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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 September 30, 2024

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 (Address of principal executive offices)	**18940 (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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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 November 7, 2024, the registrant had 3,728,172 shares of Class A common stock, $0.001 par value per share, outstanding.

HELIUS MEDICAL TECHNOLOGIES, INC.
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PART I. FINANCIAL INFORMATION
ITEM 1. Condensed Consolidated Financial Statements

Helius Medical Technologies, Inc.
Unaudited Condensed Consolidated Balance Sheets
(in thousands, except share data)

	September 30, 2024	December 31, 2023
ASSETS		
Current assets		
Cash and cash equivalents	$ 3,468	$ 5,182
Accounts receivable, net	25	117
Other receivables	499	520
Inventory, net	774	457
Prepaid expenses and other current assets	640	1,162
Total current assets	5,406	7,438
Property and equipment, net	156	178
Intangible assets, net	2	24
Operating lease right-of-use asset, net	21	52
Total assets	$ 5,585	$ 7,692
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 743	$ 531
Accrued and other current liabilities	688	1,260
Current portion of operating lease liabilities	23	45
Current portion of deferred revenue	42	43
Total current liabilities	1,496	1,879
Operating lease liabilities, net of current portion	—	12
Deferred revenue, net of current portion	94	128
Derivative liability	196	3,323
Total liabilities	1,786	5,342
Commitments and contingencies (Note 9)		
Stockholders' equity		
Class A common stock, $0.001 par value; 150,000,000 shares authorized; 3,646,121 and 714,590 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	4	1
Additional paid-in capital	171,993	162,979
Accumulated deficit	(167,771)	(159,957)
Accumulated other comprehensive loss	(427)	(673)
Total stockholders' equity	3,799	2,350
Total liabilities and stockholders' equity	$ 5,585	$ 7,692

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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenue				
Product sales, net	$ 40	$ 132	$ 335	$ 482
Other revenue	11	11	33	28
Total revenue	51	143	368	510
Cost of revenue	187	187	428	493
Gross profit (loss)	(136)	(44)	(60)	17
Operating expenses				
Selling, general and administrative expenses	2,850	2,196	7,940	7,639
Research and development expenses	1,077	722	2,735	2,292
Amortization expense	7	32	21	109
Fixed asset impairment	—	159	—	159
Total operating expenses	3,934	3,109	10,696	10,199
Loss from operations	(4,070)	(3,153)	(10,756)	(10,182)
Nonoperating income (expense)				
Interest income (expense), net	(1)	68	(14)	257
Change in fair value of derivative liability	152	(393)	3,027	2,051
Foreign exchange gain (loss)	178	(192)	(251)	62
Other income, net	55	7	180	7
Nonoperating income (expense), net	384	(510)	2,942	2,377
Loss before provision for income taxes	(3,686)	(3,663)	(7,814)	(7,805)
Provision for income taxes	—	—	—	—
Net loss	(3,686)	(3,663)	(7,814)	(7,805)
Other comprehensive income (loss)				
Foreign currency translation adjustments	(182)	191	246	(71)
Comprehensive loss	$ (3,868)	$ (3,472)	$ (7,568)	$ (7,876)
Loss per share				
Basic	$ (0.99)	$ (5.49)	$ (3.31)	$ (13.60)
Diluted	$ (0.99)	$ (5.49)	$ (3.31)	$ (13.60)
Weighted average number of common shares outstanding				
Basic	3,740,625	667,809	2,363,718	573,950
Diluted	3,740,625	667,809	2,363,718	573,950

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	Accumulated	Accumulated Other Comprehensive	
	Shares	Amount	Capital	Deficit	Loss	Total
Balance as of July 1, 2024	3,198,196	$ 3	$ 170,666	$ (164,085)	$ (245)	$ 6,339
Exercise of warrants	447,925	1	—	—	—	1
Stock-based compensation	—	—	1,327	—	—	1,327
Other comprehensive income	—	—	—	—	(182)	(182)
Net loss	—	—	—	(3,686)	—	(3,686)
Balance as of September 30, 2024	3,646,121	$ 4	$ 171,993	$ (167,771)	$ (427)	$ 3,799

	Class A Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	
	Shares	Amount	Capital	Deficit	Loss	Total
Balance as of Jul 1, 2023	565,358	$ 1	$ 160,470	$ (155,249)	$ (650)	$ 4,572
Issuance of common stock in public offering	27,875	—	284	—	—	284
Share issuance costs	—	—	(36)	—	—	(36)
Exercise of warrants	92,910	—	1,270	—	—	1,270
Settlement of restricted stock units	1,656	—	—	—	—	—
Stock-based compensation	—	—	403	—	—	403
Other comprehensive income	—	—	—	—	191	191
Net loss	—	—	—	(3,663)	—	(3,663)
Balance as of September 30, 2023	687,799	$ 1	$ 162,391	$ (158,912)	$ (459)	$ 3,021

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

	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	853,200	1	2,960	—	—	2,961
Issuance of warrants in public offering	—	—	4,829	—	—	4,829
Share issuance costs	—	—	(1,132)	—	—	(1,132)
Exercise of warrants	2,076,103	2	263	—	—	265
Settlement of restricted stock units	2,228	—	—	—	—	—
Stock-based compensation	—	—	2,094	—	—	2,094
Other comprehensive loss	—	—	—	—	246	246
Net loss	—	—	—	(7,814)	—	(7,814)
Balance as of September 30, 2024	3,646,121	$ 4	$ 171,993	$ (167,771)	$ (427)	$ 3,799

