. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Unless otherwise specified or the context otherwise requires, references to “we,” “us,” “our,” “Heliuss” or “Company” mean Heliuss Medical Technologies, Inc. and its wholly owned operating subsidiaries, Heliuss Medical, Inc., Heliuss Medical Technologies (Canada), Inc. and Revelation Neuro, Inc. The interim financial statements and this Management’s Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2024, and the related Management’s Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2024 filed with the Securities and Exchange Commission (“SEC”) on March 25, 2025 (the “2024 10-K”). All financial information is stated in U.S. dollars unless otherwise specified. Our unaudited condensed consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States (“U.S. GAAP”).

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties, including statements regarding the Company’s market, strategy, competition, capital needs, business plans and expectations. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “should,” “expect,” “plan,” “intend,” “anticipate,” “believe,” “estimate,” “predict,” “potential” or “continue,” the negative of such terms or other comparable terminology. Forward-looking statements are made, without limitation, in relation to the Company’s future growth and operational progress, the Company’s compliance with Nasdaq requirements, expected enrollment, developments and future plans regarding regulatory entities, receipt of prescriptions and progress of commercialization of the PoNS device in the U.S., the impacts of the current global macroeconomic environment on the Company, product development activities, the safety and effectiveness of the Company’s product, the manufacturing plans for the Company’s product, sufficiency of cash and availability of funds and operating costs and the Company’s ability to continue as a going concern and future liquidity. Such forward-looking statements involve risks and uncertainties, known and unknown, including capital requirements to achieve the Company’s business objectives, the impact on the Company of global macroeconomic conditions including effects from supply chain constraints, logistics challenges, labor shortages, disruptions in the banking system and financial markets, high levels of inflation and increased interest rates on the Company’s ability to operate its business and access capital markets, the success of the Company’s business plan, including the Company’s ability to secure contracts with rehabilitation clinics, obtain national Medicare coverage at an acceptable rate so that the PoNS device is covered by Medicare and Medicaid, 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, availability of funds, manufacturing, the Company’s ability to maintain and enforce its intellectual property rights, clinical trials and the clinical development process, the product development process, the regulatory submission review and approval process, the Company’s operating costs and use of cash, and the Company’s ability to achieve significant revenues and other factors discussed in the section entitled “Item 1A. Risk Factors” in our 2024 10-K and those described from time to time in the Company’s future reports filed with the SEC. While these forward-looking statements, and any assumptions upon which they are based, are made in good faith, based on information available to the Company as of the date hereof, and reflect the Company’s current judgment regarding its business plans, Heliuss cannot guarantee future results, events, levels of activity, performance or achievement and its actual results will almost always vary, sometimes materially, from any estimates, predictions, projections, assumptions or other future performance suggested herein. The Company does not intend, and undertakes no obligation, to update or revise any of the forward-looking statements as a result of new information, future events or otherwise or to conform these statements to actual results, except as required by applicable law, including the securities laws of the United States.

The following discussion and analysis of the Company’s financial condition and results of operations should be read in conjunction with its unaudited condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q.

Company Overview

We are a neurotechnology company focused on neurological wellness. Our purpose is to develop, license or acquire non-implantable technologies targeted at reducing symptoms of neurological disease or trauma.

Our product, known as the Portable Neuromodulation Stimulator, or PoNS[®], is an innovative non-implantable medical device, inclusive of a controller and mouthpiece, which delivers mild electrical stimulation to the surface of the tongue to provide treatment of gait deficit and chronic balance deficit. PoNS Therapy[®] is integral to the overall PoNS solution and is the physical therapy applied by patients during use of the PoNS device. PoNS has marketing clearance in the U.S. for use as a short-term treatment of gait deficit due to mild-to-moderate symptoms for 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. We began accepting prescriptions for PoNS in the U.S. in March 2022, and commercial sales of PoNS commenced in April 2022. PoNS is authorized for sale in Canada for three indications: (i) as a short term treatment (14 weeks) of chronic balance deficit due to mild-to-moderate traumatic brain injury and is to be used in conjunction with physical therapy; (ii) as a short term treatment (14 weeks) of gait deficit due to mild and moderate symptoms from MS and it is to be used in conjunction with physical therapy; and (iii) as a short term treatment (14 weeks) of gait deficit due to mild and moderate symptoms from stroke, to be used in conjunction with physical therapy. It has been commercially available in Canada since March 2019. PoNS is authorized for sale as a Class IIa medical device in Australia and we have been seeking a business partner to commercialize and distribute PoNS in Australia.

