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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, 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 November 3, 2023, the registrant had 708,247 shares of Class A common stock, $0.001 par value per share, outstanding.

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

	September 30, 2023	December 31, 2022
ASSETS		
Current assets		
Cash and cash equivalents	$ 6,596	$ 14,549
Accounts receivable, net	94	71
Other receivables	472	272
Inventory, net	521	589
Prepaid expenses and other current assets	893	1,216
Total current assets	8,576	16,697
Property and equipment, net	182	347
Intangible assets, net	31	140
Operating lease right-of-use asset, net	65	103
Total assets	$ 8,854	$ 17,287
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 497	$ 627
Accrued and other current liabilities	849	1,280
Current portion of operating lease liabilities	47	54
Current portion of deferred revenue	42	27
Total current liabilities	1,435	1,988
Operating lease liabilities, net of current portion	23	56
Deferred revenue, net of current portion	136	175
Derivative liability	4,239	6,917
Total liabilities	5,833	9,136
Commitments and contingencies (Note 9)		
Stockholders' equity		
Class A common stock, $0.001 par value; 150,000,000 shares authorized; 687,799 and 563,974 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	1	1
Additional paid-in capital	162,391	159,645
Accumulated deficit	(158,912)	(151,107)
Accumulated other comprehensive loss	(459)	(388)
Total stockholders' equity	3,021	8,151
Total liabilities and stockholders' equity	$ 8,854	$ 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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenue				
Product sales, net	$ 132	$ 195	$ 482	$ 497
Other revenue	11	1	28	8
Total revenue	143	196	510	505
Cost of revenue	187	101	493	313
Gross profit (loss)	(44)	95	17	192
Operating expenses				
Selling, general and administrative expenses	2,196	3,393	7,639	8,673
Research and development expenses	722	751	2,292	3,468
Amortization expense	32	47	109	141
Goodwill and fixed asset impairment	159	757	159	757
Total operating expenses	3,109	4,948	10,199	13,039
Loss from operations	(3,153)	(4,853)	(10,182)	(12,847)
Nonoperating income (expense)				
Interest income (expense), net	68	(919)	257	(919)
Change in fair value of derivative liability	(393)	5,489	2,051	5,489
Foreign exchange (loss) gain	(192)	(747)	62	(910)
Other income (expense), net	7	—	7	1
Nonoperating income (expense), net	(510)	3,823	2,377	3,661
Loss before provision for income taxes	(3,663)	(1,030)	(7,805)	(9,186)
Provision for income taxes	—	—	—	—
Net loss	(3,663)	(1,030)	(7,805)	(9,186)
Other comprehensive income (loss)				
Foreign currency translation adjustments	191	744	(71)	893
Comprehensive loss	$ (3,472)	$ (286)	$ (7,876)	$ (8,293)
Loss per share				
Basic	$ (5.49)	$ (2.90)	$ (13.60)	$ (53.77)
Diluted	$ (5.49)	$ (2.90)	$ (13.60)	$ (53.77)
Weighted average number of common shares outstanding				
Basic	667,809	355,754	573,950	170,823
Diluted	667,809	355,754	573,950	170,823

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, 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

	Class A Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	
	Shares	Amount	Capital	Deficit	Loss	Total
Balance as of July 1, 2022	83,854	$ —	$ 150,669	$ (145,191)	$ (976)	$ 4,502
Issuance of common stock in public offering	480,000	1	8,055	—	—	8,056
Share issuance costs	—	—	(752)	—	—	(752)
Settlement of restricted stock units	120	—	—	—	—	—
Stock-based compensation	—	—	1,441	—	—	1,441
Other comprehensive income	—	—	—	—	744	744
Net loss	—	—	—	(1,030)	—	(1,030)
Balance as of September 30, 2022	563,974	$ 1	$ 159,413	$ (146,221)	$ (232)	$ 12,961

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 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

	Class A Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	
	Shares	Amount	Capital	Deficit	Loss	Total
Balance as of January 1, 2022	75,570	$ —	$ 149,416	$ (137,035)	$ (1,125)	$ 11,256
Common stock issued under equity line of credit	7,827	—	644	—	—	644
Issuance of common stock in public offering	480,000	1	8,055	—	—	8,056
Share issuance costs	—	—	(758)	—	—	(758)
Settlement of restricted stock units	244	—	—	—	—	—
Common stock issued for services	173	—	34	—	—	34
Stock-based compensation	160	—	2,022	—	—	2,022
Other comprehensive loss	—	—	—	—	893	893
Net loss	—	—	—	(9,186)	—	(9,186)
Balance as of September 30, 2022	563,974	$ 1	$ 159,413	$ (146,221)	$ (232)	$ 12,961