	Class A Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares	Amount				
Balance as of January 1, 2023	564,094	$ 1	$ 159,645	$ (151,107)	$ (388)	$ 8,151
Issuance of common stock in public offering	27,875	—	284	—	—	284
Share issuance costs	—	—	(36)	—	—	(36)
Exercise of warrants	92,910	—	1,270	—	—	1,270
Settlement of restricted stock units	2,920	—	—	—	—	—
Stock-based compensation	—	—	1,228	—	—	1,228
Other comprehensive income	—	—	—	—	(71)	(71)
Net loss	—	—	—	(7,805)	—	(7,805)
Balance as of September 30, 2023	687,799	$ 1	$ 162,391	$ (158,912)	$ (459)	$ 3,021

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)

	Nine Months Ended September 30,	
	2024	2023
Cash flows from operating activities:		
Net loss	$ (7,814)	$ (7,805)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of derivative liability	(3,026)	(2,051)
Stock-based compensation expense	2,094	1,228
Foreign exchange loss (gain)	244	(71)
Depreciation expense	27	32
Amortization expense	21	109
Fixed asset impairment	—	159
Provision for (reversal of) inventory reserve	28	2
Non-cash operating lease expense	31	38
Changes in operating assets and liabilities:		
Accounts receivable	89	(23)
Other receivables	20	236
Inventory	(345)	66
Prepaid expense and other current assets	390	323
Operating lease liabilities	(34)	(40)
Accounts payable	214	(130)
Accrued and other current liabilities	(571)	(431)
Deferred revenue	(31)	(24)
Net cash used in operating activities	(8,663)	(8,382)
Cash flows from investing activities:		
Purchase of property and equipment	(5)	(26)
Net cash used in investing activities	(5)	(26)
Cash flows from financing activities:		
Proceeds from issuance of common stock	2,961	284
Proceeds from issuance of warrants	4,829	—
Proceeds from exercise of warrants	164	207
Share issuance costs	(1,000)	(36)
Net cash provided by financing activities	6,954	455
Effect of currency exchange rate changes on cash and cash equivalents	—	—
Net decrease in cash and cash equivalents	(1,714)	(7,953)
Cash and cash equivalents at beginning of period	5,182	14,549
Cash and cash equivalents at end of period	$ 3,468	$ 6,596
Supplemental cash flow information		
Non-cash investing and financing transactions:		
Derivative warrant liability reclassified to equity on exercise of warrants	$ 101	$ 628
Deferred offering costs reclassified to equity upon public offering	$ 132	$ —
Warrant proceeds due from transfer agent	$ —	$ 435

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, 2023 that was filed with the Securities and Exchange Commission on March 28, 2024 ("2023 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 2023 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.

Reverse Stock Split

At the annual meeting of stockholders on May 24, 2023, our stockholders voted to approve a reverse stock split of our outstanding Class A common stock ("Common Stock") at a ratio in the range of 1-for-10 to 1-for-80 to be determined at the discretion of the Company's Board of Directors (the "Board"). On August 11, 2023, the Board approved a 1-for-50 reverse stock split of the Company's issued and outstanding Common Stock (the "Reverse Stock Split"). Refer to Note 6 for additional information.

All issued and outstanding Common Stock and per share amounts contained in the financial statements have been retroactively adjusted to reflect this Reverse Stock Split for all periods presented. In addition, a proportionate adjustment was made to the per share exercise price and the number of shares issuable upon the exercise of all outstanding stock options, restricted stock units and warrants to purchase shares of Common Stock. In accordance with the terms of the warrant agreement for the public warrants described further in Note 6, the exercise price for these warrants was reset to the volume-weighted average price for the five days following the Reverse Stock Split. A proportionate adjustment was also made to the number of shares reserved for issuance pursuant to the Company's equity incentive compensation plans to reflect the Reverse Stock Split. Any fraction of a share of Common Stock that was created as a result of the Reverse Stock Split was rounded down to the next whole share and stockholders received cash settlement equal to the market value of the fractional share, determined by multiplying such fraction by the closing sales price of the Company's Common Stock as reported on Nasdaq on the last trading day before the Reverse Stock Split effective date. The authorized shares and par value of the Common Stock and preferred stock were not adjusted as a result of the Reverse Stock Split.

Going Concern Uncertainty

As of September 30, 2024, the Company had cash and cash equivalents of $3.5 million. For the nine months ended September 30, 2024, the Company had an operating loss of $10.8 million, and as of September 30, 2024, its accumulated deficit was $167.8 million. For the nine months ended September 30, 2024, the Company had $0.3 million 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 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 the Company will be successful in raising additional capital or that such capital, if available, will be on terms that are acceptable to the Company. If the Company is unable to raise sufficient additional capital, the Company may be compelled to reduce the scope of its operations.

