Table of Contents

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

FORM 10-Q

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

For the quarterly period ended March 31, 2023

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 May 3, 2023, the registrant had 28,215,394 shares of Class A common stock, $0.001 par value per share, outstanding.

HELIUS MEDICAL TECHNOLOGIES, INC.
INDEX

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

	March 31, 2023	December 31, 2022
ASSETS		
Current assets		
Cash and cash equivalents	$ 11,340	$ 14,549
Accounts receivable, net	11	71
Other receivables	156	272
Inventory, net	617	589
Prepaid expenses and other current assets	1,085	1,216
Total current assets	13,209	16,697
Property and equipment, net	354	347
Intangible assets, net	101	140
Operating lease right-of-use asset, net	91	103
Total assets	$ 13,755	$ 17,287
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 840	$ 627
Accrued and other current liabilities	856	1,280
Operating lease liabilities	51	54
Deferred revenue	42	27
Total current liabilities	1,789	1,988
Operating lease liabilities	46	56
Deferred revenue	157	175
Derivative liability	5,696	6,917
Total liabilities	7,688	9,136
Commitments and contingencies (Note 9)		
Stockholders' equity		
Class A common stock, $0.001 par value; 150,000,000 shares authorized; 28,213,378 and 28,207,330 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	28	28
Additional paid-in capital	160,023	159,618
Accumulated deficit	(153,601)	(151,107)
Accumulated other comprehensive loss	(383)	(388)
Total stockholders' equity	6,067	8,151
Total liabilities and stockholders' equity	$ 13,755	$ 17,287

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

Helius Medical Technologies, Inc.
Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2023	2022
Revenue		
Product sales, net	$ 106	$ 183
Other revenue	5	7
Total revenue	111	190
Cost of revenue	122	124
Gross profit (loss)	(11)	66
Operating expenses		
Selling, general and administrative expenses	2,874	2,819
Research and development expenses	886	1,764
Amortization expense	39	47
Total operating expenses	3,799	4,630
Loss from operations	(3,810)	(4,564)
Nonoperating income (expense)		
Interest income (expense), net	100	—
Change in fair value of derivative liability	1,221	—
Foreign exchange (loss) gain	(5)	217
Other income (expense), net	—	1
Nonoperating income (expense), net	1,316	218
Loss before provision for income taxes	(2,494)	(4,346)
Provision for income taxes	—	—
Net loss	(2,494)	(4,346)
Other comprehensive income (loss)		
Foreign currency translation adjustments	5	(202)
Comprehensive loss	$ (2,489)	$ (4,548)
Loss per share		
Basic	$ (0.09)	$ (1.15)
Diluted	$ (0.09)	$ (1.15)
Weighted average number of common shares outstanding		
Basic	28,209,346	3,787,871
Diluted	28,209,346	3,787,871

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

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

	Class A Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares	Amount				
Balance as of December 31, 2022	28,207,330	$ 28	$ 159,618	$ (151,107)	$ (388)	$ 8,151
Settlement of restricted stock units	6,048	—	—	—	—	—
Stock-based compensation	—	—	405	—	—	405
Other comprehensive income	—	—	—	—	5	5
Net loss	—	—	—	(2,494)	—	(2,494)
Balance as of March 31, 2023	28,213,378	$ 28	$ 160,023	$ (153,601)	$ (383)	$ 6,067

	Class A Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares	Amount				
Balance as of December 31, 2021	3,780,674	$ 4	$ 149,412	$ (137,035)	$ (1,125)	$ 11,256
Settlement of restricted stock units	1,584	—	—	—	—	—
Common stock issued for services	4,528	—	20	—	—	20
Stock-based compensation	8,011	—	402	—	—	402
Other comprehensive loss	—	—	—	—	(202)	(202)
Net loss	—	—	—	(4,346)	—	(4,346)
Balance as of March 31, 2022	3,794,797	$ 4	$ 149,834	$ (141,381)	$ (1,327)	$ 7,130