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,	
	Nine Months Ended September 30,	
	2023	2022
Cash flows from operating activities:		
Net loss	$ (7,805)	$ (9,186)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of derivative liability	(2,051)	(5,489)
Stock-based compensation expense	1,228	2,022
Common stock issued for services	—	34
Foreign exchange loss (gain)	(71)	907
Depreciation expense	32	74
Amortization expense	109	141
Goodwill and fixed asset impairment	159	757
Provision for (reversal of) inventory reserve	2	(37)
Non-cash operating lease expense	38	38
Changes in operating assets and liabilities:		
Accounts receivable	(23)	43
Other receivables	236	(24)
Inventory	66	(97)
Prepaid expense and other current assets	323	159
Operating lease liabilities	(40)	(31)
Accounts payable	(130)	(472)
Accrued and other current liabilities	(431)	(881)
Deferred revenue	(24)	(125)
Net cash used in operating activities	(8,382)	(12,167)
Cash flows from investing activities:		
Purchase of property and equipment	(26)	(19)
Proceeds from sale of property and equipment	—	6
Net cash used in investing activities	(26)	(13)
Cash flows from financing activities:		
Proceeds from issuance of common stock	284	18,644
Proceeds from exercise of warrants	207	—
Share issuance costs	(36)	(775)
Net cash provided by financing activities	455	17,869
Effect of currency exchange rate changes on cash and cash equivalents	—	(6)
Net increase (decrease) in cash and cash equivalents	(7,953)	5,683
Cash and cash equivalents at beginning of period	14,549	11,005
Cash and cash equivalents at end of period	$ 6,596	$ 16,688
Supplemental cash flow information		
Cash paid for interest (share issuance costs allocated to derivative liability)	$ —	$ 927
Non-cash investing and financing transactions:		
Right-of-use assets obtained in exchange for new lease liabilities	$ —	$ 151
Derivative warrant liability reclassified to equity on exercise of warrants	$ 628	$ —
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, 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 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.

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”) that became effective 5:00 p.m. Eastern Time on August 16, 2023. 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. Per the warrant agreement for the Public Warrants as noted 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, 2023, the Company had cash, cash equivalents and warrant proceeds receivable from the issuance of Common Stock of $7.0 million. For the nine months ended September 30, 2023, the Company had an operating loss of $10.2 million, and as of September 30, 2023, its accumulated deficit was $158.9 million. For the nine months ended September 30, 2023, the Company had $0.5 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.

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.

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 September 30, 2023 and December 31, 2022.

Inventory, net (in thousands)

	September 30, 2023	December 31, 2022
Raw materials	$ 347	$ 344
Work-in-process	87	284
Finished goods	153	39
Inventory, gross	587	667
Inventory reserve	(66)	(78)
Inventory, net	$ 521	$ 589

During the nine months ended September 30, 2023, $14 thousand of inventory was written off to the inventory reserve.

Prepaid expenses and other current assets (in thousands)

	September 30, 2023	December 31, 2022
Prepaid expenses	$ 421	$ 817
Inventory related	312	399
Deferred offering costs	160	—
Total prepaid expenses and other current assets	$ 893	$ 1,216

Accrued and other current liabilities (in thousands)

	September 30, 2023	December 31, 2022
Insurance payable	$ —	$ 592
Employees benefits	602	509
Professional services	42	119
Franchise tax	126	—
Other	79	60
Total accrued and other current liabilities	$ 849	$ 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 September 30, 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 and nine months ended September 30, 2023 and 2022 were $14 thousand, $41 thousand, $14 thousand and $42 thousand, respectively.

Maturities of operating lease liabilities as of September 30, 2023 were as follows (in thousands):

2023 (remaining)	$	14
2024		46
2025		12
Total lease payments		72
Less: imputed interest		(2)
Total lease liabilities	$	70

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 money market mutual funds and as of September 30, 2023 and money market savings account and a certificate of deposit 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 September 30, 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.

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. See Note 11 – Goodwill and Fixed Asset Impairment for further detail.

6. COMMON STOCK, PREFERRED STOCK AND WARRANTS

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 having an aggregate offering price of up to $2.0 million. Roth is entitled to a commission at a fixed commission rate equal to up to 3% of the gross proceeds pursuant to the Sales Agreement. As of September 30, 2023, 27,875 share issuances of securities have occurred in connection with the ATM generating net proceeds of $0.3M.