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 and increased inflation. 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, 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 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. The guidance requires expanded interim and annual disclosures of segment information including the disclosure of significant segment expenses that are regularly provided to the chief operating decision maker and included within segment profit and loss. The guidance is effective for the Company's fiscal 2024 Form 10-K and interim periods thereafter. 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's fiscal 2025 Form 10-K. 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.

In November 2024, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*. The guidance requires interim and annual disclosures of disaggregated information about certain income statement expense line items. The guidance is effective for the Company's fiscal 2027 Form 10-K and interim periods thereafter. The Company is currently evaluating the ASU to determine its impact on the Company's 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 September 30, 2024 and December 31, 2023.

Inventory, net (in thousands)

	September 30, 2024	December 31, 2023
Raw materials	$ 349	$ 351
Work-in-process	375	67
Finished goods	137	96
Inventory, gross	861	514
Inventory reserve	(87)	(57)
Inventory, net	$ 774	$ 457

During the nine months ended September 30, 2024, $2 thousand of inventory was written off to the inventory reserve.

Prepaid expenses and other current assets (in thousands)

	September 30, 2024	December 31, 2023
Prepaid expenses	$ 299	$ 689
Inventory related	334	333
Deferred offering costs	7	140
Total prepaid expenses and other current assets	$ 640	$ 1,162

Accrued and other current liabilities (in thousands)

	September 30, 2024	December 31, 2023
Insurance payable	$ —	$ 446
Employees benefits	586	509
Professional services	36	52
Franchise tax	30	168
Other	36	85
Total accrued and other current liabilities	$ 688	$ 1,260

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 September 30, 2024 and December 31, 2023 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

The Company has an operating lease for office space with lease terms expiring in March 2025. The lease does not contain any options to extend. Operating lease costs for the three and nine months ended September 30, 2024 and 2023 were $11 thousand and $31 thousand, $14 thousand and $41 thousand, respectively.

Maturities of operating lease liabilities as of September 30, 2024 were as follows (in thousands):

2024 (remaining)	$	12
2025		12
Total lease payments		24
Less: imputed interest		(1)
Total lease liabilities	$	23

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 September 30, 2024 and December 31, 2023, 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 September 30, 2024 and December 31, 2023 is comprised of warrants issued in connection with the registered public offering completed in August 2022 ("August 2022 Public Offering") discussed in more detail in Note 8 to our Consolidated Financial Statements included our 2023 10-K. 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.

At-The-Market Offering

On June 23, 2023, the Company entered into a Sales Agreement (the "Sales Agreement") with Roth Capital Partners, LLC ("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. As of September 30, 2024, 201,211 shares have been sold under the ATM generating net proceeds of $1.8 million.

Series B Preferred Stock

On March 23, 2023, the Board of Directors declared a dividend of one one-thousandth of a share of Series B Preferred Stock ("Series B Preferred Stock") for each outstanding share of Common Stock held of record on April 3, 2023. The value of the Series B Preferred Stock issued in connection with the stock dividend was immaterial.

The outstanding shares of Series B Preferred Stock voted together with the outstanding shares of the Company's Common Stock, as a single class, exclusively with respect to a proposal giving the Board of Directors the authority, as it determines appropriate, to implement a reverse stock split within twelve months following the approval of such proposal by the Company's stockholders as well as any proposal to adjourn any meeting of stockholders called for the purpose of voting on the foregoing matters.

Each share of Series B Preferred Stock entitled the holder to 1,000,000 votes per share and each fraction of a share of Series B Preferred Stock had a ratable number of votes. The holder of Series B Preferred Stock, as such, are not entitled to receive dividends.

At the annual meeting of stockholders of the Company held on May 24, 2023, the Company's stockholders approved an amendment to the Company's Certificate of Incorporation to effect a reverse stock split of its outstanding Common Stock. All shares of Series B Preferred Stock that did not vote in person or by proxy were redeemed in whole by the Company. Shares of Series B Preferred Stock that did vote in person or by proxy will need to request redemption from

the Company at a rate of $0.001 per share in cash. As of September 30, 2024, no shareholders of Series B Preferred Stock have requested such redemption.

Warrants

The Company issued warrants to purchase an aggregate of 720,000 shares of Common Stock ("2022 Warrants") in connection with the August 2022 Public Offering, as more fully described in Note 8 to our Consolidated Financial Statements included our 2023 10-K. The 2022 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. Accordingly, the 2022 Warrants are being accounted for as a derivative liability instrument. As a result of the Company's Reverse Stock Split on August 16, 2023, refer to Note 1, the exercise price on the 2022 Warrants was reset to $6.9135 per share based on the volume-weighted average price ("VWAP") for the five stock trading days immediately following the Reverse Stock Split. On May 9, 2024, in connection with the 2024 Public Offering, the exercise price of the 2022 Warrants was again reset to $1.6163 per share based on the VWAP for the five stock trading days immediately following the announcement of the 2024 Public Offering.

