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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 March 31, 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 May 4, 2022, the registrant had 3,797,647 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)

	March 31, 2022	December 31, 2021
ASSETS		
Current assets		
Cash	$ 6,310	$ 11,005
Accounts receivable, net	60	66
Other receivables	185	185
Inventory, net	520	476
Prepaid expenses	951	862
Total current assets	8,026	12,594
Property and equipment, net	380	409
Other assets		
Goodwill	777	763
Intangible assets, net	291	333
Other non-current assets	4	—
Operating lease right-of-use asset, net	140	3
Total other assets	1,212	1,099
TOTAL ASSETS	**$ 9,618**	**$ 14,102**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,111	$ 1,069
Accrued liabilities	1,008	1,433
Operating lease liability	51	3
Deferred revenue	29	148
Total current liabilities	2,199	2,653
Non-current liabilities		
Operating lease liability	99	—
Deferred revenue	190	193
TOTAL LIABILITIES	**2,488**	**2,846**
Commitments and contingencies (Note 6)		
STOCKHOLDERS' EQUITY		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding as of March 31, 2022 and December 31, 2021	—	—
Class A common stock, $0.001 par value; 150,000,000 shares authorized; 3,794,797 and 3,780,674 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	4	4
Additional paid-in capital	149,834	149,412
Accumulated deficit	(141,381)	(137,035)
Accumulated other comprehensive loss	(1,327)	(1,125)
TOTAL STOCKHOLDERS' EQUITY	**7,130**	**11,256**
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 9,618**	**$ 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 March 31,	
	2022	2021
Revenue:		
Product sales	$ 183	$ 77
License revenue	7	7
Total operating revenue	**190**	**84**
Cost of sales:		
Cost of product sales	124	15
Gross profit	**66**	**69**
Operating expenses:		
Research and development	1,764	1,316
Selling, general and administrative	2,819	2,197
Amortization expense	47	57
Total operating expenses	**4,630**	**3,570**
Operating loss	**(4,564)**	**(3,501)**
Other income:		
Other income	1	—
Foreign exchange gain	217	139
Total other income	**218**	**139**
Net loss	**(4,346)**	**(3,362)**
Other comprehensive income:		
Foreign currency translation adjustments	(202)	(128)
Comprehensive loss	**$ (4,548)**	**$ (3,490)**
Net loss per share		
Basic	**$ (1.15)**	**$ (1.65)**
Diluted	**$ (1.15)**	**$ (1.65)**
Weighted average shares outstanding		
Basic	**3,787,871**	**2,040,839**
Diluted	**3,787,871**	**2,040,839**

(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 for the Three Months Ended March 31, 2022 and 2021
(Except share data, amounts in thousands)

	Common Stock, $0.001 par value		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares	Amount				
Balance as of December 31, 2020	**1,484,362**	**$ 1**	**$ 123,872**	**$ (118,903)**	**$ (1,099)**	**$ 3,871**
Proceeds from the issuance of common stock from the February 2021 Offering	**744,936**	1	8,398	—	—	8,399
Warrants issuance from the February 2021 Offering	**—**	—	2,638	—	—	2,638
Share issuance costs	—	—	(1,361)	—	—	(1,361)
Proceeds from the exercise of warrants	81,633	—	1,314	—	—	1,314
Settlement of restricted stock units	937	—	—	—	—	—
Stock-based compensation	—	—	527	—	—	527
Foreign currency translation adjustments	—	—	—	—	(128)	(128)
Net loss	—	—	—	(3,362)	—	(3,362)
Balance as of March 31, 2021	**2,311,868**	**$ 2**	**$ 135,388**	**$ (122,265)**	**$ (1,227)**	**$ 11,898**

	Common Stock, $0.001 par value		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares	Amount				
Balance as of December 31, 2021	**3,780,674**	**$ 4**	**$ 149,412**	**$ (137,035)**	**$ (1,125)**	**$ 11,256**
Settlement of restricted stock units	1,584	—	—	—	—	—
Issuance of shares to a consultant for services	4,528	—	20	—	—	20
Stock-based compensation	8,011	—	402	—	—	402
Foreign currency translation adjustments	—	—	—	—	(202)	(202)
Net loss	—	—	—	(4,346)	—	(4,346)
Balance as of March 31, 2022	**3,794,797**	**$ 4**	**$ 149,834**	**$ (141,381)**	**$ (1,327)**	**$ 7,130**

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

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

	Three Months Ended March 31,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (4,346)	$ (3,362)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	402	527
Common shares issued to a consultant for services	20	—
Unrealized foreign exchange gain	(217)	(132)
Depreciation expense	25	28
Amortization expense	47	57
Provision for doubtful accounts	(23)	(11)
Non-cash lease expense	13	15
Changes in operating assets and liabilities:		
Accounts receivable	27	36
Other receivables	1	2
Inventory, net	(45)	(95)
Prepaid expenses	(88)	(44)
Operating lease liability	(3)	(15)
Accounts payable	72	234
Accrued liabilities	(425)	(160)
Deferred revenue	(142)	(1)
Net cash used in operating activities	**(4,682)**	**(2,921)**
Cash flows from investing activities:		
Purchase of property and equipment	(2)	(19)
Proceeds from sale of property and equipment	6	—
Internally developed software	—	(2)
Net cash provided by (used in) investing activities	**4**	**(21)**
Cash flows from financing activities:		
Proceeds from the issuances of common stock and warrants	—	11,037
Share issuance costs	(17)	(1,331)
Proceeds from the exercise of warrants and stock options	—	1,314
Net cash (used in) provided by financing activities	**(17)**	**11,020**
Effect of foreign exchange rate changes on cash		(12)
Net (decrease) increase in cash	(4,695)	8,066
Cash at beginning of period	11,005	3,331
Cash at end of period	**$ 6,310**	**$ 11,397**
Supplemental schedule of non-cash financing activities		
Share issuance costs included in accounts payable and accrued liabilities	—	192

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

1. DESCRIPTION OF BUSINESS

Helius Medical Technologies, Inc. (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®"), is an innovative non-surgical 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 is indicated for use in the U.S. as a short term treatment of gait deficit due to mild-to-moderate symptoms from multiple sclerosis ("MS"), and is to be used as an adjunct to a supervised therapeutic exercise program in patients 22 years of age and over by prescription only. The Company began accepting prescriptions for PoNS in the U.S., in the first quarter of 2022, and the first commercial sales began in April 2022. PoNS is authorized for sale in Canada for two indications: (i) PoNS is authorized as a short term treatment (14 weeks) of chronic balance deficit due to mild-to-moderate traumatic brain injury ("mmTBI") and is to be used in conjunction with physical therapy ("PoNS Therapy™"); and (ii) PoNS is authorized for use as a short term treatment (14 weeks) of gait deficit due to mild and moderate symptoms from MS and 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. 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 was incorporated in British Columbia, Canada on March 13, 2014. On May 28, 2014, the Company was reincorporated from British Columbia to the State of Wyoming, and on July 20, 2018, it was reincorporated from the State of Wyoming to the State of Delaware. The Company is headquartered in Newtown, Pennsylvania. On December 21, 2018, the Company's wholly owned subsidiary, NeuroHabilitation Corporation, changed its name to Helius Medical, Inc ("HMI"). On January 31, 2019, the Company formed another wholly owned subsidiary, Helius NeuroRehab, Inc., ("HNR"), a Delaware corporation. On October 10, 2019, the Company formed Helius Canada Acquisition Ltd. ("HCA"), a company incorporated under the federal laws of Canada and a wholly owned subsidiary of Helius Medical Technologies (Canada), Inc. ("HMC"), a company incorporated under the federal laws of Canada, which acquired Heuro Canada, Inc. ("Heuro") from Health Tech Connex Inc. ("HTC") on October 30, 2019.

