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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 June 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 August 9, 2022, the registrant had 28,197,189 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
(Except for share data, amounts in thousands)

	June 30, 2022	December 31, 2021
ASSETS		
Current assets		
Cash	$ 3,273	$ 11,005
Accounts receivable, net	9	66
Other receivables	187	185
Inventory, net	577	476
Prepaid expenses	996	862
Other current assets	22	—
Total current assets	5,064	12,594
Property and equipment, net	365	409
Other assets		
Goodwill	753	763
Intangible assets, net	236	333
Operating lease right-of-use asset, net	128	3
Total other assets	1,117	1,099
TOTAL ASSETS	**$ 6,546**	**$ 14,102**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,043	$ 1,069
Accrued liabilities	654	1,433
Operating lease liability	52	3
Deferred revenue	28	148
Total current liabilities	1,777	2,653
Non-current liabilities		
Operating lease liability	83	—
Deferred revenue	184	193
TOTAL LIABILITIES	**2,044**	**2,846**
Commitments and contingencies (Note 10)		
STOCKHOLDERS' EQUITY		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding as of June 30, 2022 and December 31, 2021	—	—
Class A common stock, $0.001 par value; 150,000,000 shares authorized; 4,195,113 and 3,780,674 shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively	4	4
Additional paid-in capital	150,665	149,412
Accumulated deficit	(145,191)	(137,035)
Accumulated other comprehensive loss	(976)	(1,125)
TOTAL STOCKHOLDERS' EQUITY	**4,502**	**11,256**
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 6,546**	**$ 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
(Amounts in thousands except shares and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenue:				
Product sales, net	$ 119	$ 63	$ 302	$ 140
Other revenue	—	8	7	15
Total operating revenue	**119**	**71**	**309**	**155**
Cost of sales:				
Cost of product sales	88	67	212	83
Gross profit	**31**	**4**	**97**	**72**
Operating expenses:				
Research and development	953	1,377	2,717	2,694
Selling, general and administrative	2,461	4,744	5,280	6,939
Amortization expense	47	49	94	106
Total operating expenses	**3,461**	**6,170**	**8,091**	**9,739**
Operating loss	**(3,430)**	**(6,166)**	**(7,994)**	**(9,667)**
Other income (expense):				
Other income	—	—	1	—
Foreign exchange (loss) gain	(380)	185	(163)	324
Net other income (expense)	**(380)**	**185**	**(162)**	**324**
Loss before provision for income taxes	**(3,810)**	**(5,981)**	**(8,156)**	**(9,343)**
Provision for income taxes	**—**	**—**	**—**	**—**
Net loss	**(3,810)**	**(5,981)**	**(8,156)**	**(9,343)**
Other comprehensive income (loss):				
Foreign currency translation adjustments	351	(185)	149	(313)
Comprehensive loss	**$ (3,459)**	**$ (6,166)**	**$ (8,007)**	**$ (9,656)**
Net loss per share				
Basic	**$ (0.97)**	**$ (2.58)**	**$ (2.11)**	**$ (4.29)**
Diluted	**$ (0.97)**	**$ (2.58)**	**$ (2.11)**	**$ (4.29)**
Weighted average shares outstanding				
Basic	**3,928,704**	**2,317,389**	**3,858,676**	**2,179,878**
Diluted	**3,928,704**	**2,317,389**	**3,858,676**	**2,179,878**

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
(Except share data, amounts in thousands)

	Class A Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares	Amount				
Balances as of April 1, 2022	**3,794,797**	**$ 4**	**$ 149,834**	**$ (141,381)**	**$ (1,327)**	**$ 7,130**
Common stock issued under equity line of credit	391,363		638			638
Settlement of restricted stock units	4,690	—	—	—	—	—
Common stock issued for services	4,263	—	14	—	—	14
Stock-based compensation	—	—	179	—	—	179
Other comprehensive income	—	—	—	—	351	351
Net loss	—	—	—	(3,810)	—	(3,810)
Balances as of June 30, 2022	**4,195,113**	**$ 4**	**$ 150,665**	**$ (145,191)**	**$ (976)**	**$ 4,502**

