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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, 2022

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 11, 2022, the registrant had 28,203,298 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, 2022	December 31, 2021
ASSETS		
Current assets		
Cash and cash equivalents	$ 16,658	$ 11,005
Accounts receivable, net	21	66
Other receivables	196	185
Inventory, net	609	476
Prepaid expenses and other current assets	733	862
Total current assets	18,217	12,594
Property and equipment, net	348	409
Goodwill	—	763
Intangible assets, net	178	333
Operating lease right-of-use asset, net	116	3
Total assets	$ 18,859	$ 14,102
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 570	$ 1,069
Accrued liabilities	551	1,433
Operating lease liabilities	53	3
Deferred revenue	26	148
Total current liabilities	1,200	2,653
Operating lease liabilities	70	—
Deferred revenue	173	193
Derivative liability	4,455	—
Total liabilities	5,898	2,846
Commitments and contingencies (Note 12)		
Stockholders' equity		
Class A common stock, $0.001 par value; 150,000,000 shares authorized; 28,201,282 and 3,780,674 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	28	4
Additional paid-in capital	159,386	149,412
Accumulated deficit	(146,221)	(137,035)
Accumulated other comprehensive loss	(232)	(1,125)
Total stockholders' equity	12,961	11,256
Total liabilities and stockholders' equity	$ 18,859	$ 14,102

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,	
	2022	2021	2022	2021
Revenue				
Product sales, net	$ 195	$ 102	$ 497	$ 242
Other revenue	1	7	8	22
Total revenue	196	109	505	264
Cost of revenue	101	86	313	169
Gross profit	95	23	192	95
Operating expenses				
Selling, general and administrative expenses	3,393	2,859	8,673	9,800
Research and development expenses	751	1,489	3,468	4,182
Amortization expense	47	48	141	153
Goodwill impairment	757	—	757	—
Total operating expenses	4,948	4,396	13,039	14,135
Loss from operations	(4,853)	(4,373)	(12,847)	(14,040)
Nonoperating income (expense)				
Interest expense, net	(919)	—	(919)	—
Change in fair value of derivative liability	5,489	—	5,489	—
Foreign exchange (loss) gain	(747)	(314)	(910)	10
Other income, net	—	—	1	—
Nonoperating income (expense), net	3,823	(314)	3,661	10
Loss before provision for income taxes	(1,030)	(4,687)	(9,186)	(14,030)
Provision for income taxes	—	—	—	—
Net loss	(1,030)	(4,687)	(9,186)	(14,030)
Other comprehensive income (loss)				
Foreign currency translation adjustments	744	287	893	(26)
Comprehensive loss	$ (286)	$ (4,400)	$ (8,293)	$ (14,056)
Net loss per share				
Basic	$ (0.12)	$ (2.01)	$ (0.52)	$ (6.29)
Diluted	$ (0.12)	$ (2.01)	$ (0.52)	$ (6.29)
Weighted average number of common shares outstanding				
Basic	8,543,303	2,326,893	17,761,752	2,229,422
Diluted	8,543,303	2,326,893	17,761,752	2,229,422

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 July 1, 2022	4,195,113	$ 4	$ 150,665	$ (145,191)	$ (976)	$ 4,502
Issuance of common stock in public offering	24,000,000	24	8,032	—	—	8,056
Share issuance costs	—	—	(752)	—	—	(752)
Settlement of restricted stock units	6,169	—	—	—	—	—
Stock-based compensation	—	—	1,441	—	—	1,441
Other comprehensive income	—	—	—	—	744	744
Net loss	—	—	—	(1,030)	—	(1,030)
Balance as of September 30, 2022	28,201,282	$ 28	$ 159,386	$ (146,221)	$ (232)	$ 12,961

	Class A Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares	Amount				
Balance as of January 1, 2022	3,780,674	$ 4	$ 149,412	$ (137,035)	$ (1,125)	$ 11,256
Common stock issued under equity line of credit	391,363	—	644	—	—	644
Issuance of common stock in public offering	24,000,000	24	8,032	—	—	8,056
Share issuance costs	—	—	(758)	—	—	(758)
Settlement of restricted stock units	12,443	—	—	—	—	—
Common stock issued for services	8,791	—	34	—	—	34
Stock-based compensation	8,011	—	2,022	—	—	2,022
Other comprehensive income	—	—	—	—	893	893
Net loss	—	—	—	(9,186)	—	(9,186)
Balance as of September 30, 2022	28,201,282	$ 28	$ 159,386	$ (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 Shares	Class A Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
Balance as of July 1, 2021	2,317,772	$ 2	$ 138,023	$ (128,246)	$ (1,412)	$ 8,367
Common stock issued under equity line of credit	40,000	—	577	—	—	577
Share issuance costs	31,958	—	(247)	—	—	(247)
Settlement of restricted stock units	2,400	—	—	—	—	—
Stock-based compensation	—	—	740	—	—	740
Other comprehensive income	—	—	—	—	287	287
Net loss	—	—	—	(4,687)	—	(4,687)
Balance as of September 30, 2021	2,392,130	$ 2	$ 139,093	$ (132,933)	$ (1,125)	$ 5,037

	Class A Common Stock Shares	Class A Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
Balance as of January 1, 2021	**1,484,362**	**$ 1**	**$ 123,872**	**$ (118,903)**	**$ (1,099)**	**$ 3,871**
Common stock issued under equity line of credit	40,000	—	577	—	—	577
Issuance of common stock in public offering	744,936	1	8,398	—	—	8,399
Issuance of warrants in public offering	—	—	2,638	—	—	2,638
Share issuance costs	31,958	—	(1,608)	—	—	(1,608)
Exercise of warrants	81,895	—	1,318	—	—	1,318
Exercise of stock options	214	—	2	—	—	2
Settlement of restricted stock units	3,428	—	—	—	—	—
Stock-based compensation	5,337	—	3,896	—	—	3,896
Other comprehensive loss	—	—	—	—	(26)	(26)
Net loss	—	—	—	(14,030)	—	(14,030)
Balance as of September 30, 2021	**2,392,130**	**$ 2**	**$ 139,093**	**$ (132,933)**	**$ (1,125)**	**$ 5,037**