Recent Developments

Corporate Updates

Financing

On April 24, 2025, the Company sold, in a private placement, unsecured 20% original issue discount promissory notes and issued 1,320,150 shares of common stock of the Company generating gross proceeds of \$1.3 million with cash share issuance costs of \$0.1 million for net proceeds of \$1.2 million as discussed further in Note 11 in our unaudited condensed consolidated financial statements.

On January 21, 2025, the Company entered into warrant exercise inducement offer letters with certain holders of existing Series A warrants and Series B warrants generating gross proceeds of \$3.7 million as discussed further in Note 6 in our unaudited condensed consolidated financial statements.

Nasdaq Compliance

On August 9, 2024, we received written notice (the “Notification Letter”) from The Nasdaq Stock Market LLC (“Nasdaq”) notifying us that the Company was not in compliance with the minimum bid price requirements set forth in Nasdaq Listing Rule 5550(a)(2)(the “Minimum Bid Price Requirement”) for continued listing on the Nasdaq Capital Market. Nasdaq Listing Rule 5550(a)(2) requires listed securities maintain a minimum closing bid price of \$1.00 per share, and Nasdaq Listing Rule 5810(c)(3)(A) provides that a failure to meet the minimum closing bid price requirement exists if the deficiency continues for a period of 30 consecutive business days. Based on the closing bid price of the Company’s Class A common stock (“Common Stock”) for the 30 consecutive business days prior to the date of the Notification Letter, the Company did not meet the minimum closing bid price requirement. In accordance with Nasdaq Marketplace Rule 5810(c)(3)(A), we had a period of 180 calendar days from August 9, 2024, or until February 5, 2025, to regain compliance with the Minimum Bid Price Requirement.

On February 7, 2025, we received a letter from the Listing Qualifications Department (the “Staff”) of Nasdaq indicating the Company’s continued non-compliance with the Minimum Bid Price Requirement. The letter further informed the Company that the Company’s common stock would be delisted from the Nasdaq Capital Market unless the Company appeals the Staff’s delisting determination by requesting a hearing before the Nasdaq Hearings Panel (the “Panel”). The Company had a hearing with the Nasdaq Hearing Panel on March 18, 2025. At the hearing, we presented our plan for regaining compliance with the Minimum Bid Price Requirement and requested a further extension so that we may complete

the execution of our plan. Although we believe our plan will be sufficient to enable us to regain compliance, no assurance can be provided that Nasdaq will ultimately accept our plan or that we will ultimately regain compliance with the Minimum Bid Price Requirement. As of the date of this report, we have not received a determination from the hearings panel. Our common stock will remain listed and eligible for trading on Nasdaq pending the ultimate conclusion of the hearing process.

On March 31, 2025, Company received written notice (the “Notice”) from Nasdaq stating that the Company no longer complies with the minimum stockholders’ equity requirement under Nasdaq Listing Rule 5550(b)(1)(the “Stockholders’ Equity Requirement”) for continued listing on Nasdaq Capital Market because the Company’s stockholders’ equity, as reported in the Company’s Annual Report on Form 10-K for the fourth quarter and year ended December 31, 2024, has fallen below \$2.5 million. The notice also indicates that the Company does not meet the alternative compliance standards.

On April 1, 2025, the Company received an additional letter from Nasdaq notifying the Company that, following the hearing process with respect to the Company’s deficiency with the Minimum Bid Price Requirement, Nasdaq has granted the Company an extension until June 30, 2025 to regain compliance with the Minimum Bid Price Requirement as well as the Stockholders’ Equity Requirement.