	Class A Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares	Amount				
Balances as of April 1, 2021	**2,311,868**	**$ 2**	**$ 135,388**	**$ (122,265)**	**$ (1,227)**	**$ 11,898**
Exercise of warrants	262	—	4	—	—	4
Exercise of stock options	214	—	2	—	—	2
Settlement of restricted stock units	91	—	—	—	—	—
Stock-based compensation	5,337	—	2,629	—	—	2,629
Other comprehensive loss	—	—	—	—	(185)	(185)
Net loss	—	—	—	(5,981)	—	(5,981)
Balances as of June 30, 2021	**2,317,772**	**$ 2**	**$ 138,023**	**$ (128,246)**	**$ (1,412)**	**$ 8,367**

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

	Class A Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares	Amount				
Balances 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	—	638	—	—	638
Settlement of restricted stock units	6,274	—	—	—	—	—
Common stock issued for services	8,791	—	34	—	—	34
Stock-based compensation	8,011	—	581	—	—	581
Other comprehensive income	—	—	—	—	149	149
Net loss	—	—	—	(8,156)	—	(8,156)
Balances as of June 30, 2022	**4,195,113**	**$ 4**	**$ 150,665**	**$ (145,191)**	**$ (976)**	**$ 4,502**

	Class A Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares	Amount				
Balances as of January 1, 2021	**1,484,362**	**$ 1**	**$ 123,872**	**$ (118,903)**	**$ (1,099)**	**$ 3,871**
Issuance of common stock in February 2021 offering	744,936	1	8,398	—	—	8,399
Issuance of warrants in February 2021 offering	—	—	2,638	—	—	2,638
Share issuance costs	—	—	(1,361)	—	—	(1,361)
Exercise of warrants	81,895	—	1,318	—	—	1,318
Exercise of stock options	214	—	2	—	—	2
Settlement of restricted stock units	1,028	—	—	—	—	—
Stock-based compensation	5,337	—	3,156	—	—	3,156
Other comprehensive loss	—	—	—	—	(313)	(313)
Net loss	—	—	—	(9,343)	—	(9,343)
Balances as of June 30, 2021	**2,317,772**	**$ 2**	**$ 138,023**	**$ (128,246)**	**$ (1,412)**	**$ 8,367**

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
(Amounts in thousands)

	Six Months Ended June 30,	
	2022	2021
Cash flows from operating activities:		
Net loss	$ (8,156)	$ (9,343)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	581	3,156
Common stock issued for services	34	—
Foreign exchange loss (gain)	161	(323)
Depreciation expense	50	56
Amortization expense	94	106
Provision (reversal) for doubtful accounts	—	(11)
Provision for (reversal of) inventory reserve	(37)	—
Non-cash operating lease expense	26	30
Changes in operating assets and liabilities:		
Accounts receivable	57	34
Other receivables	(4)	(13)
Inventory, net	(64)	(118)
Prepaid expenses	(134)	(98)
Other current assets	(22)	—
Operating lease liability	(19)	(31)
Accounts payable	(7)	229
Accrued liabilities	(779)	(366)
Deferred revenue	(127)	2
Net cash used in operating activities	**(8,346)**	**(6,690)**
Cash flows from investing activities:		
Purchase of property and equipment	(12)	(19)
Proceeds from sale of property and equipment	6	—
Internally developed software	—	(2)
Net cash used in investing activities	**(6)**	**(21)**
Cash flows from financing activities:		
Proceeds from issuances of common stock	644	11,037
Share issuance costs	(24)	(1,523)
Proceeds from the exercise of warrants and stock options	—	1,320
Net cash provided by financing activities	**620**	**10,834**
Effect of foreign exchange rate changes on cash	—	(29)
Net (decrease) increase in cash	(7,732)	4,094
Cash at beginning of period	11,005	3,331
Cash at end of period	**$ 3,273**	**$ 7,425**
Supplemental cash flow information:		
Non-cash investing and financing transactions;		
Right-of-use assets obtained in exchange for new lease liabilities	$ 151	$ —

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

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

1. 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 consolidated condensed 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.