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

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

	Three Months Ended March 31,	
	2023	2022
Cash flows from operating activities:		
Net loss	$ (2,494)	$ (4,346)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of derivative liability	(1,221)	—
Stock-based compensation expense	405	402
Common stock issued for services	—	20
Foreign exchange loss (gain)	5	(217)
Depreciation expense	12	25
Amortization expense	39	47
Non-cash operating lease expense	12	13
Changes in operating assets and liabilities:		
Accounts receivable	60	7
Other receivables	116	4
Inventory, net	(28)	(45)
Prepaid expense and other current assets	131	(88)
Operating lease liability	(13)	(6)
Accounts payable	213	54
Accrued and other current liabilities	(424)	(425)
Deferred revenue	(3)	(127)
Net cash used in operating activities	(3,190)	(4,682)
Cash flows from investing activities:		
Purchase of property and equipment	(19)	(2)
Proceeds from sale of property and equipment	—	6
Net cash (used in) provided by investing activities	(19)	4
Cash flows from financing activities:		
Share issuance costs	—	(17)
Net cash used in financing activities	—	(17)
Effect of currency exchange rate changes on cash and cash equivalents	—	—
Net decrease in cash and cash equivalents	(3,209)	(4,695)
Cash and cash equivalents at beginning of period	14,549	11,005
Cash and cash equivalents at end of period	$ 11,340	$ 6,310
Supplemental cash flow information		
Non-cash investing and financing transactions:		
Right-of-use assets obtained in exchange for new lease liabilities	$ —	$ 151

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, 2022 that was filed with the Securities and Exchange Commission on March 9, 2023 (“2022 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 2022 10-K. Certain prior period amounts have been reclassified to conform to the current period presentation.

On April 21, 2023, the Company filed a definitive proxy statement seeking stockholder approval for a reverse stock split of our outstanding Class A common stock at a ratio in the range of 1-for-10 to 1-for-80. Refer to Note 6 for additional information.

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.

Going Concern Uncertainty

As of March 31, 2023, the Company had cash and cash equivalents of $11.3 million. For the three months ended March 31, 2023, the Company had an operating loss of $3.8 million, and as of March 31, 2023, its accumulated deficit was $153.6 million. For the three months ended March 31, 2023, the Company had $0.1 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 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, disruptions in the banking system and financial markets, lingering effects of the COVID-19 pandemic 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.

The COVID-19 pandemic that began in late 2019 introduced significant volatility to the global economy, disrupted supply chains and had a widespread adverse effect on the financial markets. Additionally, the Company's 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, the conflict in Ukraine, disruptions in the banking system and financial markets, and steps taken by governments and central banks, particularly in response to the COVID-19 pandemic as well as other stimulus and spending programs, have led to high inflation, which has increased costs and has caused changes in fiscal and monetary policy, including an increase in interest rates. Although the Company may 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.

In the opinion of management, the interim 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.

2. RECENT ACCOUNTING PRONOUNCEMENTS

In June 2016, the Financial Accounting Standards Board issued Accounting Standards Update 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments***,** which requires measurement and recognition of expected credit losses for financial assets held and requires enhanced disclosures regarding significant estimates and judgments used in estimating credit losses**.** As the Company meets the SEC definition of a Smaller Reporting Company filer, the guidance was effective for fiscal years beginning after December 15, 2022. The adoption of this guidance on January 1, 2023 did not have a material impact on the Company's unaudited condensed consolidated financial statements.

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 of less than $1 thousand as of both March 31, 2023 and December 31, 2022.

Inventory, net (in thousands)

	March 31, 2023	December 31, 2022
Raw materials	$ 334	$ 344
Work-in-process	272	284
Finished goods	75	39
Inventory, gross	681	667
Inventory reserve	(64)	(78)
Inventory, net	$ 617	$ 589

During the three months ended March 31, 2023, $14 thousand of inventory was written off to the inventory reserve.

Prepaid expenses and other current assets (in thousands)

	March 31, 2023	December 31, 2022
Prepaid expenses	$ 687	$ 817
Inventory related	398	399
Total prepaid expenses and other current assets	$ 1,085	$ 1,216

Accrued and other current liabilities (in thousands)

	March 31, 2023	December 31, 2022
Insurance payable	$ 373	$ 592
Employees benefits	331	509
Professional services	106	119
Other	46	60
Total accrued and other current liabilities	$ 856	$ 1,280

Deferred revenue

Exclusive Distribution Agreement

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

Deferred revenue as of both March 31, 2023 and December 31, 2022 is comprised of the remaining unamortized amount under these agreements. Revenue recognized is included in other revenue in the Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss.

4. LEASES

The Company has two operating leases for office space with lease terms expiring in January 2024 and March 2025. The leases do not contain any options to extend. Operating lease costs for the three months ended March 31, 2023 and 2022 were $14 thousand and $15 thousand, respectively.