Going Concern Uncertainty

As of March 31, 2022, the Company had cash of $6.3 million. For the three months ended March 31, 2022, the Company had an operating loss of $ 4.3 million, and as of March 31, 2022, its accumulated deficit was $141.4 million. For the three months ended March 31, 2022, the Company had $0.2 million of revenue from the commercial sale of products or services. 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 Canada and the U.S. and by raising additional capital through equity or debt financings as well as by using its equity line facility entered into on September 1, 2021 with Lincoln Park Capital Fund, LLC ("Lincoln Park"), which is subject to certain limitations and conditions. There can be no assurance that the Company will be successful in raising that 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.

Risks and Uncertainties

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 quarter 2022, and patients have been and may continue to be less willing to return to these clinics, impacting our commercial activities and our 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, 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 resulted in additional supply chain disruptions. It is currently unclear how long this latest series of shutdowns will continue and we may experience future manufacturing delays, which could place constraints on our ability to produce or deliver our products and meet customer demand or increase our 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. We require 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 our access to capital and increased the cost of capital. The capital and credit markets may not be available to support future capital raising activity on favorable terms. If economic conditions decline, our future cost of equity or debt capital and access to the capital markets could be adversely affected.

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.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The condensed consolidated financial statements have also been prepared on a basis substantially consistent with 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. 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 Company's reporting currency is the U.S. Dollar ("USD$").

Use of Estimates

The preparation of the condensed consolidated financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and disclosure of contingent assets and liabilities. Significant estimates include the assumptions used in the fair value pricing model for stock-based compensation, derivative financial instruments and deferred income tax asset valuation allowance. Financial statements include estimates which, by their nature, are uncertain. Actual outcomes could differ from these estimates.

Principles of Consolidation

The accompanying unaudited condensed consolidated financial statements reflect the operations of Helius Medical Technologies, Inc. and its wholly owned subsidiaries. The usual condition for a controlling financial interest is ownership of a majority of the voting interests of an entity. However, a controlling financial interest may also exist through arrangements that do not involve controlling voting interests. As such, the Company applies the guidance of the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 810 – *Consolidation* ("ASC 810"), to determine when an entity that is insufficiently capitalized or not controlled through its voting interests, referred to as a variable interest entity should be consolidated. All intercompany balances and transactions have been eliminated.

Concentrations of Credit Risk

The Company is subject to credit risk with respect to its cash. Amounts invested in such instruments are limited by credit rating, maturity, industry group, investment type and issuer. The Company maintains cash in excess of federally insured limits in certain banks. However, the Company has not experienced any losses in such accounts and believes it is not exposed to any significant credit risk related to cash. The Company seeks to maintain safety and preservation of principal and diversification of risk, liquidity of investments sufficient to meet cash flow requirements and a competitive after-tax rate of return.

Receivables

Accounts receivables are stated at their net realizable value. In determining the appropriate allowance for doubtful accounts, the Company considers a combination of factors, such as the aging of trade receivables, its customers' financial strength, and payment history. Changes in these factors, among others, may lead to adjustments in the Company's allowance for doubtful accounts. The calculation of the allowance required judgment by Company management. As of March 31, 2022, the Company's accounts receivable of $0.1 million, is net of an allowance for doubtful accounts of $0.4 million and is the result of revenue from product sales. As of December 31, 2021, the Company's accounts receivable of $ 0.1 million, is net of an allowance for doubtful accounts of $0.4 million and is the result of revenue from product sales.

Other receivables totaling $0.2 million as of both March 31, 2022 and December 31, 2021, respectively included refunds from research and development ("R&D") tax credits, and Goods and Services Tax ("GST") and Quebec Sales Tax ("QST") refunds related to the Company's Canadian expenditures.

Inventory

The Company's inventory consists of raw materials, work in progress and finished goods of the PoNS device. Inventory is stated at the lower of cost (average cost method) or net realizable value. Adjustments to reduce the cost of inventory to its net realizable value are made if required. The Company calculates provisions for excess inventory based on inventory on hand compared to anticipated sales or usage. Management uses its judgment to forecast sales or usage and to determine what constitutes a reasonable period. There can be no assurance that the amount ultimately realized for inventories will not be materially different than that assumed in the calculation of the reserves . No inventory markdowns to net realizable value were recorded during the three month periods ended March 31, 2022 and March 31, 2021 During the three months ended March 31, 2022 existing reserves of $127 thousand were charged against work-in-process inventory. There were no existing reserves charged against inventory during 2021.

As of March 31, 2022 and December 31, 2021, inventory consisted of the following (amounts in thousands):

	As of March 31, 2022	As of December 31, 2021
Raw materials	$ 185	$ 171
Work-in-process	410	528
Finished goods	53	32
Inventory	**$ 648**	**$ 731**
Inventory reserve	(128)	(255)
Total inventory, net of reserve	**$ 520**	**$ 476**

Property and Equipment

Property and equipment are carried at cost, less accumulated depreciation. Depreciation is recognized using the straight-line method over the useful lives of the related asset or the term of the related lease. Expenditures for maintenance and repairs, which do not improve or extend the expected useful life of the assets, are expensed to operations while major repairs are capitalized. The estimated useful life for the Company's furniture and fixtures is 7 years. Equipment has an estimated useful life of 15 years, while computer software and hardware has an estimated useful life of 3 to 5 years.

As of March 31, 2022 and December 31, 2021, property and equipment consisted of the following (amounts in thousands):

	As of March 31, 2022	As of December 31, 2021
Furniture and fixtures	$ 59	$ 65
Equipment	374	373
Computer software and hardware	213	212
Property and equipment	**646**	**650**
Less accumulated depreciation	(266)	(241)
Property and equipment, net	**$ 380**	**$ 409**

Depreciation expense was $25 thousand and $28 thousand for the three months ended March 31, 2022 and 2021, respectively.

Goodwill and Other Intangible Assets

Goodwill represents the excess of purchase price over the fair values underlying net assets acquired in an acquisition. All of the Company's goodwill as of March 31, 2022 is the result of the Heuro acquisition completed in October 2019. Goodwill is not amortized, but rather is tested annually for impairment or more frequently if events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. The Company tests goodwill for impairment annually in the fourth quarter of each year using data as of October 1 of that year.

Goodwill is allocated to and evaluated for impairment at the Company's one identified reporting unit. Goodwill 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.

If the estimated fair value exceeds the carrying value, no further evaluation is required, and no impairment loss is recognized. If the carrying amount of a reporting unit, including goodwill, exceeds the estimated fair value, the excess of the carrying value over the estimated fair value is recorded as an impairment loss, the amount of which is not to exceed the total amount of goodwill allocated to the reporting unit.

The following is a summary of the activity for the period ended March 31, 2022 for goodwill:

Carrying amount at December 31, 2021	$	763
Foreign currency translation		14
Carrying amount at March 31, 2022	$	777

Definite-lived intangibles consist principally of acquired proprietary software and reacquired rights as well as internally developed software. All are amortized straight-line over their estimated useful lives. Amortization expense related to intangible assets was $47 thousand for the three months ended March 31, 2022 and $0.1 million during the three months ended March 31, 2021.

Intangible assets as of March 31, 2022 and December 31, 2021 consist of the following:

		As of March 31, 2022			As of December 31, 2021		
	Useful Life	Gross Carrying Amount	Accumulated Amortization	Net Carrying Value	Gross Carrying Amount	Accumulated Amortization	Net Carrying Value
Acquired proprietary software	5 years	154	(75)	79	151	(66)	85
Reacquired rights	3.87 years	514	(321)	193	505	(283)	222
Internally developed software	3 years	84	(65)	19	84	(58)	26
Total intangible assets		$ 752	$ (461)	$ 291	$ 740	$ (407)	$ 333

Amortization expense is anticipated to be as follows in future years:

For the Year Ending December 31,	
2022 (remaining 9 months)	140
2023	125
2024	26
	$ 291

Leases

The Company accounts for its leases under ASU No. 2016-02, *Leases.* The Company does not record an operating lease right of use ("ROU") asset and corresponding lease liability for leases with an initial term of twelve months or less and recognizes lease expense for these leases as incurred over the lease term. As of March 31, 2022, the Company had two operating leases, one for its headquarters office in Newtown, Pennsylvania and one for additional office space in Ewing, New Jersey. Operating lease ROU assets and operating lease liabilities are recognized based on the present value of lease payments over the lease term. The Company does not have a public credit rating and as such used a corporate yield with a "CCC" rating by S&P Capital IQ with a term commensurate with the term of its lease as its incremental borrowing rate in determining the present value of lease payments. Lease expense is recognized on a straight-line basis over the lease term. The Company's lease arrangements do not have lease and non-lease components which are to be accounted for separately (see Note 6).