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

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

2. RISKS AND UNCERTAINTIES

Going Concern Uncertainty

As of June 30, 2022, the Company had cash of $3.3 million. For the six months ended June 30, 2022, the Company had an operating loss of $8.0 million, and as of June 30, 2022, its accumulated deficit was $145.2 million. For the six months ended June 30, 2022, the Company had $0.3 million of net revenue from the commercial sale of products. The Company expects to continue to incur operating losses and net cash outflows until such time as it generates a level of revenue to support its cost structure. There is no assurance that the Company will achieve profitable operations, and, if achieved, whether it will be sustained on a continued basis. These factors indicate substantial doubt about the Company’s ability to continue as a going concern within one year after the date the financial statements are filed. The Company’s 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 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. As discussed in Note 11 to our unaudited condensed consolidated financial statements, on August 9, 2022, the Company closed on a public offering of its Class A common stock and warrants and received aggregate net proceeds of approximately $16.4 million. 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 and Worldwide Economic Conditions

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 has 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. While all clinics had re-opened, as of December 31, 2021, many were operating at reduced capacity well into the first half of 2022, and patients have been and may continue to be less willing to return to these clinics, impacting the Company's commercial activities and customer engagement efforts. Moreover, the Company's ability to conduct its ongoing clinical experience programs and clinical trials has been and may be impaired due to trial participants' attendance being adversely affected by COVID-19. In addition, the COVID-19 pandemic has and may continue to cause delays in the Company's suppliers' ability to ship materials that the Company relies upon as well as manufacturing delays 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 which reduced the available resources needed to build and test product resulting in production delays of the PoNS devices. 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. It is currently unclear how long this latest series of shutdowns will continue and the Company may experience future manufacturing delays, which could place constraints on the Company's ability to produce or deliver its products and meet customer demand or increase its costs.

Generally, worldwide economic conditions remain uncertain, particularly due to the COVID-19 pandemic. Access to capital markets is critical to our 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 our 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.

Disruptions in business or governmental operations due to COVID-19 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 could 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 future 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 is likely, in turn, to lead to an increase in costs and may cause 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 Company is evaluating the effect that ASU 2016-13 will have on its condensed consolidated financial statements.

4. REVENUE FROM CONTRACTS WITH CUSTOMERS

Product sales are derived from the sale of PoNS devices to clinics in Canada and directly to the patient in the U.S. For both Canada and U.S. 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 six months ended June 30, 2022 and 2021, Canada product net sales were $56 thousand, $239 thousand, $63 thousand and $140 thousand, respectively. For both the three and six months ended June 30, 2022, U.S. product net sales were $63 thousand. As of June 30, 2022 and December 31, 2021, the Company had no contract assets or liabilities on its condensed consolidated balance sheets.

5. SUPPLEMENTAL BALANCE SHEET DISCLOSURES

Components of selected captions in the condensed consolidated balance sheets consisted of the following (amounts in thousands):

Accounts receivable, net

Accounts receivable from product sales are net of allowance for doubtful accounts of $351 and $355 as of June 30, 2022 and December 31, 2021, respectively.