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,	
	2022	2021
Cash flows from operating activities:		
Net loss	$ (9,186)	$ (14,030)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of derivative liability	(5,489)	—
Stock-based compensation expense	2,022	3,896
Common stock issued for services	34	—
Foreign exchange loss (gain)	907	(26)
Depreciation expense	74	84
Amortization expense	141	153
Goodwill impairment	757	—
Provision (reversal) for doubtful accounts	—	(19)
Provision for (reversal of) inventory reserve	(37)	—
Non-cash operating lease expense	38	46
Changes in operating assets and liabilities:		
Accounts receivable	43	70
Other receivables	(24)	(19)
Inventory, net	(97)	(149)
Prepaid expense and other current assets	159	(67)
Operating lease liability	(31)	(47)
Accounts payable	(472)	270
Accrued liabilities	(881)	(38)
Deferred revenue	(125)	(49)
Net cash used in operating activities	(12,167)	(9,925)
Cash flows from investing activities:		
Purchase of property and equipment	(19)	(49)
Proceeds from sale of property and equipment	6	—
Internally developed software	—	(2)
Net cash used in investing activities	(13)	(51)
Cash flows from financing activities:		
Proceeds from issuances of common stock and warrants	18,644	11,614
Share issuance costs	(775)	(1,581)
Proceeds from exercise of warrants and stock options	—	1,320
Net cash provided by financing activities	17,869	11,353
Effect of currency exchange rate changes on cash, cash equivalents, and restricted cash	(6)	(8)
Net increase in cash, cash equivalents, and restricted cash	5,683	1,369
Cash, cash equivalents and restricted cash at beginning of period	11,005	3,331
Cash, cash equivalents and restricted cash at end of period	$ 16,688	$ 4,700
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	$ —
Non-cash share issuance costs	—	476
Share issuance costs included in accrued liabilities	—	189

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. ORGANIZATION, CONSOLIDATION AND PRESENTATION OF FINANCIAL STATEMENTS

Helius Medical Technologies, Inc. (together with its wholly owned subsidiaries the "Company") is a neurotech company focused on neurological wellness. The Company's purpose is to develop, license or acquire non-implanted technologies targeted at reducing symptoms of neurological disease or trauma. The Company's product, known as the Portable Neuromodulation Stimulator ("PoNS®") has been commercially available in Canada since March 2019. The Company began accepting prescriptions for its PoNS product in the U.S. in the first quarter of 2022, and the first commercial sales began in April 2022. PoNS is authorized for sale as a Class IIa medical device in Australia. The Company is working to establish a distribution partner for Australia but currently does not expect to have commercial sales of PoNS in Australia in 2022. The Company operates and manages its business within one operating and reportable segment. The Company's reporting currency is the U.S. Dollar ("USD$").

The accompanying unaudited condensed consolidated financial statements 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 Company's audited consolidated financial statements for the year ended December 31, 2021, included in its Annual Report on Form 10-K that was filed with the Securities and Exchange Commission on March 14, 2022 ("2021 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. In the opinion of management, the information furnished in the unaudited condensed consolidated financial statements include all adjustments (consisting of only normal, recurring adjustments), considered necessary to present fairly the results of operations, financial position and cash flows of the Company.

Certain prior period amounts have been reclassified to conform to the current period presentation.

2. RISKS AND UNCERTAINTIES

Going Concern Uncertainty

As of September 30, 2022, the Company had cash and cash equivalents of $16.7 million. For the nine months ended September 30, 2022, the Company had an operating loss of $12.8 million, and as of September 30, 2022, its accumulated deficit was $146.2 million. For the nine months ended September 30, 2022, 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 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 and planned capital expenditures.

COVID-19, Increased Inflation and Worldwide Economic Conditions

Generally, worldwide economic conditions remain uncertain, particularly due to the effects of the COVID-19 pandemic and increased inflation. Access to capital markets is critical to the Company's ability to operate. Declines and

uncertainties in these markets in the past have severely restricted raising new capital and have affected companies' ability to continue to expand or find existing development, manufacturing, regulatory and commercialization efforts. The Company requires significant capital for its current and expected operations. 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 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.

COVID-19

On March 11, 2020, the World Health Organization declared the outbreak of a novel coronavirus ("COVID-19") as a global pandemic, which has spread throughout the U.S. and around the world. The Company's business, results of operations and financial condition have been and may continue to be adversely impacted by the COVID-19 pandemic and global economic conditions. The outbreak and spread of COVID-19 have significantly increased economic uncertainty. Authorities implemented, and continue to implement, numerous measures to try to contain COVID-19, such as travel bans and restrictions, quarantines, shelter in place orders and business shutdowns. The COVID-19 pandemic initially led to the closure of PoNS authorized clinic locations across Canada from March until June 2020. Patients who completed their initial training in the clinics prior to the closures were able to continue working independently in the at-home portion of the treatment, with remote check-ins with their certified therapists. While all clinics had re-opened, as of December 31, 2021, they were all operating at reduced capacity, which limited operations to 50% capacity during the second half of 2021. Some patients returned to these clinics for treatment, but patients have been and may continue to be less willing to return to the clinics due to COVID-19, impacting the Company's commercial activities and its customer engagement efforts. This was especially true in the first half of 2021, as cases of COVID-19 increased significantly in Canada and additional restrictions, shelter in place orders and business shutdowns were imposed. The rate of vaccination increased throughout all provinces throughout 2021, facilitating the lifting of some of the previously imposed restrictions. As of April 2022, capacity has returned to 100%. The Company continues to monitor the impact of COVID-19 and adjust its operations as the circumstances change.

The Company expanded its services to include remote training and treatment, but the long-term viability of these remote programs is still being assessed. Additionally, clinical experience programs and clinical trials in Canada have experienced and may continue to experience delays in the programs as trial participant attendance has generally decreased as a result of the pandemic, and clinics and clinical research sites have experienced delays and difficulties in recruiting and re-hiring clinical site staff.

