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

FORM 10-Q

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

For the quarterly period ended June 30, 2021

OR

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

For the transition period from to

Commission File No. 001-38445

HELIUS MEDICAL TECHNOLOGIES, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**36-4787690**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
642 Newtown Yardley Road, Suite 100 Newtown, Pennsylvania (Address of principal executive offices)	**18940** **(Zip Code)**

(215) 944-6100
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Class A Common Stock, $0.001 par value per share	HSDT	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of August 6, 2021, the registrant had 2,317,772 shares of Class A common stock, $0.001 par value per share, outstanding.

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

	June 30, 2021	December 31, 2020
ASSETS		
Current assets		
Cash	$ 7,425	$ 3,331
Accounts receivable, net	51	74
Other receivables	169	156
Inventory, net	507	389
Prepaid expenses	833	735
Total current assets	8,985	4,685
Property and equipment, net	449	486
Other assets		
Goodwill	783	759
Intangible assets, net	438	527
Operating lease right-of-use asset, net	62	90
Total other assets	1,283	1,376
TOTAL ASSETS	**$ 10,717**	**$ 6,547**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 912	$ 747
Accrued liabilities	873	1,337
Operating lease liability	62	59
Deferred revenue	290	281
Total current liabilities	2,137	2,424
Non-current liabilities		
Operating lease liability	—	32
Deferred revenue	213	220
TOTAL LIABILITIES	**2,350**	**2,676**
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 June 30, 2021 and December 31, 2020	—	—
Class A common stock, $0.001 par value; 150,000,000 shares authorized; 2,317,772 and 1,484,362 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	2	1
Additional paid-in capital	138,023	123,872
Accumulated other comprehensive loss	(1,412)	(1,099)
Accumulated deficit	(128,246)	(118,903)
TOTAL STOCKHOLDERS' EQUITY	**8,367**	**3,871**
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 10,717**	**$ 6,547**

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue:				
Product sales	$ 63	$ 126	$ 140	$ 317
Fee revenue	—	—	—	9
License revenue	8	7	15	13
Total operating revenue	**71**	**133**	**155**	**339**
Cost of sales:				
Cost of product sales	67	64	83	165
Gross profit	**4**	**69**	**72**	**174**
Operating expenses:				
Research and development	1,377	1,308	2,694	2,428
Selling, general and administrative	4,744	2,394	6,939	5,255
Amortization expense	49	89	106	215
Total operating expenses	**6,170**	**3,791**	**9,739**	**7,898**
Operating loss	**(6,166)**	**(3,722)**	**(9,667)**	**(7,724)**
Other income (expense):				
Other income	—	56	—	63
Change in fair value of derivative financial instruments	—	(1)	—	3
Foreign exchange gain (loss)	185	306	324	(460)
Total other income (expense)	**185**	**361**	**324**	**(394)**
Net loss	**(5,981)**	**(3,361)**	**(9,343)**	**(8,118)**
Other comprehensive loss:				
Foreign currency translation adjustments	(185)	(255)	(313)	381
Comprehensive loss	**$ (6,166)**	**$ (3,616)**	**$ (9,656)**	**$ (7,737)**
Net loss per share				
Basic	**$ (2.58)**	**$ (2.90)**	**$ (4.29)**	**$ (7.85)**
Diluted	**$ (2.58)**	**$ (2.90)**	**$ (4.29)**	**$ (7.85)**
Weighted average shares outstanding				
Basic	**2,317,389**	**1,160,661**	**2,179,878**	**1,033,692**
Diluted	**2,317,389**	**1,160,661**	**2,179,878**	**1,033,692**

(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 June 30, 2021 and 2020
(Except share data, amounts in thousands)

	Common Stock, $0.001 par value		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
Balance as of March 31, 2020	**1,086,902**	**$ 1**	**$ 115,004**	**$ (266)**	**$ (109,530)**	**$ 5,209**
Proceeds from the issuance of common stock from At-the-Market program	202,072	—	4,240	—	—	4,240
Share issuance costs	—	—	(166)	—	—	(166)
Stock-based compensation	—	—	729	—	—	729
Foreign currency translation adjustments	—	—	—	(255)	—	(255)
Net loss	—	—	—	—	(3,361)	(3,361)
Balance as of June 30, 2020	**1,288,974**	**$ 1**	**$ 119,807**	**$ (521)**	**$ (112,891)**	**$ 6,396**

	Common Stock, $0.001 par value		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
Balance as of March 31, 2021	**2,311,868**	**$ 2**	**$ 135,388**	**$ (1,227)**	**$ (122,265)**	**$ 11,898**
Proceeds from the exercise of warrants	262	—	4	—	—	4
Proceeds from the exercise of stock options	214	—	2	—	—	2
Settlement of restricted stock units	91	—	—	—	—	—
Issuance of shares as part of compensation	5,337	—	77	—	—	77
Stock-based compensation	—	—	2,552	—	—	2,552
Foreign currency translation adjustments	—	—	—	(185)	—	(185)
Net loss	—	—	—	—	(5,981)	(5,981)
Balance as of June 30, 2021	**2,317,772**	**$ 2**	**$ 138,023**	**$ (1,412)**	**$ (128,246)**	**$ 8,367**

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

Helius Medical Technologies, Inc.