Maturities of operating lease liabilities as of March 31, 2023 were as follows (in thousands):

2023 (remaining)	$ 43
2024	46
2025	12
Total lease payments	101
Less: imputed interest	(4)
Total lease liabilities	$ 97

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. 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 certificate of deposit as of both March 31, 2023 and December 31, 2022. The carrying value of cash equivalents generally approximates fair value due to their short-term nature.

The Company's derivative liability as of March 31, 2023 and December 31, 2022 is comprised of warrants issued in connection with the registered public offering completed in August 2022 ("August 2022 Public Offering") discussed in Note 6. 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.

6. COMMON STOCK, PREFERRED STOCK AND WARRANTS

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 Class A common stock held of record on April 3, 2023 (the "Record Date"). 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 will vote together with the outstanding shares of the Company's Class A 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 (the "Reverse Stock Split Proposal"), as well as any proposal to adjourn any meeting of stockholders called for the purpose of voting on the foregoing matters (the "Adjournment Proposal").

No shares of Series B Preferred Stock may be transferred by the holder except in connection with a transfer by such holder of any shares of Class A common stock held by such holder.

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

All shares of Series B Preferred Stock that are not present in person or by proxy at any meeting of stockholders held to vote on the Reverse Stock Split Proposal and the Adjournment Proposal as of immediately prior to the opening of the polls at such meeting (the "Initial Redemption Time") will automatically be redeemed in whole, but not in part, by the Company at the Initial Redemption Time without further action on the part of the Company or the holder of shares of Series B Preferred Stock (the "Initial Redemption").

The Series B Preferred Stock is not convertible into, or exchangeable for, shares of any other class or series of stock or other securities of the Company. The Series B Preferred Stock has no stated maturity and is not subject to any sinking fund. The Series B Preferred Stock is not subject to any restriction on the redemption or repurchase of shares by the Company while there is any arrearage in the payment of dividends or sinking fund installments.

The Certificate of Designation was filed with the Delaware Secretary of State and became effective on March 24, 2023.

Warrants

The Company issued warrants to purchase an aggregate of 36,000,000 shares of Class A common stock ("Public Warrants") in connection with the August 2022 Public Offering, as more fully described in the 2022 10-K. The Public

Warrants did not meet the guidance for being classified as an equity instrument due to a potential price reset prompted by a change in an unrelated instrument's conversion rate or, in the event of a fundamental transaction, settlement rights that differ from those of the underlying common stockholders. Accordingly, the Public Warrants are being accounted for as a derivative liability instrument. The fair value of the derivative liability as of March 31, 2023 and December 31, 2022 was $5.7 million and $6.9 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.

The fair value of the Public Warrants as of March 31, 2023 and December 31, 2022 was determined using both a Monte Carlo simulation model, which uses multiple input variables to determine the probability of the occurrence of a price reset or a fundamental transaction and the Black-Scholes option pricing model. The following table includes the share price and the inputs used to estimate the fair value of the warrants:

	March 31, 2023	December 31, 2022
Stock price	$ 0.25	$ 0.31
Warrant term (in years)	4.36	4.61
Expected volatility	83.70 %	80.90 %
Risk-free interest rate	3.67 %	4.04 %
Dividend rate	0.00 %	0.00 %

The 36,000,000 of outstanding liability classified Public Warrants have an exercise price of $0.75 per share, are exercisable upon issuance and will expire five years following the date of issuance. No Public Warrants were exercised or cancelled during the three months ended March 31, 2023.

The Company has outstanding equity-classified warrants to purchase 593,924 shares of Class A common stock at a weighted average exercise price of $16.32, with expiration dates ranging from October 2023 to February 2026. During the three months ended March 31, 2023, no warrants were exercised or cancelled.

7. STOCK-BASED COMPENSATION

The Company may issue stock-based compensation awards under The Helius Medical Technologies, Inc. 2022 Equity Incentive Plan ("2022 Plan") or the Helius Medical Technologies, Inc. 2021 Inducement Plan (as amended, the "Inducement Plan"), as described more fully in the 2022 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 the initial 1,121,272 to 13,215,973. As of March 31, 2023, the remaining shares available for grant were 2,195,103 under the 2022 Plan and 474,375 under the Inducement Plan.