The COVID 19 pandemic has and may continue to cause delays in or the suspension of the Company's business partners' manufacturing operations as well as the Company's research and product development activities, regulatory workstreams and other important commercial functions. The Company is also dependent upon its suppliers for the manufacture of its PoNS device. In the second quarter of 2020, two of the Company's business partners diverted resources towards other activities related to COVID 19, resulting in delays in the Company's product development activities. Such diversion of suppliers' resources may occur again in the future, and the pandemic could limit the Company's suppliers' ability to travel or ship materials or force temporary closure of facilities that it relies upon. Manufacturing delays have occurred and may also occur as the result of labor shortages. Two of the Company's suppliers experienced significant labor shortages as a result of COVID 19 from the end of November 2021 through early January 2022. In addition, during March 2022 and continuing into the second quarter of 2022, an increase in COVID 19 related cases in certain parts of China resulted in the re-imposition of widespread shutdowns and restrictions in China and additional supply chain disruptions. These labor shortages and increases in COVID-19 cases reduced the available resources needed to build and test product which may delay the timing for the submission and approval of the Company's marketing applications with regulatory agencies. Further, the economic impact of the COVID 19 pandemic had affected, and may in the future affect, the Company's ability to access the public markets and obtain necessary capital in order to properly capitalize and continue its operations.

The extent to which the COVID 19 pandemic will continue to impact the Company's business, including its U.S. commercial launch and sales in Canada, as well as the Company's results of operations and its financial condition will

depend on future developments, which are highly uncertain and cannot be predicted. The Company does not yet know the full extent of the impact of COVID 19 on its business, operations or the global economy as a whole.

Inflationary Environment

The Company's operating results could be materially impacted by changes in the overall macroeconomic environment and other economic factors that impact customer confidence and spending, including capital spending. Changes in economic conditions, supply chain constraints, logistics challenges, labor shortages, 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. As a result of inflation, we have experienced and may continue to experience, cost increases. Although the Company may take measures to mitigate the impact of this inflation, if these measures are not effective, the Company's business, financial condition, results of operations, and liquidity could be materially adversely affected.

3. RECENT ACCOUNTING PRONOUNCEMENTS

In June 2016, the FASB issued ASU 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. In November 2019, the FASB issued ASU 2019-10, *Financial Instruments – Credit Losses (Topic 326), Derivatives and Hedging (Topic 815) and Leases (Topic 842): Effective Dates*, which amends the effective date of ASU 2016-13. Public business entities that meeting the definition of an SEC filer, excluding entities eligible to be a Smaller Reporting Company ("SRC") as defined by the SEC, are required to adopt the standard for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. All other entities are required to adopt the standard for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The Company meets the definition of an SRC and therefore the standard will not be effective until the beginning of 2023. The adoption of ASU 2016-13 is not expected to have a material impact on the Company's consolidated financial statements.

4. GOODWILL IMPAIRMENT

As more fully disclosed in the 2021 10-K, the Company tests goodwill for impairment annually in the fourth quarter of each year or when circumstances suggest that an indicator for impairment may be present. Goodwill is allocated to and evaluated for impairment at the Company's one identified reporting unit and is tested for impairment by either performing a qualitative evaluation or a quantitative test. 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 Class A common stock ("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.

5. REVENUE FROM CONTRACTS WITH CUSTOMERS

Product sales are derived from the sale of PoNS devices directly to patients in the U.S. and to clinics in Canada. For both U.S. and Canada customers, the Company's performance obligation is met, and revenue is recognized, upon delivery to the customer and the customer's acceptance. During the three and nine months ended September 30, 2022 and 2021, Canada product net sales were $56 thousand, $295 thousand, $102 thousand and $242 thousand, respectively. For the three and nine months ended September 30, 2022, U.S. product net sales were $139 thousand and $202 thousand,

respectively. As of September 30, 2022 and December 31, 2021, the Company had no contract assets or liabilities on its unaudited condensed consolidated balance sheets.

6. SUPPLEMENTAL BALANCE SHEET DISCLOSURES

The unaudited condensed consolidated balance sheets include financial instruments for which the fair market value of such instruments may differ from amounts reflected on a historical cost basis. The carrying value of cash and cash equivalents, accounts and other receivables, accounts payable and certain accrued liabilities generally approximate fair value due to their short-term nature.

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 doubtful accounts of $330 thousand and $355 thousand as of September 30, 2022 and December 31, 2021, respectively.

Inventory, net (in thousands)

	September 30, 2022	December 31, 2021
Raw materials	$ 300	$ 171
Work-in-process	318	528
Finished goods	48	32
Inventory, gross	$ 666	$ 731
Inventory reserve	(57)	(255)
Inventory, net	$ 609	$ 476

During the nine months ended September 30, 2022 existing reserves of $161 thousand were charged against work-in-process inventory and inventory reserves were decreased by $37 thousand.

Accrued expenses (in thousands)

	September 30, 2022	December 31, 2021
Employees benefits	$ 437	$ 712
Professional services	16	174
Legal fees	14	23
Royalty fees	8	10
Franchise fees	30	193
Severance	—	258
Other	46	63
Total accrued expenses	$ 551	$ 1,433

Deferred revenue

Collaborative Arrangement

The Company recorded deferred license fee revenue in connection with a Clinical Research and Co-Promotion Agreement with Health Tech Connex Inc. (“HTC”) (the “Co-Promotion Agreement”), as more fully described in the 2021 10-K. Deferred revenue as of both September 30, 2022 and December 31, 2021 included approximately $200 thousand of license fees not yet recognized under the Co-Promotion Agreement. License fee revenue recognized is included in other revenue in the unaudited condensed consolidated statements of operations and comprehensive loss. On January 31, 2022, the Company notified HTC of its material breaches under the Co-Promotion Agreement which HTC failed to cure under the terms of the Co-Promotion Agreement. As such it is the Company’s position that this exclusivity

right is no longer in effect. The Company and HTC have been discussing opportunities to work together moving forward.

Noncash Consideration in Acquisition

Deferred revenue as of December 31, 2021 included approximately $100 thousand for the fair value of the remaining 16 PoNS devices to be transferred that had been included as noncash consideration in the Company's acquisition of Heuro Canada, Inc. ("Heuro"). During the nine months ended September 30, 2022, the remaining 16 PoNS devices were transferred and the remaining $100 thousand of deferred revenue was recognized in Product Sales in the unaudited condensed consolidated statements of operations and comprehensive loss. During the nine months ended September 30, 2021, there were four PoNS devices transferred which resulted in the recognition of $30 thousand of deferred revenue in Product Sales in the unaudited condensed consolidated statements of operations and comprehensive loss.