Unaudited Condensed Consolidated Statements of Stockholders' Equity for the Six Months Ended June 30, 2021 and 2020

(Except share data, amounts in thousands)

	Common Stock, $0.001 par value		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
Balance as of December 31, 2019	**877,672**	**$ 1**	**$ 111,509**	**$ (902)**	**$ (104,773)**	**$ 5,835**
Proceeds from the issuance of common stock from At-the-Market program	232,526	—	5,043	—	—	5,043
Proceeds from issuance of common stock from the March 2020 Offering	178,776	—	1,348	—	—	1,348
Warrant issuance from the March 2020 Offering	—	—	842	—	—	842
Share issuance costs	—	—	(506)	—	—	(506)
Stock-based compensation	—	—	1,571	—	—	1,571
Foreign currency translation adjustments	—	—	—	381	—	381
Net loss	—	—	—	—	(8,118)	(8,118)
Balance as of June 30, 2020	**1,288,974**	**$ 1**	**$ 119,807**	**$ (521)**	**$ (112,891)**	**$ 6,396**

	Common Stock, $0.001 par value		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
Balance as of December 31, 2020	**1,484,362**	**$ 1**	**$ 123,872**	**$ (1,099)**	**$ (118,903)**	**$ 3,871**
Proceeds from the issuance of common stock from the February 2021 Offering	744,936	1	8,398	—	—	8,399
Warrant issuance from the February 2021 Offering	—	—	2,638	—	—	2,638
Share issuance costs	—	—	(1,361)	—	—	(1,361)
Proceeds from the exercise of warrants	81,895	—	1,318	—	—	1,318
Proceeds from the exercise of stock options	214	—	2	—	—	2
Settlement of restricted stock units	1,028	—	—	—	—	—
Issuance of shares as part of compensation	5,337	—	77	—	—	77
Stock-based compensation	—	—	3,079	—	—	3,079
Foreign currency translation adjustments	—	—	—	(313)	—	(313)
Net loss	—	—	—	—	(9,343)	(9,343)
Balance as of June 30, 2021	**2,317,772**	**$ 2**	**$ 138,023**	**$ (1,412)**	**$ (128,246)**	**$ 8,367**

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

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

	Six Months Ended June 30,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (9,343)	$ (8,118)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of derivative financial instruments	—	(3)
Stock-based compensation expense	3,156	1,571
Unrealized foreign exchange (gain) loss	(323)	433
Depreciation expense	56	67
Amortization expense	106	215
(Recovery of) provision for doubtful accounts	(11)	153
Non-cash lease expense	30	196
Intangible asset impairment	—	181
Loss from disposal of property and equipment	—	110
Gain on lease modification	—	(56)
Changes in operating assets and liabilities:		
Accounts receivable	34	1
Other receivables	(13)	226
Inventory	(118)	28
Prepaid expenses	(98)	(105)
Operating lease liability	(31)	(126)
Accounts payable	229	(1,288)
Accrued liabilities	(366)	(381)
Deferred revenue	2	(83)
Net cash used in operating activities	**(6,690)**	**(6,979)**
Cash flows from investing activities:		
Purchase of property and equipment	(19)	(3)
Proceeds from sale of property and equipment	—	61
Internally developed software	(2)	(7)
Net cash (used in) provided by investing activities	**(21)**	**51**
Cash flows from financing activities:		
Proceeds from the issuances of common stock and warrants	11,037	7,233
Share issuance costs	(1,523)	(506)
Proceeds from the exercise of warrants and stock options	1,320	—
Proceeds from Paycheck Protection Program Loan	—	323
Repayment of Paycheck Protection Program Loan	—	(323)
Net cash provided by financing activities	**10,834**	**6,727**
Effect of foreign exchange rate changes on cash	(29)	6
Net increase (decrease) in cash	4,094	(195)
Cash at beginning of period	3,331	5,459
Cash at end of period	**$ 7,425**	**$ 5,264**
Supplemental schedule of non-cash financing activities		
Share issuance costs included in accounts payable and accrued liabilities	—	54

(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 unique and non-invasive technologies targeted at reducing symptoms of neurological disease or trauma.

The Company's first 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 United States 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. It is not expected to be commercially available in the United States until the first quarter of 2022. The PoNS device is authorized for sale in Canada as a class II, non-implantable, medical device intended as a short term treatment (14 weeks) of gait deficit due to mild and moderate symptoms from MS, and chronic balance deficit due to mild-to-moderate traumatic brain injury ("mmTBI") and is to be used in conjunction with physical therapy ("PoNS Treatment™"). It has been commercially available in Canada since March 2019. The PoNS device is an investigational medical device in the European Union ("EU"), and Australia ("AUS"). It is under premarket review by the AUS Therapeutic Goods Administration.

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.

Reverse Stock Split

Effective after the close of business on December 31, 2020, the Company completed a 1-for-35 reverse stock split of its common stock. All share and per share amounts in this Quarterly Report have been reflected on a post-split basis.

Going Concern Uncertainty

As of June 30, 2021, the Company had cash of $7.4 million. For the six months ended June 30, 2021, the Company had an operating loss of $9.7 million, and as of June 30, 2021, its accumulated deficit was $128.2 million. For the six months ended June 30, 2021, 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 by raising additional capital through equity or debt financings. 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

On March 11, 2020, the World Health Organization declared the outbreak of a novel coronavirus ("COVID-19") as a global pandemic, which continues to spread throughout the United States 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 have re-opened, they are all currently operating at reduced capacity, 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. In addition, the resurgence of COVID-19 cases across Canada in the fourth quarter of 2020 and first half of 2021 has led to further restrictions on clinic activities. However, the rate of vaccination has increased throughout all provinces during the end of the second quarter of 2021. Moreover, the Company's ability to conduct its ongoing clinical experience programs and clinical trials in Canada 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, and 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.

To the extent the COVID-19 pandemic impacts the Company's ability to complete the necessary pre-commercialization activities, the Company's commercial launch in the U.S. could be impeded or delayed. The extent to which the COVID-19 pandemic will continue to impact the Company's business, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted. The Company does not know yet 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, 2020, included in its Annual Report on Form 10-K that was filed with the Securities and Exchange Commission on March 10, 2021. 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 is not currently exposed to any significant concentrations of credit risk from these financial instruments. 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 June 30, 2021, the Company's accounts receivable of $51 thousand, 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, 2020, 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 as of June 30, 2021 and December 31, 2020 included refunds from research and development ("R&D") tax credits of $1 thousand and $1 thousand, respectively, and Goods and Services Tax ("GST") and Quebec Sales Tax ("QST") refunds of $0.2 million and $0.1 million, respectively, related to the Company's Canadian expenditures. As of December 31, 2020, there was also a receivable from rent deposits of $18 thousand.