Inventory, net

	As of June 30, 2022	As of December 31, 2021
Raw materials	$ 225	$ 171
Work-in-process	349	528
Finished goods	60	32
Inventory, gross	**$ 634**	$ 731
Inventory reserve	(57)	(255)
Inventory, net	**$ 577**	**$ 476**

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

Accrued expenses

	As of	
	June 30, 2022	December 31, 2021
Employees benefits	$ 462	$ 712
Professional services	24	174
Legal fees	44	23
Royalty fees	5	10
Franchise fees	20	193
Severance	37	258
Other	62	63
Total	**$ 654**	**$ 1,433**

Deferred revenue

License Revenue

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 June 30, 2022 and December 31, 2021 included approximately $200 of license fees not yet recognized under the Co-Promotion Agreement. License fee revenue recognized is included in Other Revenue in the 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 and as such it is the Company’s position that this exclusivity right is no longer in effect. The Company and HTC are currently discussing opportunities to work together moving forward.

Product Sales

Deferred revenue as of December 31, 2021 included approximately $100 for the fair value of the remaining 16 PoNS devices to be transferred that had been included as consideration in the Company’s acquisition of Heuro Canada, Inc. (“Heuro”). During the six months ended June 30, 2022, the remaining 16 PoNS devices were transferred and the remaining $100 of deferred revenue was recognized in Product Sales in the Condensed Consolidated Statements of Operations and Comprehensive Loss. There were no PoNS devices, included as consideration in the Heuro acquisition, transferred during the six-month period ended June 30, 2021.

6. 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	2.75 years
Weighted average discount rate	4.4 %

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

2022 (remaining)	$ 27
2023	58
2024	46
2025	12
Total future lease payments	**143**
Less: interest	(8)
Present value of lease liabilities	**$ 135**

7. STOCKHOLDERS' EQUITY

During the three and six months ended June 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 June 30, 2022, the Company does not intend to issue any additional shares under the LPC Purchase Agreement.

During the three and six months ended June 30, 2022, the Company issued common stock for services of 4,263 shares and 8,791 shares, respectively, with a value at issuance of $14 thousand and $34 thousand, respectively.

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 six months ended June 30, 2022, no warrants were exercised or cancelled.

8. 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 June 30, 2022, the remaining shares available

for grant were 95,672 shares under the 2022 Plan and 31,000 shares under the Helius Medical Technologies, Inc. 2021 Inducement Plan.

During the six months ended June 30, 2022, the Company granted 443,170 stock options at a weighted average exercise price of $3.88 per share. The grant date fair values of these stock options were estimated using the Black-Scholes option pricing model using the following weighted average assumptions:

	Six Months Ended June 30, 2022
Risk-free interest rate	2.63 %
Expected volatility	74.66 %
Expected term (years)	5.62
Expected dividend yield	0.00 %
Fair value per option	$ 1.34

During the six months ended June 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 six months ended June 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 June 30, 2022, there were an aggregate of 1,070,404 stock options outstanding with a weighted average exercise price of $19.82 per share and 20,281 unvested restricted stock units outstanding with a weighted average grant date fair value of $1.48 per share.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Research and development	$ (49)	$ 162	$ 104	$ 384
Cost of sales	$ 4	$ 3	7	3
Selling, general and administrative	224	2,464	470	2,769
Total	**$ 179**	**$ 2,629**	**$ 581**	**$ 3,156**

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

As of June 30, 2022, the unrecognized compensation cost related to non-vested time-based stock options and restricted stock units was $2.6 million which will be recognized over a weighted-average remaining vesting period of approximately 2.5 years. As of June 30, 2022, the unrecognized compensation cost related to performance-based stock options was $1.2 million. Recognition of compensation expense for performance-based stock options will commence at the time it is determined to be probable that the performance conditions will be met. Compensation cost is not adjusted for estimated forfeitures, but instead is adjusted upon an actual forfeiture of an award.

9. 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.