The fair value of the 2022 Warrants as of September 30, 2024 and December 31, 2023 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:

	September 30, 2024	December 31, 2023
Stock price	$ 0.56	$ 8.04
Warrant term (in years)	2.86	3.61
Expected volatility	91.90 %	84.10 %
Risk-free interest rate	3.59 %	3.96 %
Dividend rate	0.00 %	0.00 %

The fair value of the derivative liability associated with the 2022 Warrants as of September 30, 2024 and December 31, 2023 was $0.2 million and $3.3 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. 2022 Warrants were exercised to purchase of 23,400 shares of Common Stock at $6.9135 per share for $162 thousand in net proceeds and no 2022 Warrants were cancelled during the nine months ended September 30, 2024. The portion of the derivative liability relating to the exercised warrants of $101 thousand was reclassified into stockholders' equity based on the fair value on the date of reclassification. The remaining outstanding 2022 Warrants to purchase 603,690 shares of Common Stock are classified as a derivative liability as of September 30, 2024, are exercisable upon issuance and will expire five years following the date of issuance.

The Company has outstanding equity-classified warrants to purchase 5,951,466 shares of Common Stock at a weighted average exercise price of $3.59, with expiration dates ranging from March 2025 to May 2029. The weighted average exercise price includes 94,444 Pre-funded Warrants with a nominal exercise price of $0.001 outstanding as of September 30, 2024. The weighted average exercise price excluding the outstanding Pre-funded Warrants is $3.65. During the nine months ended September 30, 2024, 2,052,778 equity-classified warrants were exercised for which 2,052,703 equity-classified warrants were settled as the result of the cashless exercise provision.

7. STOCK-BASED COMPENSATION

The Company may issue stock-based compensation awards under the Helius Medical Technologies, Inc. 2022 Equity Incentive Plan (as amended, the "2022 Plan") or the Helius Medical Technologies, Inc. 2021 Inducement Plan (as amended, the "Inducement Plan"), as described more fully in the 2023 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 September 30, 2024, the remaining shares available for grant were 17,155 under the 2022 Plan and 123,910 under the Inducement Plan.

During the nine months ended September 30, 2023, the Company granted 1,832,500 stock options out of the 2022 Plan and 23,500 stock options out of the Inducement Plan at a weighted average exercise price of $0.96 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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Risk-free interest rate	4.38 %	4.29 %	4.38 %	3.93 %
Expected volatility	128.73 %	75.26 %	128.73 %	79.43 %
Expected term (years)	5.27	5.76	5.27	5.70
Expected dividend yield	0.00 %	0.00 %	0.00 %	0.00 %
Fair value, per share	$ 0.84	$ 6.40	$ 0.84	$ 10.17

There were no restricted stock units granted during the nine months ended September 30, 2024.

As of September 30, 2024, there were an aggregate of 2,097,935 stock options outstanding with a weighted average exercise price of $9.75 per share and no unvested restricted stock units outstanding.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Cost of sales	$ 14	$ 5	$ 23	$ 14
Selling, general and administrative	1,032	330	1,660	989
Research and development	281	68	411	225
Total stock-based compensation expense	$ 1,327	$ 403	$ 2,094	$ 1,228

As of September 30, 2024, the total remaining unrecognized compensation expense related to nonvested stock options and restricted stock units was $1.9 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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Basic:				
Net loss available to common stockholders — basic	$ (3,686)	$ (3,663)	$ (7,814)	$ (7,805)
Weighted average common shares outstanding — basic [1]	3,740,625	667,809	2,363,718	573,950
Loss per share - basic	$ (0.99)	$ (5.49)	$ (3.31)	$ (13.60)
Diluted:				
Net loss available to common stockholders — diluted [2]	$ (3,686)	$ (3,663)	$ (7,814)	$ (7,805)
Weighted average common shares outstanding — diluted [1]	3,740,625	667,809	2,363,718	573,950
Loss per share — diluted	$ (0.99)	$ (5.49)	$ (3.31)	$ (13.60)

(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. As of September 30, 2024, 1,604,778 Pre-funded Warrants were exercised and 94,444 Pre-funded Warrants remained outstanding. As the remaining shares underlying the Pre-funded Warrants are exercisable for nominal consideration of $0.001 per share, 94,444 in common shares underlying the unexercised Pre-funded Warrants were considered outstanding for purposes of the calculation of loss per share for the three and nine months ended September 30, 2024. Refer to Note 6 for additional information about the 2024 Public Offering and the Pre-funded Warrants.

(2) For the nine months ended September 30, 2024 and 2023, no adjustment was made to the numerator.

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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Stock options	2,097,935	245,972	2,097,935	245,972
Restricted stock units	—	3,884	—	3,884
Warrants [1]	6,460,712	638,943	6,460,712	731,853

(1) Anti-dilutive warrants include the 2022 Warrants, Series A Warrants, Series B 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 and nine months ended September 30, 2024 and 2023, the Company recorded royalty expense from the sale of devices of

approximately $1 thousand and $13 thousand, $5 thousand and $19 thousand, respectively, in its Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss.

10. ENTERPRISE-WIDE DISCLOSURES

Operating segments are defined as components of an enterprise for which discrete financial information is available that is evaluated regularly by the chief operating decision maker ("CODM") in deciding how to allocate resources and in assessing performance. Our CODM is the Chief Executive Officer. The Company operates and manages its business within one operating and reportable segment related to the sale of PoNS devices directly to patients in the United States and to clinics in Canada.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Product sales, net:				
United States	$ 7	$ 60	$ 153	$ 310
Canada	33	72	182	172
Total product sales, net	40	132	335	482
Other revenue	11	11	33	28
Total revenue	$ 51	$ 143	$ 368	$ 510

Seven and two customers accounted for 100% and 75% of net product sales for the three and nine months ended September 30, 2024, respectively, and two customers accounted for 91% and 57% of net product sales for the three and nine months ended September 30, 2023, respectively. Three customers accounted for 98% of accounts receivable, net as of September 30, 2024 and a single customer accounted for 83% of accounts receivable, net as of December 31, 2023.