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 and six months ended June 30, 2021, respectively. Inventory markdowns to net realizable value of $0 and $2 thousand were recorded during the three and six months ended June 30, 2020, respectively.

As of June 30, 2021 and December 31, 2020, inventory consisted of the following (amounts in thousands):

	As of June 30, 2021	As of December 31, 2020
Raw materials	$ 167	$ 160
Work-in-process	526	440
Finished goods	69	44
Inventory	**$ 762**	**$ 644**
Inventory reserve	(255)	(255)
Total inventory, net of reserve	**$ 507**	**$ 389**

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 of the Company's leasehold improvements is over the shorter of its lease term or useful life of 5 years; 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 June 30, 2021 and December 31, 2020, property and equipment consisted of the following (amounts in thousands):

	As of June 30, 2021	As of December 31, 2020
Leasehold improvement	$ 64	$ 64
Furniture and fixtures	93	93
Equipment	354	335
Computer software and hardware	197	197
Property and equipment	**708**	**689**
Less accumulated depreciation	(259)	(203)
Property and equipment, net	**$ 449**	**$ 486**

Depreciation expense was $28 thousand and $29 thousand for the three months ended June 30, 2021 and 2020, respectively. Depreciation expense was $56 thousand and $67 thousand for the six months ended June 30, 2021 and 2020, 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 June 30, 2021 is the result of the Heuro acquisition completed in October 2019. Goodwill is not amortized, but rather will be 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 will test 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 ongoing effects of the COVID-19 pandemic was considered a triggering event for testing whether goodwill is impaired at June 30, 2021. As a result of the Company's quantitative assessment, the Company determined that the estimated fair value of the reporting unit exceeded the carrying value of the reporting unit. Therefore, the Company concluded that goodwill was not impaired as of any of the aforementioned periods. The Company will continue to monitor the impacts of the COVID-19 pandemic in future periods.

The following is a summary of the activity for the period ended June 30, 2021 for goodwill:

Carrying amount at December 31, 2020	$	759
Foreign currency translation		24
Carrying amount at June 30, 2021	$	783

Definite-lived intangibles consist principally of acquired customer relationships, 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 $49 thousand and $0.1 million during the three and six months ended June 30, 2021, respectively. Amortization expense related to intangible assets was $0.1 million and $0.2 million during the three and six months ended June 30, 2020. During the six months ended June 30, 2020, the Company incurred an intangible asset impairment loss of $0.2 million related to the customer relationships, all of which was incurred during the first quarter of 2020, which is included in selling, general and administrative expenses in the accompanying condensed consolidated statement of operations and comprehensive loss. During the six months ended June 30, 2021, the Company wrote-off $0.2 million of fully amortized customer relationships, all of which occurred during the first quarter of 2021.

Intangible assets as of June 30, 2021 and December 31, 2020 consist of the following:

		As of June 30, 2021			As of December 31, 2020		
	Useful Life	Gross Carrying Amount	Accumulated Amortization	Net Carrying Value	Gross Carrying Amount	Accumulated Amortization	Net Carrying Value
Customer relationships (1)	1.25 years	$ —	$ —	$ —	$ 237	$ (228)	$ 9
Acquired proprietary software	5 years	155	(52)	103	150	(35)	115
Reacquired rights	3.87 years	519	(224)	295	503	(152)	351
Internally developed software	3 years	84	(44)	40	82	(30)	52
Total intangible assets		$ 758	$ (320)	$ 438	$ 972	$ (445)	$ 527

(1) During the six months ended June 30, 2021, the Company wrote off $0.2 million of fully amortized customer relationships.

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

For the Year Ending December 31,	
2021 (remaining 6 months)	$ 96
2022	189
2023	127
2024	26
	$ 438

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. The Company had only one operating lease, which was for its headquarters office in Newtown, Pennsylvania upon the adoption date. As of June 30, 2021, the Company has not entered into any additional lease arrangements, but did modify the existing lease arrangement in the second quarter of 2020 and again in the first quarter of 2021. Operating lease ROU assets and operating lease liabilities are recognized upon the adoption date 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 arrangement does 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. For the three and six months ended June 30, 2020, the Company recorded $0.1 million and $0.3 million, respectively, in product sales. As of June 30, 2020, the control of 11 of the 55 PoNS devices included as consideration in the Heuro acquisition had been transferred resulting in revenue of $0.1 million being recognized which is included in the aforementioned $0.3 million in product sales for the six months ended June 30, 2020. For the three and six months ended June 30, 2021, the Company recorded $63 thousand and $0.1 million, respectively, in product sales. There were no PoNS devices, included as consideration in the Heuro acquisition, transferred during the six months ended June 30, 2021. As of June 30, 2021, there were 34 devices remaining to be transferred. The fair value of the remaining devices is recorded as deferred revenue of $0.3 million on the condensed consolidated balance sheet. The returns during the three and six months ended June 30, 2021 were the result of warranty returns for defective products. These returns were insignificant and any future replacements are expected to be insignificant.

Fee Revenue

During the three and six months ended June 30, 2020, the Company recognized $0 and $9 thousand, respectively, of fee revenue related to engaging new neuroplasticity clinics to provide the PoNS Treatment. These agreements were terminated in the second quarter of 2020. As a result, during the three and six months ended June 30, 2021, the Company did not recognize any fee revenue.