Foreign Currency

The Company's functional currency is the U.S. dollar. Monetary assets and liabilities denominated in foreign currencies are translated into U.S. dollars using exchange rates in effect at the balance sheet date. Opening balances related to non-monetary assets and liabilities are based on prior period translated amounts, and non-monetary assets acquired, and non-monetary liabilities incurred are translated at the approximate exchange rate prevailing at the date of the transaction. Revenue and expense transactions are translated at the

approximate exchange rate in effect at the time of the transaction. Foreign exchange gains and losses are included in the condensed consolidated statement of operations and comprehensive loss as foreign exchange gain (loss).

The functional currency of HMC and HCA, the Company's Canadian subsidiaries, is the CAD$ and the functional currency of HMI and HNR is the USD$. Transactions in foreign currencies are recorded into the functional currency of the relevant subsidiary at the exchange rate in effect at the date of the transaction. Any monetary assets and liabilities arising from these transactions are translated into the functional currency at exchange rates in effect at the balance sheet date or on settlement. Revenues, expenses and cash flows are translated at the weighted-average rates of exchanges for the reporting period. The resulting currency translation adjustments are not included in the Company's condensed consolidated statements of operations and comprehensive loss for the reporting period, but rather are accumulated and gains and losses are recorded in foreign exchange gain (loss), as a component of comprehensive loss, within the condensed consolidated statements of operations and comprehensive loss.

Stock-Based Compensation

The Company accounts for all stock-based payments and awards under the fair value-based method. The Company recognizes its stock-based compensation expense using the straight-line method. Compensation cost is not adjusted for estimated forfeitures, but instead is adjusted upon an actual forfeiture of a stock option.

The Company accounts for the granting of stock options to employees and non-employees using the fair value method whereby all awards are measured at fair value on the date of the grant. The fair value of all employee-related stock options is expensed over the requisite service period with a corresponding increase to additional paid-in capital. Upon exercise of stock options, the consideration paid by the option holder, together with the amount previously recognized in additional paid-in capital is recorded as an increase to common stock, while the par value of the shares received is reclassified from additional paid in capital. Stock options granted to employees are accounted for as liabilities when they contain conditions or other features that are indexed to other than a market, performance or service condition.

In accordance with ASU 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"), stock-based payments to non-employees are measured based on the fair value of the equity instrument issued. Compensation expense for non-employee stock awards is recognized over the requisite service period following the measurement of the fair value on the grant date over the vesting period of the award.

The Company uses the Black-Scholes option pricing model to calculate the fair value of stock options. The use of the Black-Scholes option pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected term of the option, risk-free interest rates, the value of the common stock and expected dividend yield of the common stock. Changes in these assumptions can materially affect the fair value estimate.

Awards of options that provide for an exercise price that is not denominated in: (a) the currency of a market in which a substantial portion of the Company's equity securities trades, (b) the currency in which the employee's pay is denominated, or (c) the Company's functional currency, are required to be classified as liabilities.

Revenue Recognition

In accordance with the FASB's ASC 606, *Revenue from Contracts with Customers* ("ASC 606"), the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to be entitled in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, it performs the following five steps:

(i) identify the contract(s) with a customer;
(ii) identify the performance obligations in the contract;
(iii) determine the transaction price;
(iv) allocate the transaction price to the performance obligations in the contract; and
(v) recognize revenue when (or as) the entity satisfies a performance obligation.

The Company applies the five-step model to contracts when it determines that it is probable it will collect substantially all of the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price, after consideration of variability and constraints, if any, that is allocated to the respective performance obligation when the performance obligation is satisfied.

Product Sales, net

Product sales are derived from the sale of the PoNS device to clinics. According to the supply agreement with each of these clinics, the Company's performance obligation was met when it delivered the PoNS device to the clinic's facility and the clinic assumed title of the PoNS device upon acceptance. As such, revenue is recognized at a point in time. Shipping and handling costs associated with outbound

freight before control of a product has been transferred to a customer is accounted for as a fulfillment cost and are included in cost of sales. The Company's payment terms are defined within each customers' supply agreement and are all 30 days or less. For the three months ended March 31, 2021, the Company recorded $77 thousand, in product sales. For the three months ended March 31,2022, the Company recorded $183 thousand in product sales. There were 16 PoNS devices, included as consideration in the Heuro acquisition, transferred during the three months ended March 31, 2022 resulting in revenue of $0.1 million being recognized which is included in the aforementioned $183 thousand in product sales for the three months ended March 31, 2022. There were no PoNS devices, included as consideration in the Heuro acquisition, transferred during the three-month period ended March 31, 2021. As of March 31, 2022, all 55 devices had been transferred. Any product returns during the three months ended March 31, 2022 were the result of warranty returns for defective products and were insignificant. Any future replacements are expected to be insignificant.

License Revenue

In connection with the Heuro acquisition, the Company entered into a Clinical Research and Co-Promotion Agreement with HTC (the "Co-Promotion Agreement"). The Co-Promotion Agreement had a fair value of CAD$360 thousand at the time of acquisition and a ten-year term. License revenue is recognized ratably over the ten-year term of the Co-Promotion Agreement as the performance obligation is met. During each of the three months ended March 31, 2022 and March 31, 2021, the Company recognized revenues of $7 thousand in license fees associated with the Co-Promotion Agreement. Revenue not yet recognized of $0.2 million is recorded as deferred revenue on the condensed consolidated balance sheet as of March 31, 2022. 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. The Company and HTC are currently discussing opportunities to work together moving forward.

As of March 31, 2022, and December 31, 2021, the Company had no contract assets or liabilities on its condensed consolidated balance sheets related to the supply agreements with each clinic.

Cost of Sales

Cost of product sales includes the cost to manufacture the PoNS device, inventory markdowns to net realizable value, royalty expenses, freight charges, customs duties, wages and salaries of employees involved in the management of the supply chain and logistics of fulfilling the Company's sales orders.

Income Taxes

The Company accounts for income taxes using the asset and liability method. The asset and liability method provide that deferred tax assets and liabilities are recognized for the expected future tax consequences of temporary differences between the financial reporting and tax bases of assets and liabilities, and for operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using the currently enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company records a valuation allowance to reduce deferred tax assets to the amount that is believed more likely than not to be realized.

The Company has adopted the provisions of ASC 740 *Income Taxes* regarding accounting for uncertainty in income taxes. The Company initially recognizes tax positions in the condensed consolidated financial statements when it is more likely than not the position will be sustained upon examination by the tax authorities. Such tax positions are initially and subsequently measured as the largest amount of the tax benefit that is greater than 50% likely of being realized upon ultimate settlement with the tax authority, assuming full knowledge of the position and all relevant facts. Application requires numerous estimates based on available information. The Company considers many factors when evaluating and estimating its tax positions and tax benefits. These periodic adjustments may have a material impact on the condensed consolidated statements of operations and comprehensive loss. When applicable, the Company classifies penalties and interest associated with uncertain tax positions as a component of income tax expense in its condensed consolidated statements of operations and comprehensive loss.

Research and Development Expenses

Research and development ("R&D") expenses consist primarily of personnel costs, including salaries, benefits and stock-based compensation, clinical studies performed by contract research organizations, development and manufacturing of clinical trial devices and devices for manufacturing testing and materials and supplies as well as regulatory costs related to post market surveillance, quality assurance complaint handling and adverse event reporting. R&D costs are charged to operations when they are incurred.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company operates and manages its business within one operating and reportable segment. Accordingly, the Company reports the accompanying condensed consolidated financial statements in the aggregate in one reportable segment.