There can be no assurance that we will be able to regain compliance with the minimum bid price requirement and other Nasdaq listing criteria. If we fail to meet the applicable continued listing requirements for the Nasdaq Capital Market, Nasdaq may delist our Common Stock. If such delisting should occur, it would likely have a negative effect on the price of our Common Stock and would impair an investor’s ability to sell or purchase our Common Stock when desired. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our Common Stock to become listed again, stabilize the market price or improve the liquidity of our Common Stock, prevent our Common Stock from dropping below the Nasdaq minimum bid price requirement, or prevent future non-compliance with Nasdaq’s listing requirements. Additionally, Nasdaq rules allow an expedited delisting of securities of companies that have had one or more reverse stock splits with a cumulative ratio of one for 250 or more shares over the prior two-year period. Under these rules, if a company falls out of compliance with the \$1.00 minimum bid price after completing reverse stock splits over the immediately preceding two years that cumulatively result in a ratio one for 250 shares, the company will not be able to avail itself of any compliance periods and Nasdaq will instead require the issuance of a Staff delisting determination, which is appealable to a hearings panel. Our ability to remain listed on Nasdaq may be negatively impacted by this Nasdaq rule.

Reimbursement

On March 11, 2025, the Company announced its first reimbursement payment from a major healthcare provider, Anthem Blue Cross Blue Shield, for its PoNS Device.

We are pursuing commercial insurance coverage for PoNS within the Durable Medical Equipment benefit category. On February 29, 2024, CMS assigned HCPCS Level II codes to the PoNS controller and PoNS mouthpiece, effective April 1, 2024. On May 2, 2024, CMS published a proposed fee schedule payment rates for the PoNS controller and PoNS mouthpiece to be discussed at CMS’ bi-annual Healthcare Common Procedure Coding System (“HCPCS”) public meeting to be held on May 29, 2024. For the PoNS Controller (HCPCS Code A4593), CMS preliminarily set pricing by mapping reimbursement to existing code E0745, (Neuromuscular stimulator, electronic shock unit), resulting in a capped fee of \$1,206.53. For the PoNS Mouthpiece (HCPCS code A4594), CMS based pricing on the previously offered, temporary, cash pay price of \$4,500, resulting in a total capped payment of \$3,075.53.

The Company subsequently provided CMS additional information to support reimbursement economics and presented that information at the public meeting with CMS on May 29, 2024 for consideration by CMS for determination of the final reimbursement amount for each of the PoNS controller and mouthpiece.

On October 7, 2024, CMS posted the final payment rate for the PoNS Mouthpiece (HCPCS code A4594) at \$2,963.30, which will be effective January 1, 2025 and deferred final national determination of the payment rate for the PoNS Controller (HCPCS Code A4593) to the next payment cycle. At the Company’s request, Company management subsequently met with CMS in December 2024 prior to PoNS Mouthpiece pricing taking effect on January 1, 2025 to

request that they revisit the starting point for the gap filling process to more appropriately use the market pricing established through negotiation with the VA and an insurance carrier.

On October 8, 2024, CMS published the preliminary rate for the PoNS Controller (HCPCS Code A4593) at the capped total payment of \$519.80, based on its view that the product is comparable to devices reported with HCPCS code E0730 (transcutaneous electrical nerve stimulation (TENS) device, four or more leads, for multiple nerve stimulation) effective April 1, 2025.

On January 13, 2025, CMS posted final Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies fee schedule payment rates for the PoNS Controller (HCPCS Code A4593) at the capped total payment of \$532.27 and no changes to the previous final determination for the PoNS Mouthpiece (HCPCS code A4594) were made.

We also intend to provide broad access and reimbursement for the PoNS Therapy over time through commercial insurers. Prior to broad commercial payer coverage, we anticipate the primary source of sales will be self-pay and VA patients. We expect to support the cost of the PoNS Therapy by working with advocacy groups and charitable organizations to help self-pay patients access our technology. In general, we anticipate that it will take at least 24 months to obtain broad coverage and reimbursement among government and private payers from the date that the HCPCS codes became effective.

Revelation Neuro

On March 11, 2025, we established Revelation Neuro, Inc. to pursue the development of a new gold standard of care for personalized neurorehabilitation using a non-implantable AI powered brain computer interface combining our newly developed intellectual property with Helius' existing intellectual property.