Cash, Cash Equivalents and Restricted Cash (in thousands)

	September 30, 2022	December 31, 2021
Cash and cash equivalents	$ 16,658	$ 11,005
Restricted cash included in prepaid expenses and other current assets	30	—
Total cash, cash equivalents and restricted cash	$ 16,688	$ 11,005

Cash equivalents as of September 30, 2022 consist of an investment of excess cash in an unrestricted money market savings account.

Restricted cash as of September 30, 2022 is related to a money market savings account maintained by the Company as collateral in connection with corporate credit cards.

7. 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.

The following table presents information on the lease terms and discount rates:

Weighted average remaining lease term	2.5 years
Weighted average discount rate	4.4 %

Maturities of operating lease liabilities as of September 30, 2022 were as follows (in thousands):

2022 (remaining)	$ 14
2023	57
2024	46
2025	12
Total future lease payments	129
Less: interest	(6)
Present value of lease liabilities	$ 123

8. DERIVATIVE LIABILITY

On August 9, 2022, in connection with the registered public offering discussed in Note 9, the Company issued warrants to purchase 36 million shares of common stock to investors ("Public Warrants"). The 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 period from the date of issuance through September 30, 2022.

The Company performed an analysis of the provisions of the Public Warrants and concluded that 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. As a result, the Public Warrants are being accounted for as a derivative liability instrument in the unaudited condensed consolidated balance sheets. The fair value of the derivative liability as of the issuance date on August 9, 2022 and September 30, 2022 was $9.9 million and $4.5 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 following table summarizes the assumptions used in estimating the fair value of the Public Warrants using the Black-Scholes option pricing model as of the issuance date on August 9, 2022 and as of September 30, 2022:

	August 9, 2022	September 30, 2022
Stock price	$ 0.49	$ 0.28
Exercise price	$ 0.75	$ 0.75
Warrant term	5 years	4.86 years
Expected volatility	78.27	78.41 %
Risk-free interest rate	2.97	4.06 %
Dividend rate	0.00	0.00 %

9. STOCKHOLDERS' EQUITY

On August 9, 2022, the Company closed on a registered public offering consisting of 18,560,000 shares of common stock, pre-funded warrants to purchase 5,440,000 shares of common stock and accompanying Public Warrants to purchase an aggregate of 36,000,000 shares of common stock at a combined offering price of $0.75 per share and accompanying Public Warrants, or $0.749 per pre-funded warrant and accompanying Public Warrants ("August 2022 Public Offering"). The pre-funded warrants had an exercise price of $0.001 per share and were all exercised on the closing date. As a result, an aggregate of 24,000,000 shares were issued on the closing date for gross proceeds of $18 million. In connection with the August 2022 Public Offering, the Company paid $1.7 million of share issuance costs, which consisted of placement agent fees and expenses and other offering costs.

As a result of the derivative liability classification of the Public Warrants discussed in Note 8, the gross proceeds were first allocated to the fair value of the Public Warrants as of August 9, 2022 of $9.9 million and the remaining $8.1 million in gross proceeds were allocated to stockholders' equity. The share issuance costs associated with the August 2022 Public Offering were allocated between the issuance of common stock and Public Warrants on a pro rata basis with the allocation of the gross proceeds, which resulted in $0.8 million of share issuance costs being recorded as a reduction of additional paid-in capital and $0.9 million of share issuance costs being recorded in interest expense on the unaudited condensed consolidated statements of operations and comprehensive loss.

During the nine months ended September 30, 2022, the Company issued 391,363 shares of Class A common stock ("common stock") at an average price of $1.65 per share to Lincoln Park Capital Fund, LLC ("Lincoln Park") pursuant to a purchase agreement (the "LPC Purchase Agreement") and registration rights agreement with Lincoln Park, as more fully described in the 2021 10-K. As of September 30, 2022, the Company does not intend to issue any additional shares under the LPC Purchase Agreement.

During the nine months ended September 30, 2022, the Company issued 8,791 shares common stock for services with a value at issuance of $34 thousand.

The Company has outstanding equity-classified warrants to purchase 593,924 shares of common stock at a weighted average exercise price of $16.32, with expiration dates ranging from March 2025 to February 2026. During the nine months ended September 30, 2022, no warrants were exercised or cancelled.

10. STOCK-BASED COMPENSATION

On May 23, 2022, the Company's stockholders approved the Helius Medical Technologies, Inc. 2022 Equity Incentive Plan ("2022 Plan"), which had been adopted by the Company's Board of Directors on February 16, 2022. The 2022 Plan provides for the grant of incentive stock options ("ISOs"), nonstatutory stock options ("NSOs"), stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of awards to employees, directors and consultants, including employees and consultants of the Company's affiliates. Vesting and the term of an option is determined at the discretion of the Company's Board of Directors. Initially, a maximum of 1,121,272 shares of common stock may be issued. The automatic increase provision in the 2022 Plan provides for an annual increase to the maximum number of authorized shares on January 1 of each year beginning on January 1, 2023 through January 1, 2027, to an amount equal to (i) 20% of the fully diluted number of shares of common stock outstanding on December 31 of the fiscal year before the date of each automatic increase, or (ii) a lesser number of shares determined by the Board prior to the date of the increase. The maximum number of shares of common stock that may be issued on the exercise of ISOs under the 2022 Plan is 11,212,720. Effective with the approval of the 2022 Plan, the Company ceased granting awards under the 2018 Omnibus Incentive Plan. However, outstanding stock options granted prior to the effective date of the 2022 Plan are still governed by the respective predecessor plan under which they were granted, which are described more fully in the 2021 10-K. As of September 30, 2022, the remaining shares available for grant were 256 shares under the 2022 Plan and 22,500 shares under the Helius Medical Technologies, Inc. 2021 Inducement Plan.

During the nine months ended September 30, 2022, the Company granted 595,170 stock options at a weighted average exercise price of $3.03 per share. The following table includes the weighted-average grant-date fair values of stock options granted during the periods indicated and the related weighted-average assumptions used in the Black-Scholes option pricing model:

	Three Months Ended September 30, 2022	Nine Months Ended September 30, 2022
Risk-free interest rate	3.56 %	2.86 %
Expected volatility	75.75 %	74.94 %
Expected term (years)	5.74	5.65
Expected dividend yield	0.00 %	0.00 %
Fair value per option	$ 0.36	$ 1.09

During the nine months ended September 30, 2022, the Company's non-employee directors received a grant of 24,196 restricted stock units at a weighted average grant date fair value of $1.40 per share. Share-based compensation expense for the nine months ended September 30, 2022 includes a grant to an officer of the Company of 8,011 shares of unrestricted common stock valued at $34 thousand.