Fair Value Measurements

The Company accounts for financial instruments in accordance with ASC 820, *Fair Value Measurements and Disclosures* ("ASC 820"). ASC 820 establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy under ASC 820 are described below:

Level 1 – Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

Level 2 – Quoted prices in markets that are not active or financial instruments for which all significant inputs are observable, either directly or indirectly; and

Level 3 – Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

The Company's financial instruments recorded in its condensed consolidated balance sheets consist primarily of cash, accounts receivable, other current receivables, operating lease ROU asset, accounts payable, accrued liabilities, and operating lease liability. The book values of these instruments, with the exception of non-current lease liability and operating lease ROU asset approximate their fair values due to the immediate or short-term nature of these instruments.

There were no transfers between any levels for any of the periods presented.

In addition to assets and liabilities that are recorded at fair value on a recurring basis, the Company's assets and liabilities are also subject to nonrecurring fair value measurements. Generally, assets are recorded at fair value on a nonrecurring basis as a result of impairment charges.

Basic and Diluted Net Loss per Share

Earnings or loss per share ("EPS") is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted EPS is computed by dividing net loss by the weighted average of all potentially dilutive shares of common stock that were outstanding during the periods presented.

The treasury stock method is used in calculating diluted EPS for potentially dilutive stock options and share purchase warrants, which assumes that any proceeds received from the exercise of in-the-money stock options and share purchase warrants, would be used to purchase common shares at the average market price for the period, unless including the effects of these potentially dilutive securities would be anti-dilutive.

The basic and diluted loss per share for the periods noted below is as follows (amounts in thousands except shares and per share data):

	Three Months Ended March 31,	
	2022	2021
Basic and Diluted		
Numerator:		
Net loss	$ (4,346)	$ (3,362)
Denominator:		
Weighted average common shares outstanding	3,787,871	2,040,839
Basic and diluted net loss per share	**$ (1.15)**	**$ (1.65)**

No incremental common stock equivalents, consisting of outstanding stock options, warrants and restricted stock units, were included in calculating diluted loss per share because such inclusion would be anti-dilutive due to the Company's losses for the three months ended March 31, 2022 and 2021. Common stock equivalents excluded from the computation of diluted weighted average shares outstanding were 1,379,927 and 812,173 for the three months ended March 31, 2022 and the three months ended March 31, 2021, respectively.

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.

3. COMMON STOCK AND WARRANTS

The Company's authorized capital stock pursuant to its Delaware charter consists of 150,000,000 authorized shares of Class A common stock, at a par value per share of $0.001 and 10,000,000 authorized shares of preferred stock at a par value per share of $0.001. Holders of common stock are entitled to vote at any meeting of the Company's stockholders on the basis of one vote per share of common stock owned as of the record date of such meeting. Each share of common stock entitles the holder to receive dividends, if any, as declared by the Company's Board of Directors. No dividends have been declared since inception of the Company through March 31, 2022. In the event of a liquidation, dissolution or winding-up of the Company, other distribution of assets of the Company among its stockholders for the purposes of winding-up its affairs or upon a reduction of capital, the stockholders shall, share equally, share for share, in the remaining assets and property of the Company.

March 2020 Offering

On March 20, 2020, the Company, in a registered direct offering, issued an aggregate of 178,776 shares of its common stock at a price of $12.25 per share for gross proceeds of approximately $2.2 million. Additionally, the Company issued unregistered warrants in a concurrent private placement to purchase up to 178,776 shares of its common stock at an exercise price of $16.10 per share. The underwriting discounts and commissions and offering expenses of $0.3 million were recorded to share issuance costs. As of March 31, 2022, 81,633 warrants had been exercised all during the first quarter of 2021, for gross proceeds of $1.3 million.

October 2020 Offering

On October 26, 2020, the Company issued units consisting of one share and a warrant to purchase 0.50 shares of common stock, with an aggregate issuance of 187,646 shares of common stock and warrants to purchase an aggregate of 93,817 shares of common stock at a purchase price of $18.20 per unit, resulting in gross proceeds of approximately $3.4 million, excluding the proceeds, if any, that the Company may receive in the future from the exercise of the warrants (the "October 2020 Offering"). The Company incurred $0.3 million in share issuance costs, including placement agent fees. The warrants have an initial exercise price of $15.82 per share and are exercisable for a period of three years from the date of issuance. The Company also issued warrants to the placement agent to purchase 961 shares of common stock, with an exercise price of $19.775 per share. An officer of the Company and affiliates of an officer and director of the Company participated in the October 2020 Offering on the same terms and conditions as all other purchasers, except that they paid $18.354 per unit and their warrants have an exercise price of $16.1665 per share.

February 2021 Offering

On February 1, 2021, in an underwritten public offering (the "February 2021 Offering"), the Company issued 744,936 shares of common stock and warrants to purchase up to an aggregate of 372,468 shares of common stock at a purchase price of $14.82 per unit, consisting of one share and a warrant to purchase 0.50 shares of common stock. The warrants have an initial exercise price of $16.302 per share and are exercisable for a period of five years from the date of issuance. The Company also issued warrants to the underwriter to purchase 29,797 shares of common stock, with an exercise price of $18.525 per share. Net proceeds from the February 2021 Offering after underwriter's discounts and commission and offering expenses paid by us were approximately $9.6 million. Affiliates of an officer and director participated in the February 2021 Offering on the same terms and conditions as all other purchasers.

The relative fair value of these warrants at issuance was approximately $2.6 million and was included in additional paid-in capital. As of March 31, 2022, 262 warrants had been exercised, all during the second quarter of 2021, for gross proceeds of $4 thousand.

Lincoln Park Purchase Agreement

On September 1, 2021, the Company entered into a purchase agreement (the "LPC Purchase Agreement") and a registration rights agreement with Lincoln Park. The LPC Purchase Agreement provides that, subject to the terms and conditions therein, the Company has the right, but not the obligation, to sell from time to time, at its sole discretion, to Lincoln Park up to $15.0 million of shares of its common stock over a 36-month period commencing on September 15, 2021. In addition, under the LPC Purchase Agreement, during the third quarter of 2021, the Company issued 31,958 shares of common stock to Lincoln Park as consideration for Lincoln Park's commitment to purchase shares of the Company's common stock. The $0.5 million fair value of the commitment fee shares was recorded as share issuance costs as of September 30, 2021.

Lincoln Park has no right to require the Company to sell any shares of common stock to Lincoln Park, but Lincoln Park is obligated to make purchases as the Company directs, subject to certain conditions.

Actual sales of common stock to Lincoln Park will depend on a variety of factors to be determined by the Company from time to time, including, among others, market conditions, the trading price of the common stock and determinations by the Company as to the appropriate sources of funding for the Company and its operations. The net proceeds under the LPC Purchase Agreement to the Company will depend on the frequency and prices at which the Company sells shares of its common stock to Lincoln Park.

No shares were sold under the LPC Purchase Agreement during the first quarter of 2022 and approximately $14.4 million remained available for sale under the agreement at March 31,2022.

November 2021 Offering

On November 12, 2021, in an underwritten public offering (the "November 2021 Offering"), the Company issued 1,385,031 shares of common stock at a purchase price of $8.00 per share. Net proceeds from the November 2021 Offering after underwriter's discounts and commission and offering expenses paid by us were approximately $9.9 million. Affiliates of an officer and director participated in the November 2021 Offering on the same terms and conditions as all other purchasers.