Partnership with Lovell Government Services

During the first quarter of 2024, the Company partnered with Lovell Government Services ("Lovell"), an SBA-certified Service-Disabled Veteran-Owned Small Business, to make the PoNS device available to federal healthcare systems. In May 2024, PoNS became available on the Veteran Affairs Federal Supply Schedule and General Services Administration Advantage Contracts at \$23,843.72 for the PoNS device and \$7,344.97 for the PoNS mouthpiece. In July 2024, PoNS became available to the Department of Defense and U.S. Military facilities on the Distribution and Pricing Agreement at \$23,724.50 for the PoNS device and \$7,308.25 for the PoNS mouthpiece. In December 2024, the first PoNS System sale to the VA Healthcare System through Lovell was delivered at the contracted price of \$23,844, comprised of \$16,499 for the PoNS Controller and \$7,345 for the PoNS Mouthpiece. In March 2025, pricing for PoNS under the Veteran Affairs Federal Supply Schedule and General Services Administration Advantage Contracts increased to \$26,228.09 for the PoNS device and \$8,079.48 for the PoNS mouthpiece.

In June 2024, the Company began establishing sales representative agreements with organizations and individuals to sell PoNS devices to Veterans Affairs ("VA") facilities in the U.S. The Company has since established agreements with representatives covering facilities in various states throughout the country.

Stroke Study

During the first quarter of 2024, leveraging the Breakthrough Designation, the Company reached alignment with the FDA on the registrational program to evaluate the therapeutic benefit of PoNS on gait and balance deficits in chronic stroke subjects, which originally included two initial studies. The first was an investigator-initiated randomized placebo-controlled trial ("MUSC-RCT") in approximately 60 subjects, led by Dr. Steven Kautz at the Medical University of South Carolina ("MUSC") and Dr. Mark Bowden at Brooks Rehabilitation. The second study was a company-sponsored open-label study ("HMI-OLS"), in approximately 30 subjects. Following guidance from FDA, Helius added, in May 2024, a third company-sponsored randomized placebo-controlled trial ("HMI-RCT") in approximately 60 subjects, as the pivotal study, along with the OLS, for the registrational program. All three studies shared the same design and endpoints, including primary outcomes on gait and balance improvement, as well as key secondary endpoints with Type 1 error of reduced risk of falling and maintenance of effect at 12 weeks post-treatment.

Enrollment of the stroke registrational studies started at MUSC for the MUSC-RCT in August 2023 and, at Brooks Rehabilitation, in August 2024. In June 2024, Helius started enrollment of the HMI-OLS at five U.S. Centers of Excellence for Neurorehabilitation including Shepherd Center, MGH-IHP, REHABOLOGYM, Brooks Rehabilitation and New England Neurological Center. Enrollment continued, with the HMI-RCT, in July 2024 at Neuro-Concept Rehabilitation Center, Neuphysio, Synaptic Health, Bergin Motion in Canada and REHABOLOGYM in the U.S.

The Company has completed and far exceeded the initial 90-subject target enrollment for its stroke registrational program enrolling 128 participants by December 31, 2024. With maximum enrollment of over 150 participants achieved at the end of January 2025, the Company is on track to submit for FDA authorization for stroke in the second quarter of 2025, with the plan to achieve FDA authorization by the end of 2025.

Strategic Alternatives

On November 18, 2024, the Company announced that it had initiated a process to explore a range of strategic alternatives focused on maximizing stockholder value and that the Company has engaged B. Riley Securities to act as a financial advisor in connection with such process. The Company continues to evaluate options with respect to potential strategic alternatives.

Material Trends and Uncertainties

Global Economic Conditions

Generally, worldwide economic conditions remain uncertain, in part due to supply chain disruptions, labor shortages, global conflicts, increased inflation, sustained high interest rates and unpredictable trade policies, including tariffs, customs regulations and other trade restrictions. The general economic and capital market conditions both in the U.S. and worldwide, have been volatile in recent years and at times have adversely affected our access to capital and have increased the cost of capital. The capital and credit markets may not be available to support future capital raising activity on favorable terms. If economic conditions continue to remain volatile or decline, our future cost of equity or debt capital and access to the capital markets could be adversely affected.

Our operating results could be materially impacted by changes in the overall macroeconomic environment and other economic factors. Changes in economic conditions, trade restrictions, high interest rates, supply chain constraints, logistics challenges, labor shortages, global conflicts such as the conflicts in Ukraine and in the Middle East, and steps taken by governments and central banks as well as other stimulus and spending programs, have led to higher inflation, which has led to an increase in costs and has caused changes in fiscal and monetary policy, including increased interest rates. Although we may take measures to mitigate these impacts, if these measures are not effective, our business, financial condition, results of operations, and liquidity could be materially adversely affected.