During the three months ended March 31, 2023, the Company granted 9,949,000 stock options out of the 2022 Plan at a weighted average exercise price of $0.31 per share. The options vest over three years and expire ten years after the grant date. As of March 31, 2023, there were an aggregate of 11,122,299 stock options outstanding with a weighted average exercise price of $1.70 per share and 2,016 unvested restricted stock units outstanding with a weighted average grant date fair value of $1.40 per share.

The following table includes the weighted-average assumptions used in the Black-Scholes option pricing model and the related weighted-average grant-date fair values of stock options granted during the periods indicated:

	Three Months Ended March 31,	
	2023	2022
Risk-free interest rate	3.95 %	1.95 %
Expected volatility	79.47 %	73.53 %
Expected term (years)	5.75	5.75
Expected dividend yield	0.00 %	0.00 %
Fair value, per share	$ 0.22	$ 3.01

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

	Three Months Ended March 31,	
	2023	2022
Cost of sales	$ 4	$ 3
Selling, general and administrative	320	246
Research and development	81	153
Total stock-based compensation expense	$ 405	$ 402

As of March 31, 2023, the total remaining unrecognized compensation expense related to nonvested stock options and restricted stock units was $3.6 million which will be amortized over the weighted-average remaining requisite service period of 2.7 years.

8. BASIC AND DILUTED LOSS PER SHARE

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

	Three Months Ended March 31,	
	2023	2022
Basic:		
Net loss available to common stockholders - basic	$ (2,494)	$ (4,346)
Weighted average common shares outstanding - basic	28,209,346	3,787,871
Loss per share - basic	$ (0.09)	$ (1.15)
Diluted:		
Net loss available to common stockholders - diluted [(1)]	$ (2,494)	$ (4,346)
Weighted average common shares outstanding - diluted [(1)]	28,209,346	3,787,871
Loss per share - diluted	$ (0.09)	$ (1.15)

(1) For the three months ended March 31, 2023, no adjustment was made to the numerator and no incremental shares were added to the denominator for the Public Warrants being accounted for as a derivative liability, as the Public Warrants were out-of-the-money during the period. Refer to Note 6 for additional information about the Public Warrants.

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

	Three Months Ended March 31,	
	2023	2022
Stock options	11,122,299	785,228
Restricted stock units	2,016	775
Warrants	36,593,924	593,924

9. COMMITMENTS AND CONTINGENCIES

The Company is obligated under a license agreement with Advanced NeuroRehabilitation, LLC ("ANR") to pay a 4% royalty on net revenue collected from the sale of devices covered by the patent-pending technology. During the three months ended March 31, 2023 and 2022, the Company recorded royalty expense from the sale of devices of approximately $4 thousand and $7 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):

	March 31,	
	2023	2022
Product sales, net:		
United States	$ 75	$ —
Canada	31	183
Total product sales, net	106	183
Other revenue	5	7
Total revenue	$ 111	$ 190

A single customer accounted for 14% of net product sales for the three months ended March 31, 2023 and 67% of accounts receivable, net as of March 31, 2023. A single customer accounted for 68% of net product sales for the three months ended March 31, 2022 and 89% of accounts receivable, net as of December 31, 2022.

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. ("HMI") and Helius Medical Technologies (Canada), Inc. ("HMC"). 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, 2022, 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, 2022 filed with the Securities and Exchange Commission ("SEC") on March 9, 2023 (the "2022 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 our 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 operating plans, including expected enrollment, the issuance by CMS of rules regarding coverage of emerging technologies, patient participation and other details of the PoNSTEP study, sufficiency of cash, availability of funds and operating costs. Such forward-looking statements involve risks and uncertainties, known and unknown, including capital requirements to achieve our business objectives, disruptions in the banking system and financial markets, the COVID 19 pandemic, including its impact on our Company, the effect of inflation and increased interest rates on our ability to operate our business and access capital markets, the success of our business plan, including our ability to secure contracts with rehabilitation clinics, obtain national Medicare coverage and a reimbursement code 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, labor shortage and supply chain risks, our ability to maintain and enforce our intellectual property rights, clinical trials and the clinical development process, the product development process, the regulatory submission review and approval process, our operating costs and use of cash, and our ability to achieve significant revenues and other factors discussed in the section entitled "Item 1A. Risk Factors" in this Quarterly Report on Form 10-Q and in our 2022 10-K and those described from time to time in our 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 us as of the date hereof, and reflect our current judgment regarding our business plans, we cannot guarantee future results, events, levels of activity, performance or achievement and our actual results will almost always vary, sometimes materially, from any estimates, predictions, projections, assumptions or other future performance suggested herein. We do not intend, and undertake 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 our financial condition and results of operations should be read in conjunction with our 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 neuromodulation stimulator. 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 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) for use as a short term treatment (14 weeks) of chronic balance deficit due to mild-to-moderate traumatic brain injury, or mmTBI, and is to be used in conjunction with physical therapy; (ii) for use 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

On April 21, 2023, we filed a definitive proxy statement seeking stockholder approval for a reverse stock split of our outstanding Class A common stock at a ratio in the range of 1-for-10 to 1-for-80.