Warrants

The following is a summary of the Company's warrant activity during the three months ended March 31, 2022:

	Number of Warrants	Weighted-Average Exercise Price
Outstanding as of December 31, 2021	**593,924**	**$ 16.32**
Granted	—	—
Cancelled/Expired	—	—
Exercised	—	—
Outstanding as of March 31, 2022	**593,924**	**$ 16.32**

The Company's warrants outstanding and exercisable as of March 31, 2022 were as follows:

Number of Warrants Outstanding	Exercise Price	Expiration Date
97,143	USD$16.10	March 20, 2025
17,431	USD$16.1665	October 26, 2023
76,386	USD$15.82	October 26, 2023
961	USD$19.775	October 26, 2023
372,206	USD$16.302	February 1, 2026
29,797	USD$18.525	February 1, 2026
593,924		

4. STOCK-BASED PAYMENTS

2018 Omnibus Incentive Plan

On May 15, 2018, the Company's Board of Directors authorized and approved the adoption of the 2018 Omnibus Incentive Plan, (as amended, the "2018 Plan"), which was effective upon approval by the stockholders of the Company on June 28, 2018 and under which an aggregate of 153,031 shares of common stock could be issued. This share reserve was the sum of 85,714 new shares, plus the 67,317 shares that remained available for issuance at the time of approval under the Company's 2016 Omnibus Incentive Plan (the "2016 Plan"), the predecessor incentive plan at the time of the adoption of the 2018 Plan. On April 20, 2021, the Company's Board of Directors authorized and approved an amendment, which was effective upon approval by the stockholders of the Company on May 25, 2021,

authorizing an additional 565,000 shares of common stock to be issued under the 2018 Plan. Pursuant to the terms of the 2018 Plan, the Company is authorized to grant stock options, as well as awards of stock appreciation rights, restricted stock, unrestricted shares, restricted stock units ("RSUs"), stock equivalent units and performance-based cash awards. These awards may be granted to directors, officers, employees and eligible consultants. Vesting and the term of an option is determined at the discretion of the Company's Board of Directors. Subsequent to the adoption of the 2018 Plan, the Company ceased granting awards under the 2016 Plan, the predecessor incentive plan. However, outstanding stock options granted prior to the effective date of the 2018 Plan are still governed by the 2016 Plan or the Company's 2014 Stock Incentive Plan, which preceded the 2016 Plan.

As of March 31, 2022, there was an aggregate of 8,595 shares of common stock remaining available for grant under the 2018 Plan.

2021 Inducement Plan

On July 2, 2021, the Company adopted the Helius Medical Technologies, Inc. 2021 Inducement Plan (the "Inducement Plan"), pursuant to which the Company reserved 100,000 shares of its common stock to be used exclusively for grants of awards to individuals who were not previously employees or directors of the Company, as an inducement material to the individuals' entry into employment with the Company within the meaning of Rule 5635(c)(4) of the Nasdaq Listing Rules. The Inducement Plan was approved by the Company's Board of Directors without stockholder approval pursuant to Rule 5635(c)(4) of the Nasdaq Listing Rules.

The Inducement Plan permits the grant of non-statutory stock options, stock appreciation rights, restricted stock, restricted stock units, performance stock and cash awards, and other share-based awards.

As of March 31, 2022, there was an aggregate of 52,000 shares of common stock remaining available for grant under the Company's Inducement Plan.

Stock Options

For the three months ended March 31, 2022, the Company issued 123,750 stock options to employees and directors of which none were forfeited. The Company issued no stock options to consultants during the three months ended March 31, 2022.

The following is a summary of the Company's stock option activity during the three months ended March 31, 2022:

	Number of Stock Options	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2021	**669,117**	**9.03**	**$ 37.36**	**$ —**
Granted	123,750		4.68	—
Forfeited/Cancelled	(7,639)		82.37	—
Exercised	—		—	—
Outstanding as of March 31, 2022	**785,228**	**8.96**	**$ 31.77**	**$ —**
Exercisable as of March 31, 2022	**301,630**	**8.34**	**$ 60.64**	**$ —**

Employee and Director Stock Options

As of March 31, 2022, the unrecognized compensation cost related to non-vested time-based stock options outstanding for employees and directors, was $2.9 million which will be recognized over a weighted-average remaining vesting period of approximately 3.0 years. As of March 31, 2022, the unrecognized compensation cost related to performance-based stock options for employees 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 a stock option.

The weighted average grant date fair value of employee and director stock options granted for the three months ended March 31, 2022 was $ 3.01 per option and the grant date fair values of these stock options were estimated using the Black-Scholes option pricing model using the following weighted average assumptions:

	Three Months Ended March 31, 2022
Stock price	$ 4.68
Exercise price	$ 4.68
Expected term	5.75
Expected volatility	73.53%
Risk-free interest rate	1.95%
Dividend rate	0.00%

Consultant Stock Options

As of March 31, 2022, the unrecognized compensation cost related to non-vested stock options outstanding for non-employees was $ 7 thousand which will be recognized over a weighted-average remaining vesting period of approximately 0.6 years. Compensation cost is not adjusted for estimated forfeitures, but instead is adjusted upon an actual forfeiture of a stock option.

Restricted Stock Units

During the second quarter ended June 30, 2021, the Company granted 6,343 RSUs to the Company's Board of Directors pursuant to the Non-Employee Director Compensation Policy which will vest in twelve monthly installments on the last day of each month. The fair value of the RSUs is based on the closing price of the Company's common stock on the Nasdaq Capital Market on the day of the grant.

The following is a summary of the Company's RSU award activity for the three months ended March 31, 2022:

	Number of RSUs	Weighted Average Grant Date Fair Value per Unit
Outstanding as of December 31, 2021	2,359	$ 15.76
Granted	—	—
Forfeited	—	—
Settled	(1,584)	15.89
Outstanding as of March 31, 2022	775	$ 15.53

Unrestricted Stock

On February 16, 2022, the Company granted 8,011 shares of unrestricted common stock valued at $34 thousand to an officer of the Company under the 2018 Plan and have been recorded as stock based compensation expense.

During the three months ended March 31, 2022, the Company granted 4,258 shares of unrestricted common stock to a consultant of the Company under the 2018 plan.

Stock-Based Compensation Expense

Stock-based compensation expense is classified in the Company's condensed consolidated statements of operations and comprehensive loss as follows (amounts in thousands):

	Three Months Ended March 31,	
	2022	2021
Research and development	$ 153	$ 222
Cost of sales	3	—
Selling, general and administrative	212	305
Total	**$ 368**	**$ 527**

5. ACCRUED EXPENSES

Accrued expenses consisted of the following (amounts in thousands):

	As of	
	March 31, 2022	December 31, 2021
Employees benefits	$ 378	$ 712
Professional services	123	174
Legal fees	72	23
Royalty fees	17	10
Franchise fees	50	193
Severance	147	258
Other	221	63
Total	**$ 1,008**	**$ 1,433**

6. COMMITMENTS AND CONTINGENCIES

(a) On January 22, 2013, the Company entered into a license agreement with Advanced NeuroRehabilitation, LLC ("ANR") for an exclusive right to ANR's patent pending technology, claims and knowhow. In addition to the issuance of 91,628 shares of common stock to ANR, the Company agreed to pay a 4% royalty on net revenue on the sales of devices covered by the patent-pending technology and services related to the therapy or use of devices covered by the patent-pending technology. For the three months ended March 31, 2022, the Company recorded approximately $7 thousand, in royalty expenses in its condensed consolidated statement of operations and comprehensive loss. For the three months ended March 31, 2021, the Company recorded approximately $3 thousand, in royalty expenses in its condensed consolidated statement of operations and comprehensive loss.

(b) In November 2021, the Company entered into a new lease (the "Lease Agreement") for 1,780 square feet of dedicated office space to serve as the Company's headquarters in Newtown, Pennsylvania. The term for the lease is from January 1, 2022 through March 31, 2025. Monthly rent plus utilities is approximately $4 thousand per month with a 3% annual increase. There is no option to extend. On February 1, 2022, the Company entered into a new lease for 750 square feet of dedicated office space in Ewing, New Jersey. The term for the lease is from February 1, 2022 through January 31, 2024. Monthly rent plus utilities is $985 per month for the first year increasing to $1,015 per month beginning February 1, 2023. There is no option to extend.

The following table summarizes the Company's operating lease information including future minimum lease payments under a non-cancellable lease as of March 31, 2022 (amounts in thousands).