The calculation of basic and diluted net loss per share attributable to common stock was as follows (amounts in thousands except share and per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Numerator:				
Net loss attributable to common stock—basic and diluted	$ (3,810)	$ (5,981)	$ (8,156)	$ (9,343)
Denominator:				
Weighted average basic and diluted shares outstanding	3,928,704	2,317,389	3,858,676	2,179,878
Loss per share attributable to common stock—basic and diluted	$ (0.97)	$ (2.58)	$ (2.11)	$ (4.29)

Common stock equivalents outstanding of 1,684,609 for both the three and six months ended June 30, 2022 and 1,233,230 for both the three and six months ended June 30, 2021 were not included in the computation of diluted loss per share because the effect would have been anti-dilutive.

10. COMMITMENTS AND CONTINGENCIES

The Company is obligated under a license agreement with Advanced NeuroRehabilitation, LLC (“ANR”) to pay a 4% royalty on net revenue from the sale of devices covered by the patent-pending technology. During the three months ended June 30, 2022 and 2021, the Company recorded royalty expense from the sale of devices of approximately $5 thousand and $3 thousand, respectively, in its condensed consolidated statement of operations and comprehensive loss. During the six months ended June 30, 2022 and 2021, the Company recorded royalty expense from the sale of devices of approximately $12 thousand and $6 thousand, respectively, in its condensed consolidated statement of operations and comprehensive loss.

11. SUBSEQUENT EVENTS

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 warrants to purchase an aggregate of 36,000,000 shares of common stock (“Public Warrants”) 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. The pre-funded warrants had an exercise price of $0.001 per share and were all exercised on the closing date. Net proceeds from the public offering, after deducting placement agent fees and expenses and other offering costs, were approximately $16.4 million.

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.

In conjunction with this public offering, certain performance criteria were achieved for the outstanding performance-based stock options discussed in Note 8, resulting in the vesting of the performance-based stock options. For the three months ending September 30, 2022, the Company expects to recognize additional share-based compensation expense of $1.2 million associated with the vesting of the performance-based stock options.

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 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 the Company, 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 have applied for unique HCPCS codes during the third quarter of 2021, which is a nine month process from application until coding is to be effective, if assigned. 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, and as such, it is our position that this exclusivity right is no longer in effect. We are currently in discussions with HTC to explore opportunities to work together moving forward.

As discussed further in Note 11 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 $16.4 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 has 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 have begun to return 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 have expanded our services to include remote training and treatment, but the long-term viability of these remote programs is still being assessed. Additionally, current and planned 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 which 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 could 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 is likely, in turn, to lead to an increase in costs and may cause 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 June 30, 2022 compared to the Three Months Ended June 30, 2021

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

	Three Months Ended June 30, 2022	2021	Change
Revenue:			
Product sales, net	$ 119	$ 63	$ 56
Other revenue	—	8	(8)
Total operating revenue	**119**	**71**	**48**
Cost of sales:			
Cost of product sales	88	67	21
Gross profit	**31**	**4**	**27**
Operating expenses:			
Research and development	953	1,377	(424)
Selling, general and administrative	2,461	4,744	(2,283)
Amortization expense	47	49	(2)
Total operating expenses	**3,461**	**6,170**	**(2,709)**
Operating loss	(3,430)	(6,166)	2,736
Other income (expense):			
Other income	—	—	—
Foreign exchange (loss) gain	(380)	185	(565)
Net other income (expense)	(380)	185	(565)
Loss before provision for income taxes	(3,810)	(5,981)	2,171
Provision for income taxes	—	—	—
Net loss	**$ (3,810)**	**$ (5,981)**	**$ 2,171**

Revenue

For the three months ended June 30, 2022, we recognized net product sales of $56 thousand and $63 thousand in Canada and the U.S, respectively. Net product sales were $63 thousand in Canada for the three months ended June 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 June 30, 2021 was comprised of license fee revenue related to our Co-Promotion Agreement with HTC.

Cost of Sales

For the three months ended June 30, 2022, cost of sales were $88 thousand as compared with $67 for the three months ended June 30, 2021. The increase was primarily attributable to higher product sales in the current period.