11. FIXED ASSET IMPAIRMENT

During the third quarter of 2023, the Company identified an impairment indicator associated with its property and equipment and performed interim impairment tests on the long-lived tangible assets as a result of the planned change of the Company's contract manufacturing partner. The interim impairment tests were performed using estimated market prices. The Company determined that the fair value of certain long-lived tangible assets were lower than the related book values. Additionally, for certain long-lived tangible assets, it was more likely than not that those long-lived assets would be disposed significantly before the end of their previously estimated useful lives. As a result, impairment charges of $159 thousand were recorded in the third quarter of 2023 on its long-lived tangible assets.

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," "Helius" or "Company" mean Helius Medical Technologies, Inc. and its wholly owned operating subsidiaries, Helius Medical, Inc. and Helius Medical Technologies (Canada), 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, 2023, 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, 2023 filed with the Securities and Exchange Commission ("SEC") on March 28, 2024 (the "2023 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 including the Company's plan to request that the Centers for Medicare & Medicaid Services ("CMS") revisit its final and proposed pricing for the mouthpiece and PoNS controller, expected enrollment, 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, the issuance by the CMS of rules regarding coverage of emerging technologies, clinical development plans, 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 our 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 2023 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, Helius 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

Presently, PoNS Therapy is not covered by CMS or reimbursed under contract by any third-party payers in the U.S. We are pursuing commercial insurance coverage and Medicare reimbursement 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. The Company has requested to meet with CMS 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) to be effective April 1, 2025. The Company is scheduled to discuss the preliminary decision regarding the PoNS Controller at the HCPCS public meeting on November 8, 2024 where it plans to present the differences between the PoNS Controller from TENS devices. The Company will request that CMS set pricing for the PoNS Controller using the gap filling methodology that works off the government contract and insurance.

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) 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. To regain compliance, the closing bid price of the Company's Common Stock must be at least $1.00 per share for a minimum of 10 consecutive business days at any time prior to February 5, 2025. 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 the Nasdaq Capital Market may be negatively impacted by this Nasdaq rule.

As discussed further in Note 6 to our unaudited condensed consolidated financial statements, in May 2024, the Company closed on a registered public offering of its Common Stock and warrants and received net proceeds of approximately $5.5 million.

On April 4, 2024, the Company received written notice from Nasdaq stating that the Company no longer complied with the minimum stockholders' equity requirement under Nasdaq Listing Rule 5550(b)(1) for continued listing on The Nasdaq Stock Market LLC because the Company's stockholders' equity, as reported in our 2023 10-K, had fallen below $2.5 million. The notice also indicated that the Company did not meet the alternative compliance standards. Under applicable Nasdaq rules, the Company had 45 calendar days from the date of the notice, or until May 20, 2024, to submit a plan to regain compliance. On May 31, 2024, the Company received formal notification from Nasdaq confirming that, following the consummation of a registered public offering on May 9, 2024, the Company regained compliance with the minimum stockholders' equity requirement, and that the Company satisfied all other applicable criteria for continued listing on The Nasdaq Capital Market.

During the second quarter of 2024, the Company received the first third-party reimbursement from a major insurance carrier at a 7% rebate, which results in pricing of $23,900 for the PoNS device, comprised of $16,554 for the PoNS controller and $7,347 for the PoNS mouthpiece, exclusive of rounding.

During the first quarter of 2024, the Company partnered with Lovell Government Services, 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 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 Texas and east of the Mississippi with plans to expand west.

During the first quarter of 2024, the Company reached alignment with the FDA on a registrational program to evaluate the therapeutic benefit of PoNS on gait and balance deficits in chronic stroke subjects that consists of a randomized controlled study and an open label study, targeting to enroll 60 and 30 subjects respectively, supported by additional data from an

investigator initiated clinical ("IIT") trial in collaboration with Medical University of South Carolina ("MUSC"), aiming to enroll 60 subjects at two U.S. sites, including MUSC and Brooks Rehabilitation in Jacksonville, FL. To sustain the US registration for stroke, Helius has started, in the summer of 2024, the company-sponsored pivotal randomized controlled study ("HMI-RCT") on the efficacy and safety of PoNS Therapy in people with chronic stroke at five to six Canadian and US centers of excellence for stroke rehabilitation. Sites have started enrollment in July are expected to complete target enrollment by the end of 2024. The company-sponsored open label study ("HMI-OLS"), which started early in 2024 and is currently ongoing at five U.S. sites, has completed the target enrollment of 30 participants on Sep 30, 2024. The results from the HMI- RCT and HMI-OLS will constitute the primary data package submission, which will be also supported by the results from the IIT, to obtain FDA authorization for stroke in the United States. Enrollment for the registrational program is expected to be completed by the end of 2024 with a submission to FDA targeted for mid-to-late 2025. An outcome research program to assess the effect of on-label PoNS Therapy on the risk of falling in subjects with gait and balance deficit due to stroke, traumatic brain injury, and multiple sclerosis is ongoing at three sites in Canada with results expected by the end of 2024.