For the Three Months Ended March 31, 2022		
Operating lease cost	$	—
Operating lease - operating cash flows	$	3.00
Weighted average remaining lease term		3.0 years
Weighted average discount rate		4.4%
Future minimum lease payments under non-cancellable leases as of March 31, 2022 were as follows:		
For the Period Ending December 31,		
2022 (remaining nine months)	$	42.00
2023		58
2024		48
2025		12
Total future minimum lease payments		**160**
Less imputed interest		(10)
Total liability	**$**	**150**
Reported as of March 31, 2022		
Current operating lease liability	$	51.00
Non-current operating lease liability		99
Total	**$**	**150**

(c) On December 29, 2017, HMI (formerly known as NeuroHabilitation Corporation) entered into a Manufacturing and Supply Agreement ("MSA") with KeyTronic Corporation ("KeyTronic"), for the manufacture and supply of the Company's PoNS device based upon the Company's product specifications as set forth in the MSA. Per the agreement, the Company shall provide to KeyTronic a rolling forecast for the procurement of parts and material and within normal lead times based on estimated delivery

dates for the manufacture of the PoNS device. The term of the agreement is for three years and will automatically renew for additional consecutive terms of one year, unless cancelled by either party upon 180-day written notice to the other party prior to the end of the then current term. On June 1, 2020, HMI extended the existing manufacturing agreement with KeyTronic for a second three year term from December 29, 2020 until December 31, 2023. As of March 31, 2022, the Company did not have any outstanding commitments to KeyTronic to complete the Company's forecasts for the procurement of materials necessary for the delivery of PoNS devices.

7. RELATED PARTY TRANSACTIONS

Affiliates of an officer and director participated in the February 2021 Offering and the November 2021 Offering on the same terms and conditions as all other purchasers.

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 the 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, or our 2021 Annual Report. 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 to complete pre-commercialization activities, 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, including our ability to fully access our equity line with Lincoln Park, 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 Annual Report 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.

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 the first quarter of 2022 and our first commercial sales began 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

The Company began accepting prescriptions for PoNS in the U.S. in the first quarter of 2022, and the first commercial sales began in April.

Regulatory Status Worldwide

Canadian Regulatory Status: mmTBI and MS

On October 17, 2018, we received our Canadian marketing authorization from Health Canada allowing us to commercialize the PoNS device in Canada for use as a short-term treatment (14 weeks) of balance deficit due to mmTBI.

On March 18, 2020, we received marketing authorization from Health Canada allowing us to commercialize the PoNS device in Canada for the treatment of gait deficit in patients with mild and moderate MS symptoms. Our market authorization application comprised objective statistical evidence as well as independently reviewed clinical research analysis. This label expansion expanded our addressable market in Canada to include a patient population seeking treatment options that may resolve or delay the progression of MS gait deficit symptoms.

US Regulatory Status: MS

On May 7, 2020, we received Breakthrough Designation for the PoNS device as a potential treatment for gait deficit due to symptoms of MS, to be used as an adjunct to a supervised therapeutic exercise program. The goal of the Breakthrough Devices Program is to provide patients and health care providers with timely access to these medical devices by speeding up their development, assessment, and review, while preserving the statutory standards for premarket approval, 510(k) clearance, and de novo classification and clearance, consistent with the FDA's mission to protect and promote public health.

On March 26, 2021, we received marketing authorization from the FDA of the PoNS device. The PoNS device is indicated for use as a short term treatment of gait deficit due to mild-to-moderate symptoms of 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.

On January 14, 2021, the Centers for Medicare & Medicaid Services, or CMS, issued the final rule (CMS-3372-F), 42 C.F.R. § 405.603 on the new Medicare coverage pathway referred to as Medicare Coverage of Innovative Technology, or MCIT, for FDA-designated breakthrough medical devices. The MCIT rule will provide national Medicare coverage as early as the same day as FDA market authorization for breakthrough devices and coverage would last for four years. To be eligible for coverage through MCIT, the breakthrough device must be used for the FDA approved or cleared indication(s) for use. Manufacturers will be able to opt in to MCIT and choose a start date for coverage anytime within two years from the date of FDA market authorization, but coverage will only be valid for four years from market authorization regardless of opt in date. At the end of the four year period, manufacturers are expected to have obtained coding for the specific product which can then be used as the reimbursement pathway for commercial payers. CMS announced MCIT was delayed from becoming effective March 15, 2021 to May 15, 2021 with an additional comment period during that time. On May 14, 2021, CMS announced it further delayed the effective date of the final rule until December 15, 2021 to provide CMS an opportunity to determine appropriate next steps. On September 15, 2021, CMS published a proposal that would repeal the MCIT pathway. Following a 30-day comment period included in the proposal, CMS announced on November 12, 2021 that it was repealing MCIT to address concerns that the provisions in the final rule may have not been sufficient to protect Medicare patients. CMS is expected to issue rules regarding coverage of emerging technologies; however, no specific information is available about the content of the expected rules and we cannot provide any assurance that any new rules regarding emerging technologies would be applicable to us. While we will continue to monitor this, we also remain focused on building out our reimbursement strategy for both commercial and government payers. We are still working to understand current Medicare requirements and policies for coverage, coding, and payment of durable medical equipment and assess how the PoNS device may be treated with respect to coding, coverage, and reimbursement under the Medicare program.

In September 2021, we started activities to setup and implement a new study as part of a Therapeutic Experience Program, or TEP, with NYU Langone Health as our first Center of Excellence clinical site. The TEP is a Helius-sponsored, open label observations, interventional multi-center outcome research trial designed to assess adherence to on-label PoNS therapy for improvement in gait deficits with MS in a real-world clinical setting. The study will measure subjects' adherence to PoNS therapy, which combines the PoNS device with physical therapy, to better understand the relationship between adherence to the treatment regimen and therapeutic functional outcome. The primary endpoint of the study is maintenance of gait improvement from the end of supervised therapy (Phase 1) to the end of unsupervised therapy (Phase 2) in relation to the subject's adherence to PoNS therapy. The secondary endpoints are improvement of gait and balance deficit over time, and clinical global impression of change. The study will be conducted at ten to twelve Centers of Excellence across the U.S., with an estimated average of four PoNS devices per site. Enrollment is expected to commence in first half of 2022 and continue throughout the year. Approximately forty to fifty patients with MS are expected to participate in the study.

US Regulatory Status: Stroke

In August 2021, we received Breakthrough Designation for the PoNS™ device as a potential treatment for dynamic gait and balance deficits due to symptoms from stroke, to be used as an adjunct to a supervised therapeutic exercise program in patients 22 years of age and over. With Breakthrough Designation received, a clinical trial of PoNS therapy in stroke patients in collaboration with the Medical University of South Carolina is planned to commence in the second half of 2022 with initial patient enrollments beginning late in the second half of 2022.

US Regulatory Status: mmTBI

Our U.S. regulatory strategy initially focused on pursuing de novo classification and clearance of the PoNS device from the FDA for the treatment of balance deficit due to mmTBI.

We submitted a request for de novo classification and clearance of the PoNS device to the FDA for this indication in August 2018. This request was supported by data from two of our clinical trials in mmTBI, including our registrational trial, TBI-001.

In April 2019, we announced that the FDA had completed its review and had denied our request for de novo classification and clearance of the PoNS device for the treatment of balance deficit due to mmTBI. In reaching its conclusion, the FDA noted, via a denial letter, that although the safety profile of the PoNS device is acceptable, the FDA did not have sufficient information to discern the relative independent contributions of the PoNS device and physical therapy on the improvements from baseline. The FDA noted that we could generate additional data to address its concerns and resubmit our application.

In October 2019, we had a pre-submission meeting where the FDA provided feedback needed to help complete the design of a new clinical trial intended to address the FDA's request for a trial that demonstrates the benefit of the PoNS Therapy compared to physical therapy alone. In January 2020, we received the FDA's feedback on the minutes from the October 2019 pre-submission meeting. In its feedback, the FDA provided post-meeting notes with specific recommendations regarding the trial design that were not discussed in the October 2019 pre-submission meeting.

Based on the receipt of the FDA's final minutes from the pre-submission meeting, we are assessing the feasibility of a clinical program to advance the development of a study aimed to obtain clearance for gait and balance deficits in mmTBI if nondilutive financing to fund the program becomes available.