Research and Development Expense

Research and development expenses decreased $0.4 million to $1.0 million for the three months ended June 30, 2022 as compared with the three months ended June 30, 2021. The decrease was due a $0.2 million decrease in stock-based compensation expense as well as lower net expenses following the U.S. commercial launch.

Selling, General and Administrative Expense

Selling, general and administrative expenses were $2.5 million for the three months ended June 30, 2022, a decrease of $2.3 million from the same period in 2021. The decrease was primarily due to a $2.2 million decrease 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 discussed in Note 8 to our unaudited condensed consolidated financial statements, resulting in the vesting of the performance-based stock options. For the three months ending September 30, 2022, we expect to recognize additional share-based compensation expense of $1.2 million associated with the vesting of the performance-based stock options.

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.

Foreign Exchange (Loss) Gain

Foreign exchange loss was $0.4 million for the three months ended June 30, 2022, compared to a gain of $0.2 million for the three months ended June 30, 2021. This change was primarily due to fluctuations in the Canadian to U.S. dollar exchange rates.

Six Months Ended June 30, 2022 compared to the Six Months Ended June 30, 2021

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

	Six Months Ended June 30,		
	2022	2021	Change
Revenue:			
Product sales, net	$ 302	$ 140	$ 162
Other revenue	7	15	(8)
Total operating revenue	**309**	**155**	**154**
Cost of sales:			
Cost of product sales	212	83	129
Gross profit	**97**	**72**	**25**
Operating expenses:			
Research and development	2,717	2,694	23
Selling, general and administrative	5,280	6,939	(1,659)
Amortization expense	94	106	(12)
Total operating expenses	**8,091**	**9,739**	**(1,648)**
Operating loss	**(7,994)**	**(9,667)**	**1,673**
Other income (expense):			
Other income	1	—	1
Foreign exchange (loss) gain	(163)	324	(487)
Net other income (expense)	**(162)**	**324**	**(486)**
Loss before provision for income taxes	**(8,156)**	**(9,343)**	**1,187**
Provision for income taxes	**—**	**—**	**—**
Net loss	**$ (8,156)**	**$ (9,343)**	**$ 1,187**

Revenue

For the six months ended June 30, 2022, we recognized net product sales of $239 thousand and $63 thousand in Canada and the U.S, respectively. Net product sales were $140 thousand in Canada for the six months ended June 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 six months ended June 30, 2022 and 2021 was comprised of license fee revenue related to our Co-Promotion Agreement with HTC.

Cost of Sales

Cost of sales increased $0.1 million to $0.2 million for the six months ended June 30, 2022 as compared with the six months ended June 30, 2021. The increase in net product sales contributed to a $50 thousand net increase in product cost. The remainder of the increase was primarily attributable to higher overhead costs related to salaries and benefits of employees involved in management of the supply chain.

Research and Development Expense

Research and development expenses were $2.7 million for both the six months ended June 30, 2022 and 2021. A net decrease of $0.3 million in stock-based compensation expense was primarily offset by net increases in personnel related expenses.

Selling, General and Administrative Expense

Selling, general and administrative expenses decreased $1.7 million to $5.3 million for the six months ended June 30, 2022 as compared with the six months ended June 30, 2021. The decrease was primarily due to a net decrease of $2.3 million in stock-based compensation expense, partially offset by increased compensation expenses related to personnel additions in late 2021 and the first half 2022 to support the U.S. commercial launch.

In conjunction with the August 2022 Public Offering, certain performance criteria were achieved for the outstanding performance-based stock options discussed in Note 8 to our unaudited condensed consolidated financial statements, resulting in the vesting of the performance-based stock options. For the three months ending September 30, 2022, we expect to recognize additional share-based compensation expense of $1.2 million associated with the vesting of the performance-based stock options.

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.

Foreign Exchange (Loss) Gain

Foreign exchange loss was $0.2 million for the six months ended June 30, 2022, as compared with a gain of $0.3 million for the six months ended June 30, 2021. This was primarily due to fluctuations in the Canadian to U.S. dollar exchange rate.