On March 23, 2023, our Board of Directors declared a dividend of one one-thousandth of a share of our Series B Preferred Stock, par value $0.001 per share (“Series B Preferred Stock”), on each outstanding share of our Class A common stock, to stockholders of record on April 3, 2023. Refer to Note 6 to our Unaudited Condensed Consolidated Financial Statements for additional information.

On March 21, 2023, we received a letter from the Listing Qualifications Staff of The Nasdaq Stock Market, LLC (“Nasdaq”) notifying the Company that Nasdaq has granted the Company a 180-day extension, until September 18, 2023, to regain compliance with the requirement for the Company’s Class A common stock, to maintain a minimum bid price of $1.00 per share for continued listing on the Nasdaq Capital Market, as set forth in Nasdaq Listing Rule 5550(a) (2).

On March 8, 2023, we received marketing authorization from Health Canada allowing us to commercialize the PoNS device in Canada for use as a short-term treatment of gait deficit due to mild and moderate symptoms from stroke. This expands our addressable market in Canada to include a patient population seeking treatment options that may resolve stroke gait deficit symptoms.

Pursuant to an Exclusive Distribution Agreement with Health Tech Connex Inc. (“HTC”) (“Exclusivity Agreement”), subject to certain terms and conditions, we granted to HTC the exclusive right to provide the PoNS Therapy in the Fraser Valley and Vancouver metro regions of British Columbia. HTC is to purchase the PoNS devices for use in these regions exclusively from us and on terms no less favorable than the then-current standard terms and conditions. The initial term of the Exclusivity Agreement expires on December 31, 2027, and is renewable by HTC for one additional five-year term. Refer to Note 3 to our Unaudited Condensed Consolidated Financial Statements for additional information.

Presently, PoNS Therapy is not covered by Center for Medicare and Medicaid ("CMS") or reimbursed by any third-party payors in the U.S. We are pursuing commercial insurance coverage and Medicare reimbursement for PoNS within the Durable Medical Equipment, or DME, benefit category. While there are currently no applicable Healthcare Common Procedure Coding System, or HCPCS, codes to describe the PoNS device or mouthpiece, we intend to use miscellaneous codes – E1399 (Miscellaneous durable medical equipment) and A9999 (Miscellaneous DME supply or accessory, not otherwise specified) until specific HCPCS codes are created. We initially applied for unique HCPCS codes during the third quarter of 2021. In order to address CMS's request for additional information to "further understand the PoNS device indication for use," we decided to move forward and collect additional clinical and real-world data. As such, through our ongoing PoNSTEP study and ongoing registry program, we plan to resubmit for unique HCPCS codes upon availability of a body of evidence that we consider adequate and sufficient to address CMS's questions. We expect to re-engage with CMS in mid 2023.

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 ("MCIT") rule. CMS is expected to share more about TCET with the public for comments in 2023. 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 patients. We expect to support the cost of the PoNS Therapy by offering a cash pay discount, collaborating with third parties to provide self-pay patients with financing options as well as 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.

We launched an e-commerce site in the U.S. in December 2022 and began processing orders in January 2023. Accessed via ponstherapy.com, the site is powered through a new partnership with UpScriptHealth, a leading telehealth company focused on making medications and devices available direct-to-consumer. UpScriptHealth's platform provides for (1) online health evaluations with qualified medical providers; (2) fulfillment of prescriptions required for PoNS Therapy; and (3) shipping of PoNS devices directly to the homes of eligible patients in the United States. The UpScriptHealth platform makes it possible for people with MS to have a PoNS device delivered directly to their doorstep.

Our Patient Therapy Access Program ("PTAP"), launched in June 2022 and expected to run through June 2023, provides qualifying patients access to PoNS therapy at a significantly reduced price. To qualify for the PTAP pricing, the patient must provide a letter of medical necessity and consent to the release of their medical records for the last two years. Because of the significantly reduced price, the patient must also sign a document that prohibits him/her from submitting a reimbursement claim to third-party payers. PTAP participants will also be invited to join the Company's registry program, which is designed to collect important health information to establish the value of PoNS on key therapeutic outcomes and will supplement the data collected through clinical trials and real-world data.