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 the three and six months ended June 30, 2021, the Company recognized revenues of $8 thousand and $15 thousand, respectively, 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 June 30, 2021. During the three and six months ended June 30, 2020, the Company recognized revenues of $7 thousand and $13 thousand, respectively, in license fees associated with the Co-Promotion Agreement.

As of June 30, 2021 and December 31, 2020, 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.

On March 27, 2020, President Trump signed into law the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"). The CARES Act, among other things, includes provisions relating to refundable payroll tax credits, deferment of employer side social security payments, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations, increased limitations on qualified charitable contributions, and technical corrections to tax depreciation methods for qualified improvement property. We continue to examine the impact that the CARES Act may have on our business. The CARES Act has not had a material impact on our accounting for income taxes.

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.

Derivative Financial Instruments

The Company evaluates its financial instruments and other contracts to determine if those contracts or embedded components of those contracts qualify as derivatives to be separately accounted for in accordance with ASC 815, *Derivatives and Hedging* ("ASC 815"). The result of this accounting treatment is that the fair value of the derivative is re-measured at each balance sheet date and recorded as a liability or asset and the change in fair value is recorded in the condensed consolidated statements of operations and comprehensive loss. As of December 31, 2020, the Company's derivative financial instruments accounted for in accordance with ASC 815 were comprised of warrants issued in connection with both public and/or private securities offerings. Upon settlement of a derivative financial instrument, the instrument is re-measured at the settlement date and the fair value of the underlying instrument is reclassified to equity.

The classification of derivative financial instruments, including whether such instruments should be recorded as liabilities/assets or as equity, is reassessed at the end of each reporting period. Derivative financial instruments that become subject to reclassification are reclassified at the fair value of the instrument on the reclassification date. Derivative financial instruments will be classified in the condensed consolidated balance sheet as current if the right to exercise or settle the derivative financial instrument lies with the holder.

The last of the warrants accounted for in accordance with ASC 815 expired in April 2021 and as such, as of June 30, 2021, the Company does not hold any derivative financial instruments accounted for in accordance with ASC 815.

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, operating lease liability and derivative financial instruments. The book values of these instruments, with the exception of derivative financial instruments, non-current lease liability and operating lease ROU asset approximate their fair values due to the immediate or short-term nature of these instruments.

The Company's derivative financial instruments are classified as Level 3 within the fair value hierarchy. Unobservable inputs used in the valuation of these financial instruments include volatility of the underlying share price and the expected term. See Note 3 for the inputs used in the Black-Scholes option pricing model as of December 31, 2020 and the roll forward of the Company's derivative financial instruments. The Company's derivative financial instruments were comprised of warrants classified as liabilities. The fair value of the derivative financial instruments as of December 31, 2020 was zero. The warrants classified as liabilities expired in April 2021 and as such, as of June 30, 2021, the Company does not hold any derivative financial instructions accounted for in accordance with ASC 815.

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. Due to the COVID-19 pandemic and the related risks and uncertainties, the Company's customer relationship intangible asset incurred an impairment loss during the six months ended June 30, 2020 of $0.2 million, all of which was incurred during the first quarter of 2020. The fair value of this intangible asset was determined based on Level 3 measurements within the fair value hierarchy. Inputs to these fair value measurements included estimates of the amount and timing of the asset's net future discounted cash flows based on historical data, current trends and market conditions. As of June 30, 2021, the Company's customer relationship intangible asset had been fully amortized and written off.

Basic and Diluted Net Loss per Share

Earnings or loss per share ("EPS") is computed by dividing net income (loss) by the weighted average number of common shares outstanding during the period. Diluted EPS is computed by dividing net income (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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Basic and Diluted				
Numerator:				
Net loss	$ (5,981)	$ (3,361)	$ (9,343)	$ (8,118)
Denominator:				
Weighted average common shares outstanding	2,317,389	1,160,661	2,179,878	1,033,692
Basic and diluted net loss per share	**$ (2.58)**	**$ (2.90)**	**$ (4.29)**	**$ (7.85)**

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 and six months ended June 30, 2021 and 2020. Common stock equivalents excluded from the computation of diluted weighted average shares outstanding were 1,233,230 and 388,344 for the three months ended June 30, 2021 and 2020, respectively. Common stock equivalents excluded from the computation of diluted weighted average shares outstanding were 1,233,230 and 388,344 for the six months ended June 30, 2021 and 2020, 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 consolidated financial statements.

In August 2020, FASB issued ASU 2020-06, *Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40)*, which simplifies accounting for convertible instruments by removing major separation models required under current GAAP. The ASU removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception and it also simplifies the diluted earnings per share calculation in certain areas. The guidance is effective for interim and annual periods beginning after December 15, 2021. Early adoption is permitted, but no earlier than fiscal years beginning after December 15,

2020, including interim periods within those fiscal years. FASB has specified that an entity should adopt the guidance as of the beginning of its annual fiscal year. The guidance is to be applied using either a full retrospective or modified retrospective method. In applying the full retrospective method, the cumulative effect of the accounting change should be recognized as an adjustment to the opening balance of retained earnings in the first comparative period presented. In applying the modified retrospective method, the cumulative effect of the accounting change should be recognized as an adjustment to the opening balance of retained earnings at the date of adoption. The Company early adopted ASU 2020-06 effective January 1, 2021 under the modified retrospective approach. The adoption of this guidance did not have a material impact on the Company's 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 June 30, 2021. 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.

On April 13, 2018, the Company issued 61,197 shares of its common stock and warrants to purchase 61,197 shares of the Company's common stock in an underwritten public offering at a price of $261.45 per share and accompanying warrant. On April 24, 2018, the Company closed on the sale of an additional 9,179 shares of its common stock and warrants to purchase 9,179 shares of the Company's common stock pursuant to the exercise of the underwriters' over-allotment option (collectively the "April 2018 Offering"). The Company received net proceeds of $16.3 million from the April 2018 Offering. The fair value of these warrants at issuance was approximately $7.4 million.