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 will vote 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 (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 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 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.

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, 2023, 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 ("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. As a result of the Company's Reverse Stock Split on August 16, 2023, refer to Note 1, the exercise price on the Public Warrants was reset to $6.9135 per share based on the volume-weighted average price for the five stock trading days post-split.

The fair value of the Public Warrants as of September 30, 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:

	September 30, 2023	December 31, 2022
Stock price	$ 9.49	$ 15.35
Warrant term (in years)	3.86	4.61
Expected volatility	88.70 %	80.90 %
Risk-free interest rate	4.71 %	4.04 %
Dividend rate	0.00 %	0.00 %

The fair value of the derivative liability as of September 30, 2023 and December 31, 2022 was $4.2 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. Public Warrants were exercised to purchase of 92,910 shares of Common Stock at $6.9135 per share for $642 thousand in net proceeds and no Public Warrants were cancelled during the nine months ended September 30, 2023. Of the $642 thousand net proceeds, $207 thousand was received in cash as of September 30, 2023 and $435 thousand was due from the Company's transfer agent and recorded as other receivables as of September 30, 2023. The portion of the derivative liability relating to the exercised warrants of $628 thousand was reclassified into stockholders' equity based on the fair value on the date of reclassification. The remaining outstanding Public Warrants to purchase 627,090 shares of Common Stock are classified as a derivative liability at September 30, 2023, are exercisable upon issuance and will expire five years following the date of issuance.

The Company has outstanding equity-classified warrants to purchase 11,853 shares of Common Stock at a weighted average exercise price of $815.98, with expiration dates ranging from October 2023 to February 2026. During the nine months ended September 30, 2023, no equity-classified 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 22,425 to 264,319. As of September 30, 2023, the remaining shares available for grant were 14,014 under the 2022 Plan and 9,205 under the Inducement Plan.

During the nine months ended September 30, 2023, the Company granted 222,768 stock options out of the 2022 Plan and 500 stock options out of the Inducement Plan at a weighted average exercise price of $14.63 per share. The options vest over one to four years and expire ten years after the grant date.

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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Risk-free interest rate	4.29 %	3.56 %	3.93 %	2.86 %
Expected volatility	75.26 %	75.75 %	79.43 %	74.94 %
Expected term (years)	5.76	5.74	5.70	5.65
Expected dividend yield	0.00 %	0.00 %	0.00 %	0.00 %
Fair value, per share	$ 6.40	$ 18.00	$ 10.17	$ 54.50

During the nine months ended September 30, 2023, the Company's non-employee directors received a grant of 6,644 restricted stock units at weighted average grant date fair value of $7.81 per share.

As of September 30, 2023, there were an aggregate of 245,972 stock options outstanding with a weighted average exercise price of $77.41 per share and 3,884 unvested restricted stock units outstanding with a weighted average grant date fair value of $7.81 per share.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Cost of sales	$ 5	$ 4	$ 14	$ 11
Selling, general and administrative	330	1,367	989	1,837
Research and development	68	70	225	174
Total stock-based compensation expense	$ 403	$ 1,441	$ 1,228	$ 2,022

As of September 30, 2023, the total remaining unrecognized compensation expense related to nonvested stock options and restricted stock units was $2.9 million which will be amortized over the weighted-average remaining requisite service period of 1.1 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,	
	2023	2022	2023	2022
Basic:				
Net loss available to common stockholders — basic	$ (3,663)	$ (1,030)	$ (7,805)	$ (9,186)
Weighted average common shares outstanding — basic	667,809	355,754	573,950	170,823
Loss per share - basic	$ (5.49)	$ (2.90)	$ (13.60)	$ (53.77)
Diluted:				
Net loss available to common stockholders — diluted [1]	$ (3,663)	$ (1,030)	$ (7,805)	$ (9,186)
Weighted average common shares outstanding — diluted [1]	667,809	355,754	573,950	170,823
Loss per share — diluted	$ (5.49)	$ (2.90)	$ (13.60)	$ (53.77)

[1] For the three and nine months ended September 30, 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 periods. 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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Stock options	245,972	23,490	245,972	23,490
Restricted stock units	3,884	284	3,884	284
Warrants	638,943	731,853	638,943	731,853