As of September 30, 2022, there were an aggregate of 1,174,320 stock options outstanding with a weighted average exercise price of $17.76 per share and 14,112 unvested restricted stock units outstanding with a weighted average grant date fair value of $1.40 per share.

Compensation expense related to all stock-based compensation, net of forfeitures, was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Cost of sales	$ 4	$ 2	$ 11	$ 5
Selling, general and administrative	1,367	582	1,837	3,351
Research and development	70	156	174	540
Total stock-based compensation expense	$ 1,441	$ 740	$ 2,022	$ 3,896

There were no tax benefits recognized related to stock-based compensation expense during these periods.

In conjunction with the public offering discussed in Note 9, certain performance criteria were achieved for performance-based stock options. For the three months and nine months ended September 30, 2022, the Company recognized additional share-based compensation expense of $1,184 thousand associated with the vesting of the performance-based stock options.

As of September 30, 2022, the unrecognized compensation cost related to non-vested time-based stock options and restricted stock units was $1.5 million which will be recognized over a weighted-average remaining vesting period of approximately 2.4 years. Compensation cost is not adjusted for estimated forfeitures, but instead is adjusted upon an actual forfeiture of an award.

11. BASIC AND DILUTED LOSS PER SHARE

Basic loss per share of common stock is computed by dividing net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Diluted loss per share is calculated by adjusting the weighted-average number of shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method. Diluted loss per share excludes, when applicable, the potential impact of stock options, unvested restricted stock units and common stock warrants because their effect would be anti-dilutive due to the net loss.

Basic and diluted net loss per share for the three and nine months ended September 30, 2022 and 2021 was calculated as follows (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Basic:				
Net loss available to common stockholders - basic	$ (1,030)	$ (4,687)	$ (9,186)	$ (14,030)
Weighted average common shares outstanding - basic	8,543,303	2,326,893	17,761,752	2,229,422
Net loss per share - basic	$ (0.12)	$ (2.01)	$ (0.52)	$ (6.29)
Diluted:				
Net loss available to common stockholders - diluted [1]	$ (1,030)	$ (4,687)	$ (9,186)	$ (14,030)
Weighted average common shares outstanding - diluted [1]	8,543,303	2,326,893	17,761,752	2,229,422
Net loss per share - diluted	$ (0.12)	$ (2.01)	$ (0.52)	$ (6.29)

[1] For the three and nine months ended September 30, 2022, 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 both periods. Refer to Note 8 and Note 9 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,	
	2022	2021	2022	2021
Stock options	1,174,320	641,152	1,174,320	641,152
Restricted stock units	14,112	3,943	14,112	3,943
Warrants	36,593,924	593,924	36,593,924	593,924

12. 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 September 30, 2022 and 2021, the Company recorded royalty expense from the sale of devices of approximately $8 thousand and $4 thousand, respectively, in its unaudited condensed consolidated statement of operations and comprehensive loss. During the nine months ended September 30, 2022 and 2021, the Company recorded royalty expense from the sale of devices of approximately $20 thousand and $10 thousand, respectively, in its unaudited condensed consolidated statement of operations and comprehensive loss.

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" or "our" mean Helius Medical Technologies, Inc. and its wholly owned subsidiaries, Helius Medical, Inc., or HMI, Helius Medical Technologies (Canada), Inc., or HMC, Helius Canada Acquisition Ltd., or HCA and Helius NeuroRehab, Inc., or HNR. 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, 2021, 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, 2021 filed with the Securities and Exchange Commission, or the SEC, on March 14, 2022 (the "2021 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, or 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 TEP 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, 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 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 2021 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-implanted technologies targeted at reducing symptoms of neurological disease or trauma.

Our product, known as the Portable Neuromodulation Stimulator, or PoNS®, is an innovative non-implanted 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 has marketing clearance in the U.S. for use in the U.S. as a short-term treatment of gait deficit due to mild-to-moderate symptoms for multiple sclerosis, or 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 two 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, or PoNS Therapy™; and (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. 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 are currently seeking a business partner to commercialize and distribute PoNS in Australia.

Recent Developments

We began accepting prescriptions for PoNS in the U.S. in the first quarter of 2022, and our first commercial sales began in April 2022. Presently, PoNS Therapy is not covered by Center for Medicare and Medicaid (“CMS”) or reimbursed by any third-party payors in the US.

In June 2022, the Company launched the Patient Therapy Access Program (“PTAP”) program, which will provide 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. The Company began processing orders under the PTAP program in June 2022, which is expected to run through December 31, 2022.

During 2021, we contracted with an industry consultant to conduct a health economic study of PoNS. Based upon the results of this study and comparing PoNS to other medical devices utilizing similar patented technologies we established a U.S. list price for the PoNS device of $25,700, comprised of $17,800 for the controller and $7,900 for the mouthpiece. 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 TEP study and upcoming 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 interact again with CMS in the second half of 2023.

The Company will continue monitoring 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.

In connection with our acquisition of Heuro Canada, Inc. ("Heuro") in October 2019, we entered into a Clinical Research and Co-Promotion Agreement with Health Tech Connex Inc. ("HTC") (the "Co-Promotion Agreement"), as more fully described in the 2021 10-K. Although the co-promotion provisions within the Co-Promotion Agreement terminated on December 31, 2020, the Co-Promotion Agreement remains in effect. Subject to certain terms and conditions, we granted to HTC the exclusive right to provide the PoNS Treatment in the Fraser Valley and Vancouver metro regions of British Columbia, where HTC has operated a PoNS authorized clinic since February 2019. HTC will 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. This exclusivity right has an initial term of ten years, renewable by HTC for one additional ten-year term upon sixty days' written notice to us. On January 31, 2022, we notified HTC of its material breaches under the Co-Promotion Agreement, which HTC failed to cure under the terms of the Co-Promotion Agreement. As such, it is our position that this exclusivity right is no longer in effect. We have been in discussions with HTC to explore opportunities to work together moving forward.