Each warrant issued in connection with the April 2018 Offering entitled the holder to acquire one additional share of common stock at an exercise price of CAD$428.75 per share on or before April 10, 2021. Pursuant to the guidance of ASC 815 *Derivatives and Hedging*, the Company determined that warrants issued in connection with the April 2018 Offering should be accounted for as liabilities as the ability to maintain an effective registration was outside of the Company's control and that it might be required to settle the exercise of the warrants in cash and because the exercise prices of these warrants were in a currency other than the Company's functional currency. Consequently, the Company determined the fair value of each warrant issuance using the Black-Scholes option pricing model, with the remainder of the proceeds allocated to the common shares. As of June 30, 2021, 2,025 warrants had been exercised, all during 2018, for gross proceeds of CAD$0.9 million. The remaining 68,351 warrants expired in April 2021.

The following table summarizes the weighted average assumptions used in estimating the fair value of the warrants issued in the April 2018 Offering using the Black-Scholes option pricing model as of the date of the initial closing of the offering and the date of the closing of the over-allotment option.

	April 24, 2018	April 13, 2018
Stock price	CAD$ 376.60	CAD$ 344.75
Exercise price	CAD$ 428.75	CAD$ 428.75
Warrant term	3.00 years	3.00 years
Expected volatility	64.49%	64.20%
Risk-free interest rate	2.02%	1.99%
Dividend rate	0.00%	0.00%

On January 27, 2020, the Company filed a Form S-3 shelf registration under the Securities Act which was declared effective by the SEC on February 6, 2020 (the "2020 Shelf"). In conjunction with the 2020 Shelf, on January 27, 2020, the Company entered into an At The Market Offering Agreement (the "2020 ATM") with H.C. Wainwright & Co., LLC ("Wainwright") under which the Company may offer and sell, from time to time at its sole discretion, to or through Wainwright, acting as agent and/or principal, shares of its common stock having an aggregate offering price of up to $11.34 million, which, in March 2020, was subsequently reduced to $9.15 million, including the shares previously sold under the 2020 ATM. For the six months ended June 30, 2020, under the 2020 ATM, the Company sold and issued 232,526 shares of its common stock with an aggregated market value of $5.0 million at an average price of $21.68 per share and paid Wainwright a sales commission of approximately $181 thousand related to those shares. The Company terminated the 2020 ATM effective November 25, 2020.

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. 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. Gross proceeds from the offering (the "March 2020 Offering") were approximately $2.2 million. The underwriting discounts and commissions and offering expenses of $0.3 million were recorded to share issuance costs.

Each warrant issued in connection with the March 2020 Offering entitles the holder to acquire one additional share of common stock at an exercise price of $16.10 per share, which became exercisable on September 20, 2020 and will expire on March 20, 2025. Pursuant to the guidance of ASC 480 *Distinguishing Liabilities from Equity* and ASC 815 *Derivatives and Hedging*, the Company has determined that warrants issued in

connection with the March 2020 Offering should be classified as equity as partial cash settlement under certain circumstances and provisions related to market volatility did not preclude equity classification. The relative fair value of these warrants at issuance was approximately $0.8 million and was included in additional paid-in capital. As of June 30, 2021, 81,633 warrants had been exercised, all during the first quarter of 2021, for gross proceeds of $1.3 million.

The following table summarizes the weighted average assumptions used in estimating the fair value of the warrants granted in the March 2020 Offering using the Black-Scholes option pricing model as of the date of the closing of the offering on March 20, 2020.

	March 20, 2020
Stock price	$ 12.25
Exercise price	$ 16.10
Warrant term	5.50 years
Expected volatility	82.41%
Risk-free interest rate	0.52%
Dividend rate	0.00%

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.

Pursuant to the securities purchase agreement for the October 2020 Offering, if the Company issues any shares of common stock or common stock equivalents for cash consideration, indebtedness or a combination thereof, with certain exceptions, within twelve months of the closing of the October 2020 Offering, each purchaser who subscribed for at least $250,000 has the right to participate in up to such purchaser's pro rata portion of 30% of the such subsequent financing on the same terms, conditions and price provided for in the subsequent financing.

Pursuant to the guidance of ASC 480 *Distinguishing Liabilities from Equity* and ASC 815 *Derivatives and Hedging*, the Company has determined that warrants issued in connection with the October 2020 Offering should be classified as equity as partial cash settlement under certain circumstances did not preclude equity classification. The relative fair value of these warrants at issuance was approximately $0.6 million and was included in additional paid-in capital.

The following table summarizes the weighted average assumptions used in estimating the fair value of the warrants granted in the October 2020 Offering using the Black-Scholes option pricing model as of the date of the closing of the offering on October 26, 2020.

	October 26, 2020
Stock price	$ 15.92
Exercise price	$ 15.92
Warrant term	3.00 years
Expected volatility	80.91%
Risk-free interest rate	0.18%
Dividend rate	0.00%

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.

Pursuant to the guidance of ASC 480 *Distinguishing Liabilities from Equity* and ASC 815 *Derivatives and Hedging*, the Company has determined that warrants issued in connection with the February 2021 Offering should be classified as equity as partial cash settlement under certain circumstances and provisions related to market volatility did not preclude equity classification. The relative fair value of these warrants at issuance was approximately $2.6 million and was included in additional paid-in capital. As of June 30, 2021, 262 warrants had been exercised, all during the second quarter of 2021, for gross proceeds of $4 thousand.

The following table summarizes the weighted average assumptions used in estimating the fair value of the warrants granted in the February 2021 Offering using the Black-Scholes option pricing model as of the date of the closing of the offering on February 1, 2021.