Results of Operations

Three Months Ended March 31, 2025 compared to the Three Months Ended March 31, 2024

The following table summarizes our results of operations for the three months ended March 31, 2025 and 2024 (in thousands):

	<u>Three Months Ended March 31,</u>		
	<u>2025</u>	<u>2024</u>	<u>Change</u>
Revenue:			
Product sales, net:			
United States	\$ 19	\$ 79	\$ (60)
Canada	19	45	(26)
Total product sales, net	38	124	(86)
Other revenue	11	11	—
Total revenue	49	135	(86)
Cost of revenue	121	123	(2)
Gross (loss) profit	(72)	12	(84)
Operating expenses:			
Selling, general and administrative expenses	2,994	2,633	361
Research and development expenses	945	788	157
Amortization expense	—	7	(7)
Total operating expenses	3,939	3,428	511
Loss from operations	(4,011)	(3,416)	(595)
Nonoperating income			
Interest expense, net	(6)	(8)	2
Change in fair value of derivative liability	109	1,142	(1,033)
Foreign exchange gain (loss)	50	(288)	338
Other income, net	20	54	(34)
Nonoperating income, net	173	900	(727)
Loss before provision for income taxes	(3,838)	(2,516)	(1,322)
Provision for income taxes	—	—	—
Net loss	<u>\$ (3,838)</u>	<u>\$ (2,516)</u>	<u>\$ (1,322)</u>

Revenue

The decrease in total net product sales was primarily attributable to a decrease in unit volumes for U.S. sales of PoNS systems resulting from the termination of the previously offered temporary cash pay pricing in early 2024.

Cost of Revenue

The cost of revenue for the first quarter of 2024 as compared to the same period in the prior year remained relatively flat year-to-year due to decreased unit volumes sold and decreased warranty expense offset by increases in certain inventory reserve adjustments and fixed employee costs.

Gross (Loss)profit

Gross loss for the three months ended March 31, 2025 was \$72 thousand compared to gross profit of \$12 thousand for the same period in the prior year. Decreased revenues in the first quarter of 2025 with cost of revenues remaining flat from the prior year were the primary reasons for the year-to-year variance.

Selling, General and Administrative Expense

The increase in selling, general and administrative expenses in the first quarter of 2025 as compared to the same period in prior year resulted primarily from a \$0.2 million increase in stock-based compensation expense, a \$0.1 million increase in franchise tax, and a \$0.1 million increase in employee wages and benefits, partially offset by a \$0.1 million decrease in costs relating to the transfer of third-party manufacturing and professional services.

Research and Development Expense

The increase in research and development expenses was driven primarily by an increase in produce development costs associated with enhancing the PoNS software cybersecurity as required by the FDA.

Amortization Expense

Amortization expense in the first quarter of 2024 was comprised of the amortization of acquired finite-lived intangible assets. The change in amortization expense period over period is primarily due to all intangible assets becoming fully amortized.

Nonoperating income (expense)

Interest Expense, Net

Net interest expense for the three months ended March 31, 2025 and 2024 was primarily attributable to interest expense related to the Company's insurance premium financing.

Change in Fair Value of Derivative Liability

As discussed in more detail in Note 6 to our unaudited condensed consolidated financial statements, the warrants issued in connection with the public offering completed on August 9, 2022 are being accounted for as a derivative liability instrument. The gain on change in fair value of derivative liability for the three months ended March 31, 2025 of \$0.1 million was primarily due to a decrease in our stock price.

Foreign Exchange Gain (Loss)

The change in foreign exchange gain (loss) was primarily due to fluctuations in the Canadian to U.S. dollar exchange rates.

Other Income, Net

Other income for the three months ended March 31, 2025 was primarily attributable to dividend income earned on investments of excess cash in money market mutual funds.

Liquidity and Capital Resources

The following table summarizes our cash and cash equivalents and working capital as of the end of the periods indicated in the table below (in thousands):

	March 31, 2025	December 31, 2024
Cash and cash equivalents	\$ 1,109	\$ 1,088
Working capital	1,382	1,261

Our available capital resources have been primarily used to expand our U.S. commercialization efforts, fund manufacturing activities for the PoNS device, conduct clinical trials and for working capital and general corporate purposes. Our primary sources of cash and cash equivalents have been proceeds from public and private offerings of our common stock which most recently included \$5.5 million in net proceeds we received from a public offering of our common stock and warrants completed in May 2024 (“May 2024 Public Offering”) as discussed in more detail in Note 6 to our unaudited condensed consolidated financial statements.