As discussed further in Note 9 to our unaudited condensed consolidated financial statements, in August 2022, the Company closed on a public offering of its Class A common stock and warrants ("August 2022 Public Offering") and received net proceeds of approximately $16.3 million.

Material Trends and Uncertainties

COVID-19 Pandemic

On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 as a global pandemic, which has spread throughout the U.S. and around the world. The Company's business, results of operations and financial condition have been and may continue to be adversely impacted by the COVID-19 pandemic and global economic conditions. The outbreak and spread of COVID-19 have significantly increased economic uncertainty. Authorities implemented, and continue to implement, numerous measures to try to contain the virus, such as travel bans and restrictions, quarantines, shelter in place orders, and business shutdowns. The COVID-19 pandemic initially led to the closure of PoNS authorized clinic locations across Canada from March until June 2020. Patients who completed their initial training in the clinics prior to the closures were able to continue working independently in the at-home portion of the treatment, with remote check-ins with their certified therapists. While all clinics have re-opened, as of December 31, 2021, they were all operating at reduced capacity, which limited operations to 50% capacity during the second half of 2021. Some patients returned to these clinics for treatment, but patients have been and may continue to be less willing to return to the clinics due to COVID-19, impacting our commercial activities and our customer engagement efforts. This was especially true in the first half of 2021, as cases of COVID-19 increased significantly in Canada and additional restrictions, shelter in place orders, and business shutdowns were imposed. The rate of vaccination increased throughout all provinces throughout 2021, facilitating the lifting of some of the previously imposed restrictions. As of April 2022, capacity has returned to 100%. We continue to monitor the impact of COVID-19 and adjust our operations as the circumstances change.

We expanded our services to include remote training and treatment, but the long-term viability of these remote programs is still being assessed. Additionally, clinical experience programs and clinical trials in Canada have experienced and may continue to experience delays in the programs as trial participant attendance has generally decreased as a result of the pandemic, and clinics and clinical research sites have experienced delays and difficulties in recruiting and re-hiring clinical site staff.

The COVID 19 pandemic has and may continue to cause delays in or the suspension of our business partners' manufacturing operations, our research and product development activities, our regulatory workstreams, our research

and development activities and other important commercial functions. We are also dependent upon our suppliers for the manufacture of our PoNS device. In the second quarter of 2020, two of our business partners diverted resources towards other activities related to COVID 19, resulting in delays in our product development activities. Such diversion of suppliers' resources may occur again in the future, and the pandemic could limit our suppliers' ability to travel or ship materials or force temporary closure of facilities that we rely upon. Manufacturing delays have occurred and may also occur as the result of labor shortages. Two of our suppliers experienced significant labor shortages as a result of COVID 19 from the end of November 2021 through early January 2022. In addition, during March 2022 and continuing into the second quarter of 2022, an increase in COVID 19 related cases in certain parts of China resulted in the re-imposition of widespread shutdowns and restrictions in China and additional supply chain disruptions. These labor shortages and increases in COVID-19 cases reduced the available resources needed to build and test product which may delay the timing for the submission and approval of our marketing applications with regulatory agencies. Further, the economic impact of the COVID 19 pandemic had affected, and may in the future affect, our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

The extent to which the COVID 19 pandemic will continue to impact our business, including our U.S. commercial launch and sales in Canada, as well as our results of operations and our financial condition will depend on future developments, which are highly uncertain and cannot be predicted. We do not yet know the full extent of the impact of COVID 19 on our business, operations or the global economy as a whole.

Inflationary Environment

Our operating results could be materially impacted by changes in the overall macroeconomic environment and other economic factors that impact customer confidence and spending, including capital spending. Changes in economic conditions, supply chain constraints, logistics challenges, labor shortages, 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. As a result of inflation, we have experienced and may continue to experience, cost increases. Although the Company may take measures to mitigate the impact of this inflation, if these measures are not effective, the Company's business, financial condition, results of operations, and liquidity could be materially adversely affected.

Other Trends and Uncertainties

Beginning in late 2021, production delays began to negatively impact the ability of our contract manufacturer to successfully ramp up production during 2022 to fulfill orders for both commercial sales and clinical trials, which has been exacerbated by both labor and supply chain shortages currently being experienced by many industries in the U.S.

To successfully commercialize, we need to continue to build infrastructure necessary to grow our business including adding headcount and implementing or upgrading business systems. Competition for talent in today's labor market may impact our ability to add headcount and to recruit talent with the expertise we need to develop our commercial infrastructure.

In response to the aforementioned challenges and trends, we have supplemented our personnel including quality resources at our contract manufacturer. Additionally, we continue to actively recruit and source candidates to fill positions as we build out our team to support our anticipated growth.

Results of Operations

Three Months Ended September 30, 2022 compared to the Three Months Ended September 30, 2021

The following table summarizes our results of operations for the three months ended September 30, 2022 and 2021 (in thousands):

	Three Months Ended September 30, 2022	2021	Change
Revenue:			
Product sales, net	$ 195	$ 102	$ 93
Other revenue	1	7	(6)
Total revenue	196	109	87
Cost of revenue	101	86	15
Gross profit	95	23	72
Operating expenses:			
Selling, general and administrative	3,393	2,859	534
Research and development	751	1,489	(738)
Amortization expense	47	48	(1)
Goodwill impairment	757	—	757
Total operating expenses	4,948	4,396	552
Loss from operations	(4,853)	(4,373)	(480)
Nonoperating income (expense)			
Interest expense, net	(919)	—	(919)
Change in fair value of derivative liability	5,489	—	5,489
Foreign exchange (loss) gain	(747)	(314)	(433)
Other income (expense), net	—	—	—
Nonoperating income (expense), net	3,823	(314)	4,137
Loss before provision for income taxes	(1,030)	(4,687)	3,657
Provision for income taxes	—	—	—
Net loss	$ (1,030)	$ (4,687)	$ 3,657

Revenue

For the three months ended September 30, 2022, we recognized net product sales of $139 thousand and $56 thousand in the U.S and Canada, respectively. Net product sales were $102 thousand in Canada for the three months ended September 30, 2021. All product sales in Canada for both periods were generated through product sales of our PoNS device pursuant to our executed supply agreements with neuroplasticity clinics in Canada. Other revenue for the three months ended September 30, 2021 was comprised of license fee revenue related to our Co-Promotion Agreement with HTC.