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, 2023 and 2022, the Company recorded royalty expense from the sale of devices of approximately $5 thousand, $19 thousand, $8 thousand and $20 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,	
	2023	2022	2023	2022
Product sales, net:				
United States	$ 60	$ 139	$ 310	$ 202
Canada	72	56	172	295
Total product sales, net	132	195	482	497
Other revenue	11	1	28	8
Total revenue	$ 143	$ 196	$ 510	$ 505

Two customers accounted for 91% and 57% of net product sales for the three and nine months ended September 30, 2023 and three customers accounted for 95% of accounts receivable, net as of September 30, 2023. A single customer accounted for 11% and 29% of net product sales for the three and nine months ended September 30, 2022 and a single customer accounted for 89% of accounts receivable, net as of December 31, 2022.

11. GOODWILL AND FIXED ASSET IMPAIRMENT

Fixed Asset Impairment

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 a planned change of the Company's contract manufacturing partner to be completed in less than one year from September 30, 2023. The interim impairment tests were performed using estimated market prices. The Company has determined that the fair value of certain long-lived tangible assets is lower than the related book values. Additionally, for certain long-lived tangible assets, it is more likely than not that those long-lived assets will 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 on its long-lived tangible assets.

Goodwill Impairment

Goodwill was allocated to and evaluated for impairment at the Company's one identified reporting unit and was tested for impairment by performing a quantitative test rather than a qualitative evaluation. The qualitative evaluation is an assessment of factors to determine whether it is more likely than not that a reporting unit's fair value is less than its carrying amount. The Company may elect not to perform the qualitative assessment for its reporting unit and perform the quantitative impairment test. The quantitative goodwill impairment test requires the Company to compare the carrying value of the reporting unit's net assets to the estimated fair value of the reporting unit.

The significant decline in the price of the Company's Common Stock following the Company's registered public offering in August 2022 was considered a triggering event for testing whether goodwill was impaired. The Company performed a quantitative assessment as of September 30, 2022 and determined that the carrying value of the reporting unit exceeded the estimated fair value. As a result, the Company recorded a goodwill impairment charge of $757 thousand, reducing the goodwill balance to zero.

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 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 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 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. 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 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, 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 2022 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 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) 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) 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 September 28, 2023, the Company announced that Wolters Kluwer Health – Medi-Span® assigned universal product code numbers to the Company's PoNS system and mouthpiece. The NDC/UPC/HRI codes for the PoNS system is 64288-00046 at $25,700 and the PoNS mouthpiece is 64288-00043 at $7,900.

On August 31, 2023, we received formal notification (the "Notification") from Nasdaq confirming that we have regained compliance, and that we satisfy all other applicable criteria for continued listing on the Nasdaq Stock Market. 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 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 ("Common Stock"), to maintain a minimum bid price of $1.00 per share for continued listing on the Nasdaq Stock Market, as set forth in Nasdaq Listing Rule 5550(a)(2). As a result of the determination, the listing matter is closed.

At the annual meeting of stockholders on May 24, 2023, stockholders voted to approve a reverse stock split of our outstanding 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. Effective 5:00 p.m. on August 16, 2023, the company completed a 1-for-50 reverse stock split of its Common Stock. All share and per share amounts in this Quarterly Report have been reflected on a post-split basis.

On August 11, 2023, our Board of Directors approved a 1-for-50 reverse stock split of the Company's issued and outstanding shares of Common Stock (the "Reverse Stock Split") effective August 16, 2023. On August 15, 2023, the Company filed with the Secretary of State of the State of Delaware a Certificate of Amendment to its Certificate of Incorporation to effect the Reverse Stock Split. The Reverse Stock Split became effective as of 5:00 p.m. Eastern Time on August 16, 2023, and the Company's Common Stock began trading on a split-adjusted basis when the Nasdaq Stock Market opened on August 17, 2023.

During the third quarter of 2023, the Company began implementing the transition of the manufacturing of PoNS systems and mouthpieces to Minnetronix, Inc. from its current contract manufacturer, Key Tronic Corporation. The Company expects the bulk of this transition to be completed by the end of 2023 and fully completed by mid-2024.

Presently, PoNS Therapy is not covered by Center for Medicare and Medicaid (“CMS”) or reimbursed 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, 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, in the second quarter of 2023, resubmitted 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 receive a preliminary response to our application from CMS in the fourth quarter of 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 rule. CMS is expected to provide additional information about TCET to 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.