During the third quarter of 2023, the Company began implementing the transition of the manufacturing of PoNS device controllers and mouthpieces to Minnetronix, Inc. from its previous contract manufacturer, Key Tronic Corporation. The Company expects the transition to be substantially completed by the end of 2024.

We will continue to monitor the development of CMS's new pathway for coverage of innovative new devices, Transitional Coverage of Emerging Technology ("TCET"), which is replacing the repealed Medicare Coverage of Innovative Technologies rule. CMS is expected to provide additional information about TCET to the public for comments in 2024. As we follow the evolution of TCET, we will continue to assess our evidence generation strategy to reach the greatest potential to gain CMS reimbursement benefits as a result of our breakthrough designation in MS.

We also intend to provide broad access and reimbursement for the PoNS Therapy over time through commercial insurers. Prior to the initiation of CMS or 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.

Material Trends and Uncertainties

Global Economic Conditions

Generally, worldwide economic conditions remain uncertain, in part due to supply chain disruptions, labor shortages, global conflicts and increased inflation. 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, 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 September 30, 2024 compared to the Three Months Ended September 30, 2023

The following table summarizes our results of operations for the three months ended September 30, 2024 and 2023 (in thousands):

	Three Months Ended September 30, 2024	2023	Change
Revenue:			
Product sales, net:			
United States	$ 7	$ 60	$ (53)
Canada	33	72	(39)
Total product sales, net	40	132	(92)
Other revenue	11	11	—
Total revenue	51	143	(92)
Cost of revenue	187	187	—
Gross loss	(136)	(44)	(92)
Operating expenses:			
Selling, general and administrative expenses	2,850	2,196	654
Research and development expenses	1,077	722	355
Amortization expense	7	32	(25)
Fixed asset impairment	—	159	(159)
Total operating expenses	3,934	3,109	825
Loss from operations	(4,070)	(3,153)	(917)
Nonoperating income (expense)			
Interest income (expense), net	(1)	68	(69)
Change in fair value of derivative liability	152	(393)	545
Foreign exchange gain (loss)	178	(192)	370
Other income, net	55	7	48
Nonoperating income (expense), net	384	(510)	894
Loss before provision for income taxes	(3,686)	(3,663)	(23)
Provision for income taxes	—	—	—
Net loss	$ (3,686)	$ (3,663)	$ (23)

Revenue

The decrease in net product sales for the three months ended September 30, 2024 as compared to the same period in the prior year was primarily attributable to a decrease in U.S. sales of PoNS systems after the termination of our Patient Therapy Access Program ("PTAP") on June 30, 2023 as well as the termination of the previously offered temporary cash pay pricing in May 2024.

Cost of Revenue

The cost of revenue for the three months ended September 30, 2024 reflects adjustments to excess inventory reserves resulting from advanced purchases relating to our third-party contract manufacturer transition and in part from adjustments to the production forecast based upon the continued delay by CMS in establish reimbursement pricing for the PoNS Mouthpiece and Controller.

Gross Loss

Gross loss for the three months ended September 30, 2024 was $136 thousand compared to $44 thousand for the same period in the prior year. The decrease was primarily a result of lower sales compared to the same period in the prior year and the impact of the inventory adjustment in cost of revenue.

Selling, General and Administrative Expense

The increase in selling, general and administrative expenses in the third quarter of 2024 as compared to the same period in prior year resulted primarily from a $0.9 million increase in stock-based compensation expense, partially offset by a $0.2 million decrease in costs relating to the transfer of third-party manufacturing as well as a $0.2 million in asset impairment expense in the prior year period.

Research and Development Expense

The increase in research and development expenses was driven primarily by an increase in clinical trial activities for stroke and risk of fall programs.

Amortization Expense

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

Fixed Asset Impairment

During the nine months ended September 30, 2023, we recorded an impairment of $159 thousand for certain machinery used in the production of our inventory.

Nonoperating income (expense)

Interest Income (Expense), Net

Net interest expense for the three months ended September 30, 2024 compared to net interest income in the prior year period resulted from lower cash balances earning interest income year to year, respectively, offset by interest expense related to lease commitments.

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 September 30, 2024 of $0.2 million was primarily due to a decrease in our stock price.

Foreign Exchange Loss

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

Other Income, Net

Other income for the three months ended September 30, 2024 was primarily attributable to dividend income earned on investments of excess cash in money market mutual funds.