European Regulatory Status

In December 2018, we submitted an application for a CE Mark, which, if approved, would allow us to market the PoNS device in the EU. During the second quarter of 2019, we engaged with regulators in Europe to answer questions that we received from them as part of their review of our PoNS device for CE marking. In August 2019, we withdrew our application from the EU marketing process due to uncertainty in Europe caused by the switch from the Medical Device Directive, or MDD, to the Medical Device Regulation, or MDR, Brexit, and the withdrawal of Lloyd's Register Quality Assurance, our notified body, from the EU notified body business. We have engaged G-MED NA (North America) as our new ISO registrar and will reconsider submitting to the EU when conditions stabilize.

Australian Regulatory Status

In the third quarter of 2019, we initiated the submission of our application to the Therapeutic Goods Administration, or TGA. We supplemented our submission with additional data based on questions supplied to date and provided responses to additional questions during the third quarter of 2020. In November 2021, we received market authorization from the TGA for the sale of PoNS as a Class IIa medical device. In Australia, PoNS is intended for short term use by healthcare professionals as an adjunct to a therapeutic exercise program to improve balance and gait. PoNS is not intended to be used alone without an exercise program. We are working to establish a distribution partner for Australia but currently do not expect to have commercial sales of PoNS in Australia in 2022.

Canadian Commercialization Activities

In March 2019, we commenced the commercialization of our PoNS Therapy in Canada, where PoNS became the first and only device authorized by Health Canada for the treatment of balance deficit due to mmTBI. Throughout 2019, we made important progress in advancing and refining our commercialization strategy in Canada building access, awareness and credibility for the PoNS Therapy, including the acquisition of the Heuro Canada operating entity of HTC. These efforts, which were led by our local Canadian commercial team, included the establishment of our authorized clinic network throughout Canada, launching digital marketing campaigns, and building key opinion leader and advocacy networks.

On March 18, 2020, the Company received notification that its Canadian Class II license amendment application for the treatment of gait deficit in patients with mild and moderate symptoms from MS, when used in conjunction with physical therapy, was successful and received marketing authorization for PoNS from Health Canada.

Following in-depth market analysis and field intelligence, our Canadian commercial team began an expansion plan to increase the number of authorized PoNS clinics. During the year ended December 31, 2021, we authorized 6 new clinical locations to have 37 clinic

locations as of December 31, 2021. As of March 31, 2022, we have 41 authorized PoNS clinic locations across Canada. In addition to continuing to increase the number of clinic locations, we have shifted our focus to driving patient throughput to these clinics. Sales performance in Canada continues to be impacted by the COVID-19 pandemic due to space restrictions that the provincial governments have imposed as well as the risk tolerance of patients and therapists.

In collaboration with Toronto Rehabilitation Institute (part of University Health Network), we are continuing our clinical experience program, the results of which we will look to publish in 2022.

We continue to refine our go-to-market pricing model. In 2020, we implemented a modified pricing approach which is focused on reducing the need for clinics and patients to pay large, upfront costs at the start of treatment. We have also experimented with various promotional pricing programs resulting in lower unit prices for both PoNS system purchases and mouthpieces in order to increase access to the PoNS Therapy and drive market awareness which we believe resulted in an increase in the volume of units sold, beginning in the second half of 2020. We extended the promotional pricing through the end of 2021 including any order placed and accepted, but not fulfilled before December 31, 2021. The promotional pricing was discontinued in 2022 when new pricing was established.

The value dossiers for mmTBI and MS that were created in mid-2020 to fully demonstrate in both scientific and financial terms, the merits of PoNS Therapy for claimants are now being utilized along with submissions from clinics on behalf of their patients. The dossiers are provided to our clinics across Canada to submit as part of treatment plans with reimbursement applications to the payer community. Our reimbursement strategy for mmTBI is focused initially on the auto collision insurance and workers' compensation, or WC, market as well as long-term disability cases. Our reimbursement strategy for MS is focused on commercial insurers/extended health benefits.

As part of our overall PoNS Therapy strategy, we are also gathering comprehensive health economic assessments of treatment outcomes. These data will, in-turn, be used to support our applications for WC, auto insurance and commercial insurance reimbursement initiatives in Canada, the U.S. and other markets around the world. We believe the Canadian commercial experience will be extremely valuable to prepare us for our launches in the U.S. and internationally.

The real-world results from the collective experience of our patients that have completed the 14-week PoNS Therapy, in Canada thus far, have been encouraging. Consistent with what we observed in our two clinical trials, one for 5 weeks and the other for 14 weeks, commercial MS and mmTBI patients demonstrated improvements in balance and gait within the first two weeks followed by continued improvement over the following twelve weeks. The majority of patients had a mean patient adherence to treatment of over 90% and showed significant improvement in their balance and gait with a meaningful clinical difference at the end of their treatment. The consistency of the patient results from our initial commercial experience supports our plans to expand access PoNS Therapy in Canada.

U.S. Commercialization Activities

As previously stated, on March 26, 2021, we received marketing authorization from the FDA for the PoNS device. The PoNS device is indicated for use as a short-term treatment of gait deficit due to mild-to-moderate symptoms of 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.

Throughout the pre-commercial phase during 2021, we developed and refined our commercial strategy including a focus on payer strategy, both government and commercial, securing distribution licenses in various states and beginning to build relationships with key large neurorehabilitation centers, which focus on treatment of MS patients. We continue to generate data on outcomes of the PoNS Therapy generated from treatment of patients in Canada and ensuring that our scientific data is presented at many of the key national and international neurology and neuromodulation meetings. We believe this scientific dissemination may begin to pave the way to establishing the PoNS Therapy as the standard of care for the treatment of MS-related gait deficit.

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. We have targeted specific Key Opinion Leaders (i.e. neurologists and physiatrists) and their associated neurorehabilitation centers, where selected physical therapists will be trained to deliver the PoNS Therapy. To further develop and implement the PoNS commercialization strategy, we have hired a Vice President of Sales and Marketing, North America, have identified the initial launch areas within the U.S., and we have and expect to continue to build out our commercial team, including field sales, reimbursement specialists, and marketing and operational support commensurate with PoNS sales activity.

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 $25,000, 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.

Share Purchase Agreement and Co-Promotion Agreement

On October 30, 2019, we and HTC entered into a Share Purchase Agreement, or the SPA, whereby we, through our wholly owned subsidiary, acquired Heuro from HTC. Under the terms of the SPA, total consideration of approximately $1.6 million was transferred to HTC, which included (1) the repayment to HTC for their investment in the set-up of Heuro's initial commercial infrastructure including, the establishment of five authorized PoNS clinics across Canada, (2) the current market value of 55 PoNS devices which we also provided to HTC under the SPA, (3) the forgiveness of the CAD$750,000 receivable from the September 2018 strategic alliance agreement and (4) the exclusivity rights granted to HTC in the Co-Promotion Agreement, as defined below, to provide PoNS Treatment in the Fraser Valley and Vancouver metro regions of British Columbia.

In connection with the Share Purchase Agreement, on October 30, 2019, we entered into a Clinical Research and Co-Promotion Agreement with HTC, or the Co-Promotion Agreement, whereby each company agreed to promote the sales of the PoNS Treatment and the NeuroCatch™ device throughout Canada. The co-promotion provisions within the Co-Promotion Agreement terminated on December 31, 2020, although the Co-Promotion Agreement remains in effect. Also, 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.

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.