	February 1, 2021
Stock price	$ 14.82
Exercise price	$ 16.47
Warrant term	5.00 years
Expected volatility	75.02%
Risk-free interest rate	0.42%
Dividend rate	0.00%

The following table summarizes warrants accounted for as liabilities and recorded as derivative financial instruments on the Company's condensed consolidated balance sheets for the six months ended June 30, 2021 and 2020 (amounts in thousands):

	Six Months Ended June 30,	
	2021	2020
Fair value of warrants at beginning of period	**$ —**	**$ 5**
Exercise of warrants	—	—
Foreign exchange losses	—	—
Change in fair value of warrants during the period	—	(4)
Fair value of warrants at end of period	**$ —**	**$ 1**

Prior to their expiration in April 2021, these warrants were classified as derivative financial instruments in the Company's condensed consolidated balance sheet as of December 31, 2020 and were required to be re-measured at each reporting period, with the change in fair value recorded as a gain or loss in the change in fair value of derivative financial instruments, included in other income (expense) in the Company's condensed consolidated statements of operations and comprehensive loss. The fair value of the warrants continued to be classified as a liability until they were exercised or expired. No warrants were included in the table for 2021 as all warrants classified as liabilities were underwater prior to expiring in April 2021. As of June 30, 2021, there are no warrants outstanding classified as derivative financial instruments.

The fair value of all warrants classified as derivative financial instruments outstanding as of December 31, 2020 were estimated using the Black-Scholes option pricing model with the following weighted average assumptions:

	December 31, 2020
Stock price	CAD$ 17.15
Exercise price	CAD$ 428.75
Warrant term	0.27 years
Expected volatility	64.48%
Risk-free interest rate	0.06%
Dividend rate	0.00%

The following is a summary of the Company's warrant activity during the six months ended June 30, 2021:

	Number of Warrants		Weighted Average Exercise Price	
	CAD	US	CAD$	USD$
Outstanding as of December 31, 2020	**68,351**	**273,554**	**$ 428.75**	**$ 16.04**
Granted	—	402,265	—	16.47
Cancelled/Expired	(68,351)	—	428.75	—
Exercised	—	(81,895)	—	16.10
Outstanding as of June 30, 2021	**—**	**593,924**	**$ —**	**$ 16.32**

The Company's warrants outstanding and exercisable as of June 30, 2021 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

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 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 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 June 30, 2021, there was an aggregate of 127,328 shares of common stock remaining available for grant under the Company's 2018 Plan.

For the six months ended June 30, 2021, the Company issued 532,068 stock options to employees and directors of which 5,500 were forfeited. The Company issued no stock options to consultants during the six months ended June 30, 2021.

The following is a summary of the Company's stock option activity during the six months ended June 30, 2021:

	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, 2020	**113,558**	**7.75**	**$ 159.33**	**$ —**
Granted	532,068		15.00	—
Forfeited/Cancelled	(14,396)		105.15	—
Exercised	(214)		10.50	—
Outstanding as of June 30, 2021	**631,016**	**9.47**	**$ 38.92**	**$ —**
Exercisable as of June 30, 2021	**252,920**	**8.97**	**$ 26.73**	**$ —**

Employee and Director Stock Options As of June 30, 2021, the unrecognized compensation cost related to non-vested time-based stock options outstanding for employees and directors, was $3.9 million which will be recognized over a weighted-average remaining vesting period of approximately 3.5 years. As of June 30, 2021, 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 six months ended June 30, 2021 was $11.27 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:

	Six Months Ended June 30, 2021
Stock price	$ 15.10
Exercise price	$ 15.00
Expected term	7.17 years
Expected volatility	1.19%
Risk-free interest rate	85.99%
Dividend rate	0.00%

Consultant Stock Options

As of June 30, 2021, the unrecognized compensation cost related to non-vested stock options outstanding for non-employees was $13 thousand which will be recognized over a weighted-average remaining vesting period of approximately 0.3 years. Compensation cost is not adjusted for estimated forfeitures, but instead is adjusted upon an actual forfeiture of a stock option.

Restricted Stock Units

Beginning in the fourth quarter of 2019, certain members of the Company's executive management team elected to receive RSUs in lieu of cash compensation under the 2018 Plan that vest upon issuance. The fair value of the RSUs was based on the closing price of the Company's common stock on the day of the grant. Subsequent to the March 31, 2021 pay period, no members of the Company's executive management team continued to elect to receive RSUs in lieu of cash compensation.

During the second quarter of 2021, the Company granted 2,668 RSUs to an officer of the Company under the 2018 Plan that were scheduled to vest on October 2, 2021. The fair value of the RSUs is based on the closing price of the Company's common stock on the day of the grant.

During the second quarter of 2021, the Company granted 5,622 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 day of the grant.

The following is a summary of the Company's RSU award activity for the six months ended June 30, 2021:

	Number of RSUs	Weighted Average Grant Date Fair Value per Unit
Outstanding as of December 31, 2020	168	$ 13.20
Granted	9,150	15.46
Settled	(1,028)	14.50
Outstanding as of June 30, 2021	8,290	$ 15.53

Unrestricted Stock

On April 1, 2021, the Company granted 5,337 shares of unrestricted Class A Common Stock to an officer 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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Research and development	$ 162	$ 243	$ 384	$ 482
Cost of sales	3	(2)	3	(1)
Selling, general and administrative	2,464	488	2,769	1,090
Total	**$ 2,629**	**$ 729**	**$ 3,156**	**$ 1,571**

5. ACCRUED EXPENSES

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

	As of	
	June 30, 2021	December 31, 2020
Employees benefits	$ 457	$ 496
Professional services	107	292
Legal fees	144	133
Royalty fees	3	12
Severance	139	347
Other	23	57
Total	**$ 873**	**$ 1,337**

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 and six months ended June 30, 2021, the Company

recorded approximately $3 thousand and $6 thousand, respectively, in royalty expenses in its condensed consolidated statement of operations and comprehensive loss. For the three and six months ended June 30, 2020, the Company recorded approximately $5 thousand and $10 thousand, respectively, in royalty expenses in its condensed consolidated statement of operations and comprehensive loss.