Cost of Revenue

For the three months ended September 30, 2022, cost of revenues was $101 thousand as compared with $86 thousand for the three months ended September 30, 2021. The increase was primarily attributable to overhead costs, including salaries and benefits of employees involved in management of the supply chain and, to a lesser extent, higher product sales in the current period.

Selling, General and Administrative Expense

Selling, general and administrative expenses were $3.4 million for the three months ended September 30, 2022, an increase of 0.5 million from the same period in 2021. The increase was primarily due to a $0.8 million net increase in stock-based compensation expense. In conjunction with the August 2022 Public Offering, certain performance criteria were achieved for the outstanding performance-based stock options, which resulted in the recognition of $1.2 million of

share-based compensation expense associated with their vesting. This additional expense was offset by lower stock- based compensation expense in the current period for time-based awards.

Research and Development Expense

Research and development expenses decreased $0.7 million for the three months ended September 30, 2022 as compared with the three months ended September 30, 2021. The decrease was primarily due to lower net expenses following the U.S. commercial launch, as well as decreases of $0.1 million in each of stock-based compensation and bonus expense.

Amortization Expense

Amortization expense consists of the periodic amortization of intangible assets, including proprietary software and reacquired rights recognized in connection with the acquisition of Heuro in October 2019 and internally developed software. The change in amortization expense period over period is primarily due to fluctuations in the Canadian to U.S. dollar exchange rates.

Goodwill Impairment

During the three months ended September 30, 2022, we recorded a goodwill impairment charge of $757 thousand, reducing the goodwill balance to zero. The significant decline in the price of our common stock following the August 2022 Public Offering was considered a triggering event for testing whether goodwill was impaired. Management performed a quantitative assessment as of September 30, 2022 and determined that the carrying value of our single reporting unit exceeded the estimated fair value. Refer to Note 4 to our unaudited condensed consolidated financial statements for additional information.

Nonoperating income (expense)

Interest Expense, Net

The Company recorded $0.9 million of interest expense in the three months ended September 30, 2022 in connection with the derivative liability classification of warrants issued in connection with the August 2022 Public Offering. Refer to Note 9 to our unaudited condensed consolidated financial statements for additional information. The interest expense in the period was offset by $8 thousand of interest income earned on an investment of excess cash in an unrestricted money market savings account.

Change in Fair Value of Derivative Liability

As discussed in more detail in Note 8 to our unaudited condensed consolidated financial statements, the warrants issued in connection with the August 2022 Public Offering are being accounted for as a derivative liability instrument. The change in fair value of derivative liability for the three months ended September 30, 2022 of $5.5 million is the result of the decrease in fair value from the date of issuance on August 9, 2022 and September 30, 2022, due to a decrease in the Company's stock price.

Foreign Exchange (Loss) Gain

Foreign exchange loss was $0.7 million for the three months ended September 30, 2022, compared to $0.3 million for the three months ended September 30, 2021. The increase in the loss was primarily due to fluctuations in the Canadian to U.S. dollar exchange rates.

Nine Months Ended September 30, 2022 compared to the Nine Months Ended September 30, 2021

The following table summarizes our results of operations for the nine months ended September 30, 2022 and 2021 (in thousands):

	Nine Months Ended September 30, 2022	2021	Change
Revenue:			
Product sales, net	$ 497	$ 242	$ 255
Other revenue	8	22	(14)
Total revenue	505	264	241
Cost of revenue	313	169	144
Gross profit	192	95	97
Operating expenses:			
Selling, general and administrative	8,673	9,800	(1,127)
Research and development	3,468	4,182	(714)
Amortization expense	141	153	(12)
Goodwill impairment	757	—	
Total operating expenses	13,039	14,135	(1,096)
Loss from operations	(12,847)	(14,040)	1,193
Nonoperating income (expense)			
Interest expense, net	(919)	—	(919)
Change in fair value of derivative liability	5,489	—	5,489
Foreign exchange (loss) gain	(910)	10	(920)
Other income (expense), net	1	—	1
Nonoperating income (expense), net	3,661	10	3,651
Loss before provision for income taxes	(9,186)	(14,030)	4,844
Provision for income taxes	—	—	—
Net loss	$ (9,186)	$ (14,030)	$ 4,844

Revenue

For the nine months ended September 30, 2022, we recognized net product sales of $202 thousand and $295 thousand in the U.S and Canada, respectively. Net product sales were $242 thousand in Canada for the nine months ended September 30, 2021. All product sales in Canada for both periods were generated through product sales of our PoNS device pursuant to our executed supply agreements with neuroplasticity clinics in Canada. Other revenue for the nine months ended September 30, 2022 and 2021 was comprised of license fee revenue related to our Co-Promotion Agreement with HTC.

Cost of Revenue

Cost of revenues increased $0.1 million to $0.3 million for the nine months ended September 30, 2022 as compared with the nine months ended September 30, 2021. The increase was primarily attributable to overhead costs, including salaries and benefits of employees involved in management of the supply chain and third-party distribution costs.

Selling, General and Administrative Expense

Selling, general and administrative expenses decreased $1.1 million to $8.7 million for the nine months ended September 30, 2022 as compared with the nine months ended September 30, 2021. The decrease was primarily due to a net decrease of $1.5 million in stock-based compensation expense, partially offset by increased compensation expenses related to personnel additions in late 2021 and early in 2022 to support the U.S. commercial launch.

Research and Development Expense

Research and development expenses decreased $0.7 million for the nine months ended September 30, 2022 as compared with the nine months ended September 30, 2021. The decrease was primarily due to decreases of $0.4 million in stock-based compensation expense and $0.1 million in bonus expense as well as lower net expenses following the U.S. commercial launch.

Amortization Expense

Amortization expense consists of the periodic amortization of intangible assets, including proprietary software and reacquired rights recognized in connection with the acquisition of Heuro in October 2019 and internally developed software. The change in amortization expense period over period is primarily due to fluctuations in the Canadian to U.S. dollar exchange rates.

Nonoperating income (expense)

Interest Expense, Net

The Company recorded $0.9 million of interest expense in the nine months ended September 30, 2022 in connection with the derivative liability classification of warrants issued in connection with the August 2022 Public Offering. Refer to Note 9 to our unaudited condensed consolidated financial statements for additional information. The interest expense in the period was offset by $8 thousand of interest income earned on an investment of excess cash in an unrestricted money market savings account.