Statement of Cash Flows

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

	Six Months Ended June 30,		
	2022	2021	Change
Net cash used in operating activities	$ (8,346)	$ (6,690)	$ (1,656)
Net cash used in investing activities	(6)	(21)	15
Net cash provided by financing activities	620	10,834	(10,214)
Effect of foreign exchange rate changes on cash	—	(29)	29
Net (decrease) increase in cash	$ (7,732)	$ 4,094	$ (11,826)

Net Cash Used in Operating Activities

Net cash used in operating activities increased $1.7 million to $8.4 million for the six months ended June 30, 2022 as compared with $6.7 million for the prior year period. The $1.2 million decrease in the net loss was offset by a net decrease of $2.1 million in noncash expenses and net decreases in accounts payable, accrued liabilities and deferred revenue.

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 six months ended June 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 six months ended June 30, 2022, 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. As of June 30, 2022, we do not intend to issue any additional shares under the LPC Purchase Agreement.

Net cash provided by financing activities during the six months ended June 30, 2021 consisted of $9.5 million in net proceeds from the from the February 2021 public offering of common stock and $1.3 million from the exercise of warrants and stock options.

Liquidity and Capital Resources

Our 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 exercises of stock options and warrants. During the six months ended June 30, 2022 we received approximately $0.6 million from the sale of common stock under the LPC Purchase Agreement discussed above.

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 June 30, 2022 and December 31, 2021 (amounts in thousands):

	June 30, 2022	December 31, 2021
Cash	$ 3,273	$ 11,005
Working capital	3,287	9,941

Cash Requirements

August 2022 Public Offering

On August 9, 2022, we received net proceeds of approximately $16.4 million from the August 2022 Public Offering described in Note 11 to our unaudited condensed consolidated financial statements.

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 $8.2 million and $9.3 million for the six months ended June 30, 2022 and 2021, respectively. As of June 30, 2022, we had an accumulated deficit of $145.2 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 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 June 30, 2022, except for the updated risk factors set forth immediately below, our risk factors have not changed materially from those risk factors previously disclosed in our 2021 10-K and Quarterly Report on Form 10-Q for the quarter ended March 31, 2022. You should carefully consider the risk factors discussed below and in Part I, “Item 1A. Risk Factors” in our 2021 10-K and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2022. You should carefully consider the risk factors discussed below and in Part I, “Item 1A. Risk Factors” in our 2021 10-K and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2022. The risks described below and in our 2021 10-K are not the only risks facing us. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially and adversely affect our business, financial condition and/or operating results.

We depend on third parties for the manufacture and distribution of our product and the loss of our third-party manufacturer and distributor could harm our business.

We depend on our third-party contract manufacturing partner to manufacture and supply our PoNS device for clinical and commercial purposes, and this contract manufacturer manufactured the units for our engineering and device verification testing and is building the launch quantities for commercialization. Additionally, we depend on a different third-party distribution partner to warehouse and ship our products to customers. Our reliance on a third-party manufacturer and a distribution provider to supply us with our PoNS device and to provide such other distribution services exposes us to risks that could delay our sales or result in higher costs or lost product revenues. In addition, our manufacturers have experienced and could continue to experience difficulties, including, but not limited to, those caused by the COVID-19 pandemic, in securing long-lead time components, achieving volume production, quality control and quality assurance or suffer shortages of qualified personnel, or fail to follow and remain in compliance with the FDA-mandated Quality System Regulations, or QSR, compliance which is required for all medical devices, or fail to document their compliance to QSRs, any of which could result in their inability to manufacture sufficient quantities of our commercially available product to meet market demand or lead to significant delays in the availability of materials for our product and/or FDA enforcement actions against them and/or us.