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 March 31, 2022 compared to the Three Months Ended March 31, 2021

The following table summarizes our results of operations for the three months ended March 31, 2022 and 2021 (amounts in thousands):

	Three Months Ended March 31,		
	2022	2021	Change
Revenue:			
Product sales	$ 183	$ 77	$ 106
License revenue	7	7	—
Total operating revenue	**190**	**84**	**106**
Cost of sales:			
Cost of product sales	124	15	109
Gross profit	**66**	**69**	**(3)**
Operating expenses:			
Research and development	1,764	1,316	448
Selling, general and administrative	2,819	2,197	622
Amortization expense	47	57	(10)
Total operating expenses	**4,630**	**3,570**	**1,060**
Operating loss	**(4,564)**	**(3,501)**	**(1,063)**
Other income:			
Other income	1	—	1
Foreign exchange gain	217	139	78
Total other income	**218**	**139**	**79**
Net loss	**$ (4,346)**	**$ (3,362)**	**$ (984)**

Revenue

For the three months ended March 31, 2022, we recognized revenue of $190 thousand, of which $183 thousand was generated through product sales of our PoNS device in Canada pursuant to our executed supply agreements with neuroplasticity clinics in Canada and included approximately $120 thousand of PoNS devices delivered pursuant to the Co-Promotion Agreement with HTC. We recognized revenue of $77 thousand for the three months ended March 31, 2021, through product sales of our PoNS device in Canada pursuant to our executed supply agreements with neuroplasticity clinics in Canada. License fee revenue related to our C-Promotion Agreement with HTC was $7 thousand for the three months ended March 31, 2022, and March 31, 2021 respectively.

Cost of Sales

Cost of product sales includes the cost to manufacture the PoNS device, royalty expense, freight charges, customs duties as well as wages and salaries of employees involved in the management of the supply chain and logistics of fulfilling our sales orders. For the three months ended March 31, 2022, we incurred $124 thousand in cost of sales. For the three months ended March 31, 2021, we

incurred $15 thousand in cost of sales. The increase was primarily attributable to overhead costs including wages and salaries of employees and contractors involved in the management of the supply chain and the production ramp to meet anticipated demand related to the U.S. launch.

Research and Development Expense

Research and development, or R&D, expenses were $1.8 million for the three months ended March 31, 2022 compared to $1.3 million for the three months ended March 31, 2021, an increase of $0.5 million. The increase was primarily attributable to cost related to on-going product improvement in the PoNS device and increased personnel expenses to support clinical development activities.

Selling, General and Administrative Expense

Selling, general and administrative, or SG&A, expenses were $2.8 million for the three months ended March 31, 2022 compared to $2.2 million for the three months ended March 31, 2021, an increase of approximately $0.6 million. The increase was primarily due to increased compensation expenses related to personnel additions in late 2021 and the first quarter 2022 to support 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 on October 30, 2019 and internally developed software. For the three months ended March 31, 2022, amortization expense was $47 thousand compared to $57 thousand for the comparable period in 2021.

Foreign Exchange Gain

Foreign exchange gain was $0.2million for the three months ended March 31, 2022, compared to a gain of $0.1 million for the three months ended March 31, 2021. This was primarily due to fluctuations in the foreign exchange rate as it relates to the amount of Canadian dollars held at the end of each reporting period.

Statement of Cash Flows

The following table summarizes our cash flows for the three months ended March 31, 2022, and 2021 (amounts in thousands):

	Three Months Ended March 31,		
	2022	2021	Change
Net cash used in operating activities	$ (4,682)	$ (2,921)	$ (1,761)
Net cash provided by (used in) investing activities	4	(21)	25
Net cash (used in) provided by financing activities	(17)	11,020	(11,037)
Effect of exchange rate changes on cash	—	(12)	12
Net (decrease) increase in cash	$ (4,695)	$ 8,066	$ (12,761)

Net Cash Used in Operating Activities

Net cash used in operating activities during the three months ended March 31, 2022 was $4.7 million. This was comprised primarily of net loss of $4.3 million, the reduction of accrued liabilities for annual bonus payments and the reduction for deferred revenue related to product sales in the first quarter 2022, offset by $0.4 million of stock-based compensation payments and unrealized foreign exchange gain of $0.2 million.

Net cash used in operating activities during the three months ended March 31, 2021 was $2.9 million. This was comprised of net loss of $3.4 million, offset primarily by $0.5 million of stock-based compensation payments.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was $4 thousand for the three months ended March 31, 2022 compared to net cash used in investing activities of $21 thousand during the three months ended March 31, 2021 and were primarily related to the sales and purchase of furniture and equipment in each of the respective periods.

Net Cash (Used in) Provided by Financing Activities

Net cash used in financing activities was $17 thousand during the three months ended March 31, 2022 for payment of issuance costs for common stock issued in November 2021.

Net cash provided by financing activities during the three months ended March 31, 2021 was $11.0 million, which consisted of proceeds from the issuance of common stock from the February 2021 Offering, net of share issuance costs, and proceeds from the exercise of warrants.

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 major sources of cash have been proceeds from various public and private offerings of our common stock and exercises of stock options and warrants. From June 2014 through March 31, 2022, we raised approximately $130.6 million in gross proceeds from various public and private offerings of our common stock as well as the exercise 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 March 31, 2022 and December 31, 2021 (amounts in thousands):

	March 31, 2022	December 31, 2021
Cash	$ 6,310	$ 11,005
Working capital	$ 5,827	$ 9,941

Cash Requirements

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 $4.3 million and $3.4 million for the three months ended March 31, 2022 and 2021, respectively. As of March 31, 2022, we had an accumulated deficit of $141.4 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 will be sufficient to fund our operations into the third quarter of 2022, 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.

Contractual and Other Obligations

We have entered into arrangements that contractually obligate us to make payments that will affect our liquidity and cash flows in future periods. Such arrangements include those related to our lease commitments.

Lease Commitments

Our cash requirements greater than twelve months from various contractual obligations and commitments include operating lease liabilities. Our lease commitments reflect payments due for our lease arrangement for office space at our head office located in Newtown, Pennsylvania. As of March 31, 2022, our contractual commitment for our leases was $0.2 million. The amount of lease commitments reflects payments due for the new lease in Newtown, Pennsylvania that commenced on January 1, 2022 and is contracted to terminate on March 31, 2025 as well as the lease in Ewing, New Jersey that commenced on February 1, 2022 and is contracted to terminate on January 31, 2024. See Note 6 “Commitments and Contingencies” to our unaudited condensed consolidated financial statements under Part I, Item 1, “Condensed Consolidated Financial Statements” in this this Quarterly Report on Form 10-Q.

Other Obligations

We enter into contracts in the normal course of business with various third parties for clinical trials, testing and manufacturing, and other services and products for operating purposes. These contracts provide for termination upon notice. Payments due upon cancellation generally consist only of payments for services provided or expenses incurred, including non-cancellable obligations of our service

providers, up to the date of cancellation. These payments have not been separately included within these contractual and other obligations disclosures.

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 Annual Report. There have been no changes in critical accounting policies in the current year from those described in our 2021 Annual Report.

Recently Issued Accounting Pronouncements

The information set forth in Note 2 "Summary of Significant Accounting Policies" to our unaudited condensed consolidated financial statements under Part I, Item 1, "Condensed Consolidated Financial Statements" is incorporated herein by reference.

ITEM 3. Quantitative and Qualitative Disclosures about Market Risk

Not applicable.

ITEM 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(b) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, under the direction of our Chief Executive Officer and our Chief Financial Officer, we have evaluated our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of the end of the period covered by this report. Our management has concluded that the financial statements included elsewhere in this Quarterly Report on Form 10-Q present fairly, in all material respects, our financial position, results of operations and cash flows in conformity with generally accepted accounting principles.

Changes in Internal Control over Financial Reporting

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

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

Our business is subject to risks and events that, if they occur, could adversely affect our financial condition and results of operations and the trading price of our securities. During the three months ended March 31, 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 Annual Report. You should carefully consider the risk factors discussed below and in Part I, "Item 1A. Risk Factors" in our 2021 Annual Report. The risks described below and in our 2021 Annual Report 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.

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

Not applicable.

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)
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.

† Indicates a management contract or compensatory plan.

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

SIGNATURES

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

HELIUS MEDICAL TECHNOLOGIES, INC.

Dated: May 12, 2022

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

Dated: May 12, 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 March 31, 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: May 12, 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 March 31, 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: May 12, 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 MARCH 31, 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 March 31, 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: May 12, 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 MARCH 31, 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 March 31, 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: May 12, 2022

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