Nine Months Ended September 30, 2024 compared to the Nine Months Ended September 30, 2023

The following table summarizes our results of operations for the nine months ended September 30, 2024 and 2023 (in thousands):

	Nine Months Ended September 30, 2024	2023	Change
Revenue:			
Product sales, net:			
United States	$ 153	$ 310	$ (157)
Canada	182	172	10
Total product sales, net	335	482	(147)
Other revenue	33	28	5
Total revenue	368	510	(142)
Cost of revenue	428	493	(65)
Gross profit (loss)	(60)	17	(77)
Operating expenses:			
Selling, general and administrative expenses	7,940	7,639	301
Research and development expenses	2,735	2,292	443
Amortization expense	21	109	(88)
Fixed asset impairment	—	159	(159)
Total operating expenses	10,696	10,199	497
Loss from operations	(10,756)	(10,182)	(574)
Nonoperating income			
Interest income (expense), net	(14)	257	(271)
Change in fair value of derivative liability	3,027	2,051	976
Foreign exchange gain (loss)	(251)	62	(313)
Other income, net	180	7	173
Nonoperating income, net	2,942	2,377	565
Loss before provision for income taxes	(7,814)	(7,805)	(9)
Provision for income taxes	—	—	—
Net loss	$ (7,814)	$ (7,805)	$ (9)

Revenue

The decrease in net product sales for the nine months ended September 30, 2024 as compared to the same period in the prior year was primarily attributable to decreased U.S. sales of PoNS systems after the termination of PTAP on June 30, 2023 and the temporary cash pay pricing in May 2024.

Cost of Revenue

The cost of revenue decrease for the nine months ended September 30, 2024 was primarily attributable to lower sales and inventory adjustments compared to the same period in the prior year.

Gross Profit (loss)

Gross loss for the nine months ended September 30, 2024 was $60 thousand compared to gross profit of $17 thousand for the same period in the prior year. The decrease was primarily a result of lower sales compared to the same period in the prior year, partially offset by lower inventory adjustment.

Selling, General and Administrative Expense

The increase in selling, general and administrative expenses in the nine months ended September 30, 2024 as compared to the same period in prior year was primarily attributable to a $0.9 million increase in stock-based compensation expense, partially offset by an absence of $0.2 million in asset impairment and a $0.3 million decrease in professional fees.

Research and Development Expense

The increase in research and development expenses year-to-year was primarily comprised of clinical trial activities for stroke and risk of fall programs.

Amortization Expense

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

Fixed Asset Impairment

During the nine months ended September 30, 2023, we recorded an impairment of $159 thousand for certain machinery used in the production of our inventory.

Nonoperating income

Interest Income (Expense), Net

Net interest expense for the nine months ended September 30, 2024 compared to net interest income in the prior year period resulted from lower cash balances earning interest income year to year, respectively, offset by interest expense related to lease commitments.

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 nine months ended September 30, 2024 of $3.0 million was primarily due to a decrease in our stock price.

Foreign Exchange 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 nine months ended September 30, 2024 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):

	September 30, 2024	December 31, 2023
Cash and cash equivalents	$ 3,468	$ 5,182
Working capital	3,910	5,559

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 included $16.3 million in net proceeds we received from a public offering of our Common Stock and warrants completed in August 2022 as discussed in more detail in Note 8 to our Consolidated Financial Statements included our 2023 10-K. 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 nine months ended September 30, 2024 the Company issued and sold shares with gross proceeds of $1.4 million under the ATM. As discussed in more detail in Note 6, the Company received gross proceeds of $0.2 million from the issuance of shares upon the exercise of warrants and a $5.5 million net proceeds from the 2024 Public Offering in the nine months ended September 30, 2024.

Statement of Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2024 and 2023 (in thousands):

	Nine Months Ended September 30,		
	2024	2023	Change
Net cash used in operating activities	$ (8,663)	$ (8,382)	$ (281)
Net cash used in investing activities	(5)	(26)	21
Net cash provided by financing activities	6,954	455	6,499
Effect of foreign exchange rate changes on cash	—	—	—
Net decrease in cash and cash equivalents	$ (1,714)	$ (7,953)	$ 6,239

Net Cash Used in Operating Activities

The higher level of cash used in operating activities in the nine months ended September 30, 2024 primarily resulted from the increase in selling, general and administrative 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 nine months ended September 30, 2024, we received net proceeds of $5.5 million from the issuance of Common Stock and warrants under the 2024 Public Offering, and $1.3 million in net proceeds from the issuance and sale of shares under the ATM. In addition, we received $0.2 million in net proceeds from the exercise of warrants.

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 $7.8 million for each of the nine months ended September 30, 2024 and 2023. As of September 30, 2024, we had an accumulated deficit of $167.8 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 $5.5 million net proceeds from the issuance of Common Stock and warrants in May 2024 will be sufficient to fund our operations into 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 expenditure 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 2023 10-K. There have been no changes in critical accounting policies in the current year from those described in our 2023 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 nine months ended September 30, 2024, our risk factors have not changed materially from those risk factors previously disclosed in our 2023 10-K except as set forth below. You should carefully consider the risk factors discussed in Part I, "Item 1A. Risk Factors" in our 2023 10-K. The risks described in our 2023 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 Listing Qualifications Staff (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 Nasdaq Marketplace Rule 5550(a)(2) (the "Minimum Bid Price Requirement").

In accordance with Nasdaq Marketplace Rule 5810(c)(3)(A), we have a period of 180 calendar days from August 9, 2024, or until February 5, 2025, to regain compliance with the Minimum Bid Price Requirement. If at any time before February 5, 2025, the closing bid price of our Common Stock closes at or above $1.00 per share for a minimum of 10 consecutive business days (which number days may be extended by Nasdaq), Nasdaq will provide written notification that we have achieved compliance with the Minimum Bid Price Requirement, and the matter would be resolved.