(b) In March 2017, the Company entered into a lease for office space in Newtown, Pennsylvania. The initial term of the lease was from July 1, 2017 through December 31, 2022, with an option to extend until 2027. In July 2017, the Company amended the contract to commence the lease on July 17, 2017 through January 16, 2023, with an option to extend until January 2028. Lease extension options were not included in the lease term as it was not reasonably certain that the Company would elect to utilize the option to extend. Monthly rent plus utilities were approximately $20 thousand per month beginning in January 2018 with a 3% annual increase. In May 2020, the Company terminated its lease and entered into a new lease (the "Lease Amendment") for a smaller footprint of the current office space in Newtown, Pennsylvania. Lease payments under the original contract will be made through December 2020. The Lease Amendment was determined to be a partial termination that qualified as a change of accounting of the existing lease and not a separate contract. As such, the ROU assets and operating lease liabilities were remeasured using an incremental borrowing rate at the date of modification. The carrying value of the ROU asset decreased on a basis proportionate to the partial termination by approximately $0.4 million and the related lease liability decreased by approximately $0.4 million. The Company recorded a gain of approximately $0.1 million resulting from the difference between the reduction in the lease liability and the proportionate reduction of the ROU asset. This amount was recorded as a component of other income in the condensed consolidated statement of operations and comprehensive loss during the second quarter of 2020. The initial lease term of the Lease Amendment was from July 1, 2020 through June 30, 2021, with options to extend for successive six month periods. Two lease extension options were included in the lease term as it was reasonably certain that the Company would elect to utilize the option to extend for this period of time. Monthly rent plus utilities is approximately $5 thousand per month beginning in January 2021 with a 3% annual increase. In January 2021, the lease term of the Lease Amendment was amended to go through September 30, 2021, with options to extend monthly thereafter. No other amendments were made. The Company's assessment of the lease term it would elect to utilize has not changed.

The following table summarizes the Company's operating lease information including future minimum lease payments under a non-cancellable lease as of June 30, 2021 (amounts in thousands).

For the Six Months Ended June 30, 2021		
Operating lease cost	$	5
Operating lease - operating cash flows	$	31
Weighted average remaining lease term		1.00 years
Weighted average discount rate		7.2%
Future minimum lease payments under non-cancellable lease as of June 30, 2021 were as follows:		
For the Period Ending December 31,		
2021 (remaining six months)	$	32
2022		32
Total future minimum lease payments		**64**
Less imputed interest		(2)
Total liability	**$**	**62**
Reported as of June 30, 2021		
Current operating lease liability		62
Non-current operating lease liability		—
Total	**$**	**62**

(c) On December 29, 2017, HMI (formerly known as NeuroHabilitation Corporation) entered into a Manufacturing and Supply Agreement ("MSA") with Key Tronic Corporation ("Key Tronic"), 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 Key Tronic 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 Key Tronic for a second three year term from December 29, 2020 until December 31, 2023. As of June 30, 2021, the Company did not have any outstanding commitments to Key Tronic to complete the Company's forecasts for the procurement of materials necessary for the delivery of PoNS devices.

7. RELATED PARTY TRANSACTIONS

During the three and six months ended June 30, 2020, the Company paid approximately $0 and $5 thousand, respectively, in consulting fees to a director of the Company. No consulting fees were paid to this director during the three and six months ended June 30, 2021.

An officer of the Company and affiliates of an officer and director subscribed for units in the Company's October 2020 Offering.

Affiliates of an officer and director participated in the February 2021 Offering.

8. SUBSEQUENT EVENTS

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 Class A 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.

Departure of Executive Officer

On July 26, 2021, the Company reported that the employment of Joyce LaViscount, Chief Operating Officer of the Company ended on July 20, 2021. As of August 12, 2021, terms of the separation have not been finalized.

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, 2020, 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, 2020 filed with the Securities and Exchange Commission, or the SEC, on March 10, 2021, or our 2020 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, sufficiency of cash, availability of funds and operating costs. Such forward-looking statements involve risks and uncertainties, known and unknown, including risks and uncertainties relating to the COVID-19 pandemic, including its impact on the Company, the success of our business plan, availability of funds, our ability to maintain and enforce our intellectual property rights, government regulations, 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 2020 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-invasive technologies targeted at reducing symptoms of neurological disease or trauma.

Our first 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 United States as a short term treatment of gait deficit due to mild-to-moderate symptoms for 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. It is not expected to be commercially available in the United States until the first quarter of 2022. The PoNS device is authorized for sale in Canada as a class II, non-implantable medical device intended as a short term treatment (14 weeks) of gait deficit due to mild and moderate symptoms from MS and chronic balance deficit due to mild-to-moderate traumatic brain injury (mmTBI) and is to be used in conjunction with physical therapy (PoNS Treatment™). It has been commercially available in Canada since March 2019. The PoNS device is an investigational medical device in the European Union (EU), and Australia (AUS). The device is currently under premarket review by the AUS Therapeutic Goods Administration.

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 chronic 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. We believe this label expansion will significantly expand our addressable market opportunity in Canada to include a patient population that is motivated to pursue treatment options which 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 FDA's mission to protect and promote public health.

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.

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. We are evaluating the recent announcement and its implications for our reimbursement strategy. 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.

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 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 chronic 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 Treatment 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 finalized our clinical protocol for a new trial, TBI-002, intended to support a request for de novo classification and clearance of the PoNS device. TBI-002 will be a multi-center, randomized trial in the U.S. and Canada consisting of 103 subjects with balance deficit due to mmTBI. Although TBI-002 will take longer and be more costly than the design that we had discussed at our October 2019 pre-submission meeting, we believe that the chances of obtaining FDA de novo classification and clearance will be significantly increased if we incorporate the FDA's pre-submission feedback into this next trial design.