Material Trends and Uncertainties

Global Economic Conditions

Generally, worldwide economic conditions remain uncertain, particularly due to the conflict between Russia and Ukraine, disruptions in the banking system and financial markets, the lingering effects of the COVID-19 pandemic and increased inflation. The general economic and capital market conditions both in the U.S. and worldwide, have been volatile in the past and at times have adversely affected our 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, our future cost of equity or debt capital and access to the capital markets could be adversely affected.

The COVID-19 pandemic that began in late 2019 introduced significant volatility to the global economy, disrupted supply chains and had a widespread adverse effect on the financial markets. Additionally, 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, disruptions in the banking system and financial markets, the conflict in Ukraine, and steps taken by governments and central banks, particularly in response to the COVID-19 pandemic as well as other stimulus and spending programs, have led to higher inflation, which has led to an increase in costs and has caused changes in fiscal and monetary policy, including increased interest rates. Although we may take measures to mitigate these impacts, if these measures are not effective, our business, financial condition, results of operations, and liquidity could be materially adversely affected.

Results of Operations

Three Months Ended March 31, 2023 compared to the Three Months Ended March 31, 2022

The following table summarizes our results of operations for the three months ended March 31, 2023 and 2022 (in thousands):

	Three Months Ended March 31, 2023	2022	Change
Revenue:			
Product sales, net:			
United States	$ 75	$ —	$ 75
Canada	31	183	(152)
Total product sales, net	106	183	(77)
Other revenue	5	7	(2)
Total revenue	111	190	(79)
Cost of revenue	122	124	(2)
Gross profit (loss)	(11)	66	(77)
Operating expenses:			
Selling, general and administrative	2,874	2,819	55
Research and development	886	1,764	(878)
Amortization expense	39	47	(8)
Total operating expenses	3,799	4,630	(831)
Loss from operations	(3,810)	(4,564)	754
Nonoperating income (expense)			
Interest income (expense), net	100	—	100
Change in fair value of derivative liability	1,221	—	1,221
Foreign exchange (loss) gain	(5)	217	(222)
Other income (expense), net	—	1	(1)
Nonoperating income (expense), net	1,316	218	1,098
Loss before provision for income taxes	(2,494)	(4,346)	1,852
Provision for income taxes	—	—	—
Net loss	$ (2,494)	$ (4,346)	$ 1,852

Revenue

The decrease in net product sales for the three months ended March 31, 2023 as compared with the same period in the prior year was primarily attributable to lower Canada product sales, partially offset by net product sales in the United States. Commercial product sales in the United States commenced in April 2022. Canada product sales for the three months ended March 31, 2022 included approximately $120 thousand of revenue recognized in connection with the delivery of the remaining 16 PoNS devices that had been included as noncash consideration in the Company's acquisition of Heuro Canada, Inc.

Cost of Revenue

The cost of revenue remained relatively unchanged period over period primarily due to fixed overhead costs, which are primarily comprised of salaries and benefits of employees involved in management of the supply chain.

Selling, General and Administrative Expense

The net increase in selling, general and administrative expenses was the result of a $0.4 million net increase in professional fees incurred primarily in connection with certain registration statement filings with the Securities and Exchange Commission, which was largely offset by a $0.3 million decrease in personnel related costs.

Research and Development Expense

The decrease in research and development expenses was driven primarily by a decrease in product development expenses and clinical trial activities as we transitioned our focus from product development and clinical trials to U.S. commercialization activities.

Amortization Expense

Amortization expense is 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.

Nonoperating income (expense)

Interest Income (Expense), Net

Net interest income for the three months ended March 31, 2023 was primarily attributable to interest income earned on investments of excess cash in an unrestricted money market savings account and a certificate of deposit.

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 change in fair value of derivative liability for the three months ended March 31, 2023 of $1.2 million is due to a decrease in our stock price.