The Notification Letter also disclosed that in the event we do not regain compliance with the Rule by February 5, 2025, we may be eligible for additional time. To qualify for additional time, we would be required to meet the applicable market value of publicly held shares requirement for continued listing and all other applicable standards for initial listing on The Nasdaq Capital Market, with the exception of the bid price requirement, and would need to provide written notice of our intention to cure the deficiency during the second compliance period. If we meet these requirements, Nasdaq will inform us that it has been granted an additional 180 calendar days. However, if it appears to the Staff that we will not be able to cure the deficiency, or if we are otherwise not eligible, Nasdaq will provide notice that our securities will be subject to delisting.

We intend to continue actively monitor the closing bid price for our Common Stock between now and February 5, 2025, and will consider available options to resolve the deficiency and regain compliance with the Minimum Bid Price Requirement. If we do not regain compliance within the allotted compliance period, including any extensions that may be

granted by Nasdaq, Nasdaq will provide notice that our Common Stock will be subject to delisting. We would then be entitled to appeal that determination to a Nasdaq hearings panel. There can be no assurance that we will regain compliance with the Minimum Bid Price Requirement during the 180-day compliance period, secure a second period of 180 calendar days to regain compliance, or maintain compliance with the other Nasdaq listing requirements.

If our Common Stock is delisted from Nasdaq, our ability to raise capital through public offerings of our securities and to finance our operations could be adversely affected. 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.

If CMS does not change its position on the reimbursement rates of the PoNS Controller and Mouthpiece, the use of our products may decline and our ability to generate revenue may be decreased.

In the U.S., the commercial success of our existing and any future products largely depends on the extent to which governmental payers at the federal and state levels, including Medicare and Medicaid, private health insurers and other third-party payers provide coverage for and establish adequate reimbursement levels for our products. The existence of coverage and adequate reimbursement for our products by government and private payers is critical to market acceptance of our existing and future products. Suppliers are not likely to furnish our existing and any future products if they do not receive adequate reimbursement for our products.

Many private payers currently base their reimbursement policies on the coverage decisions and payment amounts determined by CMS, which administers the Medicare program. On October 7, 2024, CMS posted the final payment rate for the PoNS Mouthpiece at $2,963.30 to be effective January 1, 2025 and deferred final national determination of the payment rate for the PoNS Controller to the next payment cycle. On October 8, 2024, CMS published the preliminary rate for the PoNS Controller at the capped total payment of $519.80 to be effective April 1, 2025. We have requested to meet with CMS prior to the PoNS Mouthpiece pricing taking effect on January 1, 2025 to request that CMS considers increasing this rate by revisiting the starting point for the gap filling process to more appropriately use the market pricing established through our prior negotiation with the VA and an insurance carrier. In addition, we are scheduled to discuss the preliminary decision regarding the PoNS Controller at the HCPCS public meeting on November 8, 2024. At this meeting, we plan to request that CMS consider increasing the PoNS Controller reimbursement rate by presenting the differences between the PoNS Controller from TENS devices as CMS has based the current preliminary rate on its view that the PoNS Controller is comparable to devices reported with HCPCS code E0730 (transcutaneous electrical nerve stimulation (TENS) device, four or more leads, for multiple nerve stimulation). At this meeting, we will also request that CMS set pricing for the PoNS Controller using the gap filling methodology that works off the government contract and insurance.

If CMS is unwilling to change its positions with regards to the PoNS Controller and Mouthpiece reimbursement rates, we may not be able to sell our product profitably, and it could adversely affect our ability to market and sell our products and negatively affect our financial performance.

We are currently in the process of transitioning our manufacturing functions to a new contract manufacturer and any delays in the manufacturing process as a result of this transition could harm our business.

We have depended on our third-party contract manufacturing partner, Key Tronic Corporation, to manufacture and supply our PoNS device for clinical and commercial purposes. During the third quarter of 2023, the Company began implementing the transition of the manufacturing of PoNS systems and mouthpieces to Minnetronix, Inc. While the Company expects this transition to be substantially completed by the end of 2024, it is possible that the transition could create delays or disruptions in the manufacturing process. Any delays or disruptions in the manufacturing of our PoNS device during this transition could negatively impact our business.

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 nine months ended September 30, 2024, 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

Exhibit No.	Description of Exhibit
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)
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: November 12, 2024

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

Dated: November 12, 2024

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

EXHIBIT 31.1

CERTIFICATIONS

I, Dane C. Andreeff, certify that:

1) I have reviewed this report on Form 10-Q for the period ended September 30, 2024 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: November 12, 2024

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

EXHIBIT 31.2

CERTIFICATIONS

I, Jeffrey S. Mathiesen, certify that:

1) I have reviewed this report on Form 10-Q for the period ended September 30, 2024 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: November 12, 2024

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

EXHIBIT 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
HELIUS MEDICAL TECHNOLOGIES, INC.
FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2024
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 September 30, 2024 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: November 12, 2024

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

EXHIBIT 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
HELIUS MEDICAL TECHNOLOGIES, INC.
FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2024
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 September 30, 2024 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: November 12, 2024

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