Our Patient Therapy Access Program (“PTAP”), launched in June 2022 and effective through June 2023, provided qualifying patients access to PoNS therapy at a significantly reduced price. The PTAP was not renewed and terminated on June 30, 2023.

Material Trends and Uncertainties

Global Economic Conditions

Generally, worldwide economic conditions remain uncertain, particularly due to the conflicts 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 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.

Changes in economic conditions, supply chain constraints, logistics challenges, labor shortages, the 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 we have taken and may continue to 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, 2023 compared to the Three Months Ended September 30, 2022

The following table summarizes our results of operations for the three months ended September 30, 2023 and 2022 (in thousands):

	Three Months Ended September 30, 2023	2022	Change
Revenue:			
Product sales, net:			
United States	$ 60	$ 139	$ (79)
Canada	72	56	16
Total product sales, net	132	195	(63)
Other revenue	11	1	10
Total revenue	143	196	(53)
Cost of revenue	187	101	86
Gross profit (loss)	(44)	95	(139)
Operating expenses:			
Selling, general and administrative expenses	2,196	3,393	(1,197)
Research and development expenses	722	751	(29)
Amortization expense	32	47	(15)
Goodwill and fixed asset impairment	159	757	(598)
Total operating expenses	3,109	4,948	(1,839)
Loss from operations	(3,153)	(4,853)	1,700
Nonoperating income (expense)			
Interest income (expense), net	68	(919)	987
Change in fair value of derivative liability	(393)	5,489	(5,882)
Foreign exchange (loss) gain	(192)	(747)	555
Other income (expense), net	7	—	7
Nonoperating income (expense), net	(510)	3,823	(4,333)
Loss before provision for income taxes	(3,663)	(1,030)	(2,633)
Provision for income taxes	—	—	—
Net loss	$ (3,663)	$ (1,030)	$ (2,633)

Revenue

The decrease in net product sales for the three months ended September 30, 2023 as compared with the same period in the prior year was primarily attributable to decreased unit sales of PoNS systems in the U.S. following the termination of the PTAP on June 30, 2023, partially offset by increased net product sales in Canada.

Cost of Revenue

The increase in cost of revenue for the three months ended September 30, 2023 as compared with the same period in the prior year is due to fixed overhead costs, which were primarily comprised of salaries and benefits of employees involved in management of the supply chain and certain production costs.

Gross Profit (Loss)

Gross loss for the three months ended September 30, 2023 was $44 thousand compared to gross profit of $95 thousand for the same period in the prior year. This was a result of reduced absorption of fixed overhead costs across the lower unit volume of PoNS system sales in the third quarter of 2023 as compared to the prior year comparable period.

Selling, General and Administrative Expense

The decrease in selling, general and administrative expenses in the third quarter of 2023 as compared to 2022 resulted primarily from a $1.2 million decrease in performance based stock-based compensation, partially offset by a $0.2 million increase in salaries and wages during the current year period.

Research and Development Expense

Research and development expense was relatively flat year-to-year and was primarily comprised of clinical research and support.

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.

Goodwill and Fixed Asset Impairment

During the three months ended September 30, 2023, we recorded an impairment of $159 thousand for certain machinery used in the production of our inventory. During the three months ended September 30, 2022, we recorded a goodwill impairment charge of $757 thousand, reducing the goodwill balance to zero.

Nonoperating income (expense)

Interest Income (Expense), Net

Net interest income for the three months ended September 30, 2023 was primarily attributable to interest income earned on investments of excess cash in an unrestricted money market savings account, money market mutual funds, treasury bills 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 decrease in the change in fair value of derivative liability for the three months ended September 30, 2023 of $0.4 million was primarily due to the effect of the exercise price reset of the Public Warrants following the Reverse Stock Split.

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.

Nine Months Ended September 30, 2023 compared to the Nine Months Ended September 30, 2022

The following table summarizes our results of operations for the nine months ended September 30, 2023 and 2022 (in thousands):