Foreign Exchange (Loss) Gain

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

Liquidity and Capital Resources

The following table summarizes our cash and cash equivalents and working capital as of December 31, 2022 and 2021 (in thousands):

	March 31, 2023	December 31, 2022
Cash and cash equivalents	$ 11,340	$ 14,549
Working capital	11,420	14,709

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 Class A common stock, which most recently included $16.3 million in net proceeds we received from a public offering of our Class A common stock and warrants completed in August 2022 (“August 2022 Public Offering”) as discussed in more detail in Note 8 to our Consolidated Financial Statements included our 2022 10-K.

As discussed in more detail in Note 6 to our Unaudited Condensed Consolidated Financial Statements, the outstanding shares of Series B Preferred Stock will vote together with the outstanding shares of the Company's Class A 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. If these proposals do not receive approval at a meeting of stockholders duly called for the purpose of voting thereon, the Company may be unable to regain compliance with Nasdaq's minimum bid price requirement within the required period of time, which could lead to our Class A common stock being delisted. If we are unable to maintain the listing of our Class A common stock on Nasdaq, we may face difficulty raising additional capital.

Statement of Cash Flows

The following table summarizes our cash flows for the three months ended March 31, 2023 and 2022 (in thousands):

	Three Months Ended March 31,		
	2023	2022	Change
Net cash used in operating activities	$ (3,190)	$ (4,682)	$ 1,492
Net cash (used in) provided by investing activities	(19)	4	(23)
Net cash used in financing activities	—	(17)	17
Effect of foreign exchange rate changes on cash	—	—	—
Net increase in cash and cash equivalents	$ (3,209)	$ (4,695)	$ 1,486

Net Cash Used in Operating Activities

The lower level of cash used in operating activities in the three months ended March 31, 2023 primarily resulted from the decrease in net loss for the three months ended March 31, 2023 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

We did not complete any public or private offerings of our Class A common stock during the three months ended March 31, 2023 and 2022. During the three months ended March 31, 2022, we paid $17 thousand of accrued share issuance costs related to a public offering of Class A common stock completed in November 2021.

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 $2.5 million and $4.3 million for the three months ended March 31, 2023 and 2022, respectively. As of March 31, 2023, we had an accumulated deficit of $153.6 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 will be sufficient to fund our operations through 2023, 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 2022 10-K. There have been no changes in critical accounting policies in the current year from those described in our 2022 10-K.

Recently Issued Accounting Pronouncements

The information set forth in Note 2 to our Unaudited Condensed Consolidated Financial Statements under Part I, Item 1, “Condensed Consolidated Financial Statements” is incorporated herein by reference.

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

Changes in Internal Control over Financial Reporting

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

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

Our business is subject to risks and events that, if they occur, could adversely affect our financial condition and results of operations and the trading price of our securities. During the three months ended March 31, 2023, our risk factors have not changed materially from those risk factors previously disclosed in our 2022 10-K. You should carefully consider the risk factors discussed in Part I, “Item 1A. Risk Factors” in our 2022 10-K. The risks described in our 2022 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.Click or tap here to enter text.

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

None.

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 Registrant's Registration Statement on Form 8-A, filed with the Securities and Exchange Commission on March 24, 2023)
3.5	Bylaws as amended and restated (incorporated by reference to Exhibit 3.3 to the Form 10-Q filed August 9, 2018)
31.1#	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2#	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1#*	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2#*	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS#	Inline XBRL Instance Document
101.SCH#	Inline XBRL Taxonomy Extension Schema Document
101.CAL#	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB#	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE#	Inline XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF#	Inline XBRL Taxonomy Extension Definition Linkbase Document
104#	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

Filed herewith.

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

HELIUS MEDICAL TECHNOLOGIES, INC.

Dated: May 11, 2023

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

Dated: May 11, 2023

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 March 31, 2023 of Helius Medical Technologies, Inc.

2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions);

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 11, 2023

/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 March 31, 2023 of Helius Medical Technologies, Inc.

2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions);

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 11, 2023

/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 MARCH 31, 2023
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I am the Chief Executive Officer of Helius Medical Technologies, Inc., a Delaware corporation (the "Company"). I am delivering this certificate in connection with the Form 10-Q of the Company for the quarter ended March 31, 2023 and filed with the Securities and Exchange Commission ("Form 10-Q").

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

Date: May 11, 2023

/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 MARCH 31, 2023
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I am the Chief Financial Officer of Helius Medical Technologies, Inc., a Delaware corporation (the "Company"). I am delivering this certificate in connection with the Form 10-Q of the Company for the quarter ended March 31, 2023 and filed with the Securities and Exchange Commission ("Form 10-Q").

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

Date: May 11, 2023

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