In addition, the Company received net proceeds of \$0.2 million from the issuance of shares upon the exercise of warrants for the year ended December 31, 2024.

As discussed in more detail in Note 6 to our unaudited condensed consolidated financial statements, the Company entered into a sales agreement related to our at-the-market offering program (“ATM”) under which we may offer and sell shares having gross proceeds up to \$2.0 million. During the year ended December 31, 2024, the Company issued and sold shares with net proceeds of \$1.3 million under the ATM and during the three months ended March 31, 2025, the Company issued and sold shares with net proceeds of \$0.1 million under the ATM.

On January 21, 2025, the Company entered into warrant exercise inducement offer letters and new warrant issuance which generated \$3.4 million in net proceeds as discussed in more detail in Note 6 to our unaudited condensed consolidated financial statements.

On April 24, 2025, the Company sold, in a private placement, unsecured 20% original issue discount promissory notes and issued 1,320,150 shares of common stock of the Company generating gross proceeds of \$1.3 million with cash share issuance costs of \$0.1 million for net proceeds of \$1.2 million as discussed further in Note 11 in our unaudited condensed consolidated financial statements.

Statement of Cash Flows

The following table summarizes our cash flows for the three months ended March 31, 2025 and 2024 (in thousands):

	Three Months Ended March 31,		Change
	2025	2024	
Net cash used in operating activities	\$ (3,536)	\$ (3,001)	\$ (535)
Net cash used in investing activities	—	(5)	5
Net cash provided by financing activities	3,557	1,463	2,094
Effect of foreign exchange rate changes on cash	—	(1)	1
Net increase (decrease) in cash and cash equivalents	<u>\$ 21</u>	<u>\$ (1,544)</u>	<u>\$ 1,565</u>

Net Cash Used in Operating Activities

The higher level of cash used in operating activities in the three months ended March 31, 2025 primarily resulted from the increase in selling, general and administrative expenses and research and development expenses as compared with the same period in the prior year.

Net Cash Used in Investing Activities

Our investing activities are primarily related to the purchases of property and equipment.

Net Cash Provided by Financing Activities

During the three months ended March 31, 2025, \$3.4 million in net proceeds were generated from entering into a warrant inducement with current warrant holders and net proceeds of \$0.1 million from issuance and sales of shares under the ATM.

Cash Requirements

Our ability to generate product revenues sufficient to achieve profitability will depend heavily on the successful commercialization of PoNS Therapy in the U.S. Our net loss was \$3.8 million and \$2.5 million for the three months ended March 31, 2025 and 2024, respectively. As of March 31, 2025, we had an accumulated deficit of \$175.5 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future. These and other factors indicate substantial doubt about our ability to continue as a going concern. Refer to Note 1 to our unaudited condensed consolidated financial statements for additional discussion about our going concern uncertainty.

We intend to use our available capital resources primarily to expand our U.S. commercialization efforts, fund manufacturing activities for the PoNS device, conduct clinical trials and for working capital and general corporate purposes. We believe that our existing capital resources, as well as the \$1.2 million net proceeds from the sales of promissory notes and issuance of shares in April of 2025 along with \$3.4 million net proceeds from the exercise of the Existing Warrants by the Holders and \$0.1 million net proceeds from the issuance and sale under the ATM in January of 2025 will be sufficient to fund our operations into the second quarter of 2025, but we will be required to seek additional funding through the sale of equity or debt financing to continue to fund our operations thereafter. We will need additional funding for our planned clinical trial for stroke. The amount required to fund operations thereafter will depend on various factors, including timing of approval of clinical trials, duration and result of clinical trials and other factors that affect the cost of the clinical trial, manufacturing costs of product, development of our product for new indications and demand for our authorized products in the market.

There can be no assurance that we will be successful in raising additional capital or that such capital, if available, will be on terms that are acceptable to us. If we are unable to raise sufficient additional capital, we may be compelled to reduce the scope of our operations and planned capital expenditures or sell certain assets, including intellectual property, and we may be forced to cease or wind down operations, seek protection under the provisions of the U.S. Bankruptcy Code, or liquidate and dissolve our company.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based upon our unaudited condensed consolidated financial statements that have been prepared in accordance with U.S. GAAP. This preparation requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities.