If we are unable to obtain adequate supplies of our product that meet our specifications and quality standards, it will be difficult for us to compete effectively. While we have supply and quality agreements in place with our manufacturer, they may change the terms of our future orders or choose not to supply us with products in the future. Furthermore, if such manufacturer fails to perform its obligations, we may be forced to purchase our product from other third-party manufacturers, which we may not be able to do on reasonable terms or in sufficient time, if at all. In addition, if we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer or the reverification of an existing manufacturer could negatively affect our ability to produce and distribute our product in a timely manner.

The market price of our common stock has been and may be volatile and fluctuate substantially, which could result in substantial losses for our common stock.

Securities of microcap and small-cap companies, including biotechnology companies in particular, have experienced substantial volatility in the recent past, often based on factors unrelated to the companies' financial performance or prospects. We believe that trading in our stock has been and will likely continue to be subject to significant volatility.

These factors include macroeconomic developments in North America and globally and market perceptions of the attractiveness of particular industries. Factors unrelated to our performance that may affect the price of our common stock include the following: the extent of analytical coverage available to investors concerning our business may be limited if investment banks with research capabilities do not follow us, a reduction in trading volume and general market interest in our common stock may affect an investor's ability to trade significant numbers of shares of our common stock: the size of our public float may limit the ability of some institutions to invest in our common stock. As a result of any of these factors, the market price of our common stock at any given point in time may not accurately reflect our long-term value. The price of our common stock may increase or decrease in response to a number of events and factors, including changes in financial estimates, our acquisitions and financings, quarterly variations in our operating results, the operating and share price performance of other companies that investors may deem comparable and purchase or sale of blocks of our common stock. These factors, or any of them, may materially adversely affect the prices of our common shares regardless of our operating performance.

The market price of our common stock is affected by many other variables which are not directly related to our success and are, therefore, not within our control. These include other developments that affect the breadth of the public market for shares of our common stock and the attractiveness of alternative investments. The effect of these and other factors on the market price of our common stock is expected to make our common stock price volatile in the future, which may result in losses to investors.

Our common stock is listed on the Nasdaq Capital Market, or Nasdaq. We can provide no assurance that we will be able to comply with the continued listing requirements over time and that our common stock will continue to be listed on Nasdaq.

Our common stock is currently listed on the Nasdaq Capital Market. However, we can give no assurance that we will be able to satisfy the continued listing requirements of Nasdaq in the future, including maintaining a minimum closing bid price of $1.00 per share. Since August 5, 2022, the closing price of our common stock has been below $1.00. If the closing bid price of our common stock is below $1.00 per share for 30 consecutive business days, we will receive a deficiency notice from Nasdaq advising us that we have a certain period of time, typically 180 days, to regain compliance by maintaining a minimum closing bid price of at least $1.00 for at least ten consecutive business days, although Nasdaq could require a longer period. If we fail to maintain compliance with the minimum closing bid price requirement, or any other of the continued listing requirements of Nasdaq, the exchange may take steps to de-list our common stock. If such delisting should occur, it would likely have a negative effect on the price of our common stock and would impair an investor's ability to sell or purchase our common stock when desired. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement, or prevent future non-compliance with Nasdaq's listing requirements.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)
10.1	Helius Medical Technologies, Inc. 2022 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on February 18, 2022)
10.2	Helius Medical Technologies, Inc. 2022 Equity Incentive Plan Form of Option Agreement (incorporated by reference to Exhibit 10.3 to the Form 8-K filed on February 18, 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: August 15, 2022

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

Dated: August 15, 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 June 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: August 15, 2022

/s/ Dane C. Andreeff

Dane C. Andreeff
Chief Executive Officer and Director
(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 June 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: August 15, 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 JUNE 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 June 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: August 15, 2022

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

EXHIBIT 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
HELIUS MEDICAL TECHNOLOGIES, INC.
FORM 10-Q FOR THE QUARTER ENDED JUNE 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 June 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: August 15, 2022

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