	Nine Months Ended September 30, 2023	2022	Change
Revenue:			
Product sales, net:			
United States	$ 310	$ 202	$ 108
Canada	172	295	(123)
Total product sales, net	482	497	(15)
Other revenue	28	8	20
Total revenue	510	505	5
Cost of revenue	493	313	180
Gross profit (loss)	17	192	(175)
Operating expenses:			
Selling, general and administrative expenses	7,639	8,673	(1,034)
Research and development expenses	2,292	3,468	(1,176)
Amortization expense	109	141	(32)
Goodwill and fixed asset impairment	159	757	(598)
Total operating expenses	10,199	13,039	(2,840)
Loss from operations	(10,182)	(12,847)	2,665
Nonoperating income (expense)			
Interest income (expense), net	257	(919)	1,176
Change in fair value of derivative liability	2,051	5,489	(3,438)
Foreign exchange (loss) gain	62	(910)	972
Other income (expense), net	7	1	6
Nonoperating income (expense), net	2,377	3,661	(1,284)
Loss before provision for income taxes	(7,805)	(9,186)	1,381
Provision for income taxes	—	—	—
Net loss	$ (7,805)	$ (9,186)	$ 1,381

Revenue

Net product sales of PoNS systems in the U.S. increased for the nine months ended September 30, 2023 as compared with the same period in the prior year, primarily attributable to patients' efforts to secure favorable PTAP pricing prior to the termination of PTAP on June 30, 2023 as well as the fact that commercial product sales in the United States did not commence until April 2022. This increase was offset by lower Canada product sales resulting mostly from prior year sales including 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 increase in cost of revenue for the nine months ended September 30, 2023 as compared to the prior year was primarily attributable to increased fixed overhead costs, which were primarily comprised of salaries and benefits of employees involved in management of the supply chain.

Gross Profit

Gross profit for the nine months ended September 30, 2023, decreased compared to the same period in the prior year. The decrease in gross profit resulted primarily from the increase in fixed overhead costs year over year, and a greater mix of lower margin PoNS system sales under the PTAP in the U.S. during the current year period.

Selling, General and Administrative Expense

The decrease in selling, general and administrative expenses for the nine months ended September 30, 2023 was primarily the result of a decrease in stock-based compensation of $0.8 million along with decreased personnel costs of $0.4 million and a decrease in insurance of $0.2 million, offset by an increase of $0.3 million in professional services.

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 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.

Nonoperating income (expense)

Interest Income (Expense), Net

Net interest income for the nine months ended September 30, 2023 was primarily attributable to interest income earned on investments of excess cash in an unrestricted money market savings account, money market mutual funds, treasury bills 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 nine months ended September 30, 2023 of $2.0 million was due to a decrease in our stock price, partially offset by the effect of the exercise price reset on the Public Warrants due to the Reverse Stock Split.

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 the end of the periods indicated in the table below (in thousands):

	September 30, 2023	December 31, 2022
Cash and cash equivalents	$ 6,596	$ 14,549
Working capital	7,141	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 Common Stock, which most recently included $16.3 million in net proceeds we received from a public offering of our 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 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 three months ended September 30, 2023 the Company issued and sold shares with gross proceeds of $0.3 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 in the three months ended September 30, 2023.

Statement of Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2023 and 2022 (in thousands):

	Nine Months Ended September 30,		
	2023	2022	Change
Net cash used in operating activities	$ (8,382)	$ (12,167)	$ 3,785
Net cash used in investing activities	(26)	(13)	(13)
Net cash provided by financing activities	455	17,869	(17,414)
Effect of foreign exchange rate changes on cash	—	(6)	6
Net increase (decrease) in cash and cash equivalents	$ (7,953)	$ 5,683	$ (13,636)

Net Cash Used in Operating Activities

The lower level of cash used in operating activities in the nine months ended September 30, 2023 primarily resulted from the decrease in selling, general and administrative expenses and research and development expenses as compared with the same period in the prior year.

Net Cash Used in Investing Activities

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

Net Cash Provided by Financing Activities

During the nine months ended September 30, 2023, we received net proceeds of $0.3 million 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.

Net cash provided by financing activities during the nine months ended September 30, 2022 was $16.9 million, which consisted of $16.3 million in aggregate net proceeds from the issuances of Common Stock in the February 2021 public offering of Common Stock and under the Purchase Agreement, dated September 1, 2021, with Lincoln Park Capital Fund, LLC and $1.3 million from the exercise of warrants and stock options.

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 and $9.2 million for the nine months ended September 30, 2023 and 2022, respectively. As of September 30, 2023, we had an accumulated deficit of $158.9 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) 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, 2023, our risk factors have not changed materially from those risk factors previously disclosed in our 2022 10-K except as set forth below. 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.

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 fully completed by mid-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

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	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	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: November 9, 2023

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

Dated: November 9, 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 September 30, 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: November 9, 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 September 30, 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: November 9, 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 JUNE 30, 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 September 30, 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: November 9, 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 JUNE 30, 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 September 30, 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: November 9, 2023

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