Our critical accounting policies and estimates are described in Item 7 “Management’s Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Policies and Estimates” of our 2024 10-K. There have been no changes in critical accounting policies in the current year from those described in our 2024 10-K.

ITEM 3. Quantitative and Qualitative Disclosures about Market Risk

Not applicable.

ITEM 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(b) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, under the direction of our Chief Executive Officer and our Chief Financial Officer, we have evaluated our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of the end of the period covered by this report. Our management has concluded that the financial statements included elsewhere in this Quarterly Report on Form 10-Q present fairly, in all material respects, our financial position, results of operations and cash flows in conformity with generally accepted accounting principles.

Changes in Internal Control over Financial Reporting

There has not been any change in our internal control over financial reporting (as such term is defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act) during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we are subject to litigation and claims arising in the ordinary course of business. We are not currently a party to any material legal proceedings, and we are not aware of any pending or threatened legal proceeding against us that we believe could have a material adverse effect on our business, operating results or financial condition.

Item 1A. Risk Factors

Our business is subject to risks and events that, if they occur, could adversely affect our financial condition and results of operations and the trading price of our securities. During the three months ended March 31, 2025, our risk factors have not changed materially from those risk factors previously disclosed in our 2024 10-K except as set forth below. You should carefully consider the risk factors discussed in Part I, “Item 1A. Risk Factors” in our 2024 10-K. The risks described in our 2024 10-K are not the only risks facing us. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially and adversely affect our business, financial condition and/or operating results.

Nasdaq may delist our Common Stock from its exchange which could limit your ability to make transactions in our securities and subject us to additional trading restrictions.

On August 9, 2024, we received a Notification Letter from the Staff of Nasdaq notifying us that because the closing bid price of our Common Stock was below \$1.00 per share for the prior 30 consecutive business days, we are not in compliance with the minimum bid price requirement for continued listing on the Nasdaq Capital Market, as set forth in the Minimum Bid Price Requirement. On February 7, 2025, we received a second Notification Letter from the Staff notifying us that the 180-day compliance period had expired and that we are ineligible for an additional 180-day period due to the Company’s noncompliance with the \$5,000,000 minimum stockholders’ equity initial listing requirement for the Nasdaq Capital Market.

As a result, the second Notification Letter informed us that our listed common stock would be subject to delisting pending the request of an appeal with regards to this determination. The Company had a hearing with the Nasdaq Hearing Panel on March 18, 2025. On March 31, 2025, we received written notice Staff stating that the Company no longer complies with the Stockholders’ Equity Requirement for continued listing on The Nasdaq Stock Market LLC because the Company’s stockholders’ equity, as reported in the Company’s Annual Report on Form 10-K for the fourth quarter and year ended December 31, 2024, has fallen below \$2.5 million. The notice also indicates that the Company does not meet the alternative compliance standards.

On April 1, 2025, the Company received the Extension Notice from Nasdaq notifying the Company that, following the hearing process with respect to the Company’s deficiency with the Minimum Bid Price Requirement, Nasdaq has granted the Company an extension, until June 30, 2025 to regain compliance with the Minimum Bid Price Requirement as well as the Stockholders’ Equity Requirement.

If our common stock is delisted by Nasdaq, the price of our common stock may decline and our common stock may be eligible to be quoted on the OTC Bulletin Board, another over-the-counter quotation system, or on the pink sheets, which would negatively affect the liquidity of our common stock and an investor may find it more difficult to dispose of their common stock or obtain accurate quotations as to the market value of our common stock. Any such delisting action may materially adversely affect our ability to raise capital or pursue strategic transactions on acceptable terms, or at all.

In addition, if our common stock is delisted from the Nasdaq Capital Market and the trading price remains below \$5.00 per share, trading in our common stock might also become subject to the requirements of certain rules promulgated under the Exchange Act, which require additional disclosure by broker-dealers in connection with any trade involving a stock defined as a “penny stock” (generally, any equity security not listed on a national securities exchange that has a market price of less than \$5.00 per share, subject to certain exceptions).

We also believe that delisting would likely result in decreased liquidity and/or increased volatility in our Common Stock and could harm our business and future prospects. In addition, we believe that, if our Common Stock is delisted, our stockholders would likely find it more difficult to obtain accurate quotations as to the price of the Common Stock and it may be more difficult for stockholders to buy or sell our Common Stock at competitive market prices, or at all.