Change in Fair Value of Derivative Liability

As discussed in more detail in Note 8 to our unaudited condensed consolidated financial statements, the warrants issued in connection with the August 2022 Public Offering are being accounted for as a derivative liability instrument. The change in fair value of derivative liability for the nine months ended September 30, 2022 of $5.5 million is the result of the decrease in fair value from the date of issuance on August 9, 2022 and September 30, 2022, due to a decrease in the Company's stock price.

Foreign Exchange (Loss) Gain

Foreign exchange loss was $0.9 million for the nine months ended September 30, 2022, compared to a gain of $10 thousand for the nine months ended September 30, 2021. The loss in the current period was primarily due to fluctuations in the Canadian to U.S. dollar exchange rates.

Statement of Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2022 and 2021 (in thousands):

	Nine Months Ended September 30,		
	2022	2021	Change
Net cash used in operating activities	$ (12,167)	$ (9,925)	$ (2,242)
Net cash used in investing activities	(13)	(51)	38
Net cash provided by financing activities	17,869	11,353	6,516
Effect of foreign exchange rate changes on cash	(6)	(8)	2
Net increase in cash, cash equivalents and restricted cash	$ 5,683	$ 1,369	$ 4,314

Net Cash Used in Operating Activities

Net cash used in operating activities increased $2.3 million to $12.2 million for the nine months ended September 30, 2022 as compared with cash used of $9.9 million in the prior year period. The higher level of cash used in operating activities in the current period primarily resulted from decreases in accounts payable and accrued liabilities.

Net Cash Used in Investing Activities

Our investing activities are primarily related to the purchase of property and equipment and, to a lesser extent, internally developed software. During the nine months ended September 30, 2022, net cash used in investing activities were net of $6 thousand in proceeds from the sale of furniture and equipment.

Net Cash Provided by Financing Activities

During the nine months ended September 30, 2022, we received net proceeds of $16.3 million from the August 2022 Public Offering described in Note 9 to our unaudited condensed consolidated financial statements. In addition, we received $0.6 million in net proceeds from the sale of 391,363 shares of common stock to Lincoln Park Capital Fund, LLC ("Lincoln Park") pursuant to a purchase agreement (the "LPC Purchase Agreement") and registration rights agreement with Lincoln Park, as more fully described in the 2021 10-K. We do not intend to issue any additional shares under the LPC Purchase Agreement.

Net cash provided by financing activities during the nine months ended September 30, 2021 was $11.4 million, which consisted of $10.0 million in aggregate net proceeds from the issuances of common stock in the February 2021 public offering of common stock and under the LPC Purchase Agreement and $1.3 million from the exercise of warrants and stock options.

Liquidity and Capital Resources

Our unaudited condensed consolidated financial statements have been prepared assuming that we will continue as a going concern and, accordingly, do not include adjustments relating to the recoverability and realization of assets and classification of liabilities that might be necessary should we be unable to continue in operation. Our primary sources of cash have been proceeds from various public and private offerings of our common stock and, to a lesser extent, exercises of stock options and warrants.

We currently have limited working capital and liquid assets. The following table summarizes our cash and working capital (which we define as current assets less current liabilities) as of September 30, 2022 and December 31, 2021 (in thousands):

	September 30, 2022	December 31, 2021
Cash and cash equivalents	$ 16,658	$ 11,005
Working capital	17,017	9,941

Cash Requirements

August 2022 Public Offering

Additional Funding 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 $9.2 million and $14.0 million for the nine months ended September 30, 2022 and 2021, respectively. As of September 30, 2022, we had an accumulated deficit of $146.2 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future. 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, including the net proceeds from the August 2022 Public Offering, will be sufficient to fund our operations into the third quarter of 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 2021 10-K. There have been no changes in critical accounting policies in the current year from those described in our 2021 10-K.

Recently Issued Accounting Pronouncements

The information set forth in Note 3 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 September 30, 2022, our risk factors have not changed materially from those risk factors previously disclosed in our 2021 10-K and Quarterly Reports on Form 10-Q for the quarters ended March 31, 2022 and June 30, 2022. You should carefully consider the risk factors discussed in Part I, "Item 1A. Risk Factors" in our 2021 10-K and our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2022 and June 30, 2022. The risks described in our 2021 10-K and our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2022 and June 30, 2022 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	Bylaws as amended and restated (incorporated by reference to Exhibit 3.3 to the Form 10-Q filed August 9, 2018)
4.1	Form of Warrant to purchase shares of common stock (incorporated by reference to Exhibit 4.1 to the Form 8-K filed August 9, 2022)
4.2	Warrant Agency Agreement dated as of August 9, 2022 by and between Helius Medical Technologies, Inc. and American Stock Transfer & Trust Company, LLC (incorporated by reference to Exhibit 4.2 to the Form 8-K filed August 9, 2022)
4.3	Form of Pre-Funded Warrant to purchase shares of common stock (incorporated by reference to Exhibit 4.3 to the Form 8-K filed August 9, 2022)
10.1	Form of Securities Purchase Agreement by and between Helius Medical Technologies, Inc. and the purchasers named therein (incorporated by reference to Exhibit 10.1 to the Form 8-K filed August 9, 2022)
10.2	Placement Agency Agreement dated as of August 5, 2022 by and between Helius Medical Technologies, Inc. and Roth Capital Partners, LLC (incorporated by reference to Exhibit 10.2 to the Form 8-K filed August 9, 2022)
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 Section302 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 14, 2022

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

Dated: November 14, 2022

By: /s/ Jeffrey S. Mathiesen
Jeffrey S. Mathiesen
Chief Financial Officer and Treasurer
(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, 2022 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 14, 2022

/s/ Dane C. Andreeff
Dane C. Andreeff
Chief Executive Officer
(Principal 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, 2022 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 14, 2022

/s/ Jeffrey S. Mathiesen
Jeffrey S. Mathiesen
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
HELIUS MEDICAL TECHNOLOGIES, INC.
FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2022
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, 2022 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 14, 2022

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

EXHIBIT 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
HELIUS MEDICAL TECHNOLOGIES, INC.
FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2022
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, 2022 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 14, 2022

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