We continue to actively monitor our performance with respect to the listing standards and will consider available options to resolve any deficiency and maintain compliance with the Nasdaq rules. There can be no assurance that we will be able to maintain compliance or, if we fall out of compliance, regain compliance with any deficiency, or if we implement an option that regains our compliance, maintain compliance thereafter.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Rule 10b5-1 Trading Plans – Directors and Section 16 Officers

During the three months ended March 31, 2025, none of the Company’s directors or Section 16 officers adopted or terminated any contract, instruction or written plan for the purchase or sale of Company securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) of the Exchange Act or any “non-Rule 10b5-1 trading arrangement”.

Item 6. Exhibits

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
3.1	Certificate of Conversion filed with the Delaware Secretary of State on July 18, 2018 (incorporated by reference to Exhibit 3.1 to the Form 10-Q filed August 9, 2018)
3.2	Certificate of Incorporation, as corrected (incorporated by reference to Exhibit 3.1 to the Form 8-K filed October 30, 2018)
3.3	Certificate of Amendment to Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Form 8-K filed on December 31, 2020)
3.4	Certificate of Designation of the Series B Preferred Stock of the Registrant (incorporated by reference to Exhibit 3.1(a) to the Registration Statement on Form 8-A, filed on March 24, 2023)
3.5	Corrected Certificate of Amendment to Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Form 8-K filed on August 16, 2023)
3.6	Second Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Form 8-K filed March 15, 2024)
4.1	Form of Inducement Warrants (incorporated by reference to Exhibit 4.1 to the Form 8-K filed on January 24, 2025)
10.1	Form of Inducement Letter (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on January 24, 2025)
31.1#	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2#	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1#*	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2#*	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS#	Inline XBRL Instance Document
101.SCH#	Inline XBRL Taxonomy Extension Schema Document
101.CAL#	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB#	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE#	Inline XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF#	Inline XBRL Taxonomy Extension Definition Linkbase Document
104#	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

Filed herewith.

* These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

SIGNATURES

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, thereunto duly authorized.

HELIUS MEDICAL TECHNOLOGIES, INC.

Dated: May 1, 2025

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

Dated: May 1, 2025

By: /s/ Jeffrey S. Mathiesen
Jeffrey S. Mathiesen
*Chief Financial Officer, Treasurer and Secretary
(Principal Financial
Officer and Principal Accounting Officer)*

CERTIFICATIONS

I, Dane C. Andreeff, certify that:

- 1) I have reviewed this report on Form 10-Q for the period ended March 31, 2025 of Helius Medical Technologies, Inc.
- 2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 1, 2025

/s/ Dane C. Andreeff
Dane C. Andreeff
Chief Executive Officer

CERTIFICATIONS

I, Jeffrey S. Mathiesen, certify that:

- 1) I have reviewed this report on Form 10-Q for the period ended March 31, 2025 of Helius Medical Technologies, Inc.
- 2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 1, 2025

/s/ Jeffrey S. Mathiesen
Jeffrey S. Mathiesen
Chief Financial Officer

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER
HELIUS MEDICAL TECHNOLOGIES, INC.
FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 2025
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I am the Chief Executive Officer of Helius Medical Technologies, Inc., a Delaware corporation (the "Company"). I am delivering this certificate in connection with the Form 10-Q of the Company for the quarter ended March 31, 2025 and filed with the Securities and Exchange Commission ("Form 10-Q").

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, I hereby certify that, to the best of my knowledge, the Form 10-Q fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 1, 2025

/s/ Dane C. Andreeff

Dane C. Andreeff

Chief Executive Officer

**CERTIFICATION OF CHIEF FINANCIAL OFFICER
HELIUS MEDICAL TECHNOLOGIES, INC.
FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 2025
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I am the Chief Financial Officer of Helius Medical Technologies, Inc., a Delaware corporation (the "Company"). I am delivering this certificate in connection with the Form 10-Q of the Company for the quarter ended March 31, 2025 and filed with the Securities and Exchange Commission ("Form 10-Q").

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, I hereby certify that, to the best of my knowledge, the Form 10-Q fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 1, 2025

/s/ Jeffrey S. Mathiesen

Jeffrey S. Mathiesen

Chief Financial Officer