TBI-002 will proceed in two phases: a run-in phase, followed by a treatment phase. During the run-in phase, all subjects will receive 5 weeks of physical therapy alone. Subjects will then be randomized and assigned to one of two groups in the treatment phase where subjects will either receive up to 10 weeks of physical therapy with the PoNS device or 10 weeks of physical therapy without the PoNS device. The primary effectiveness endpoint of TBI-002 will be a responder analysis.

Prior to the COVID-19 pandemic, our expectation was that we would move forward with the revised protocol and estimated that enrollment would begin in April 2020 with the completion of the trial and submission to the FDA in the second quarter of 2021. However, the launch of the TBI-002 trial has been temporarily suspended, and we are evaluating our options for funding and timing to commence the trial or potentially look at other indications, including stroke, cerebral palsy, Parkinson's disease, baby boomers balance, and neurological wellness, as well as label expansion for our existing indications.

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. We are currently awaiting action from TGA on our application.

Canada Commercialization Efforts

From a real-world results perspective, in Canada thus far, the collective experience of our patients that have completed the 14-week PoNS Treatment have been encouraging. Consistent with what we saw in our two clinical trials, one for 5 weeks and the other for 14 weeks, commercial MS and mmTBI patients are demonstrating improvements in balance and gait within the first two weeks followed by continued improvement over the following twelve weeks. The majority of patients have 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 to the PoNS Treatment in Canada.

March 2019 marked the commercialization of our PoNS Treatment 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 Treatment. 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.

During the third quarter of 2019, we made the strategic decision to change our business model in Canada in order to accelerate the adoption of our novel technology. On October 30, 2019, we acquired the Heuro Canada operating entity from HTC which allowed us to streamline the decision-making process and increase our ability to react to evolving market factors as the market for the PoNS Treatment is being developed.

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, 2020, we authorized 24 new clinical locations to have 31 clinic locations as of December 31, 2020. As of June 30, 2021, we have 33 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 33 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 the Toronto Rehabilitation Institute (part of University Health Network), we are continuing our clinical experience program, the results of which we look to publish in 2021.

We continue to refine our go-to-market pricing model based on market feedback. Our modified pricing approach 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 treatment and drive market awareness which we expect to result in an increase in the volume of units sold, which was seen in the second half of 2020. We intend to keep the promotional pricing in place at least through the end of the third quarter of 2021.

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 Treatment for claimants are now being implemented 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 accident insurance and workers' compensation 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 Treatment strategy, we are also gathering comprehensive health economic assessments of treatment outcomes. These data will, in-turn, be used to support our applications for workers' compensation, auto insurance and commercial insurance reimbursement initiatives in Canada, the United States and other markets around the world. The Canadian commercial experience will be extremely valuable to prepare us for our launches in the United States and internationally.

US Pre-Commercialization Efforts

As noted above, 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. Despite the marketing authorization, the PoNS device is not currently commercially available in the United States, and we expect it will not be commercially available until the first quarter of 2022.

In this pre-commercial phase, we are working on the development of our commercial strategy focused on working with CMS on attaining four years of Medicare coverage under the MCIT pathway for PoNS as a Breakthrough Designated Device, attaining distribution licenses 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 Treatment 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 Treatment as the standard of care for the treatment of MS-related gait deficit.

To commercialize the PoNS Treatment in the United States, we plan to target specific Key Opinion Leaders (neurologists and physiatrists) and their associated neurorehabilitation centers (physical therapists). PoNS certified neurorehabilitation centers will be trained to deliver the PoNS Treatment. Importantly, this focused strategy will also allow us to inspect whether we are generating patient outcomes similar to those seen in our clinical trials. To further develop and implement the PoNS commercialization strategy, we have hired a Vice President of Sales and Marketing and have identified the initial launch areas within the US.

We are planning to pursue Medicare coverage for PoNS under the CMS voluntary MCIT program within the Durable Medical Equipment, or DME, benefit category. While there are no currently applicable Healthcare Common Procedure Coding System, or HCPCS, codes to describe the PoNS system or Mouthpiece, our expectation is that we will 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 intend to apply for unique HCPCS codes in the next application cycle, which is a nine month process from application until coding would be effective. We also intend to provide broad access and reimbursement for the PoNS Treatment over time through Commercial insurers. At launch, prior to the initiation of CMS or broad payer coverage, we anticipate the primary source of sales will be self-pay patients. We will support the cost of the PoNS Treatment by 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 at least a 24-month window to obtain broad coverage and reimbursement among government and private payers. We plan to work in parallel with non-traditional payers, such as WC, auto insurance and the military, by engaging with them and providing them with relevant health economic and return-to-work data obtained through our Canadian commercial experience.

COVID-19 Pandemic

On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 as a global pandemic, which continues to spread throughout the United States 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 have been 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, they are all currently operating at reduced capacity within provincial guidelines, which during the second quarter of 2021 limited operations to 25% capacity, with capacity as low as 15% in Ontario. 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 is 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 has increased throughout all provinces during the end of the second quarter of 2021 facilitating the lifting of some of the previously imposed restrictions.

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 or could 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. As noted above, prior to the COVID-19 pandemic, our expectation was that we would move forward with the launch of our TBI-002 trial and we had estimated that enrollment would begin in April

2020 with the completion of the trial and submission to the FDA in the second quarter of 2021. However, the launch of the TBI-002 trial has been suspended and we are evaluating our options for funding and timing to commence the trial or potentially look at other indications.

The COVID-19 pandemic and other outbreaks may 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, and 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. Disruptions in business operations or governmental operations due to COVID-19 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.

To the extent the COVID-19 pandemic impacts our ability to complete necessary pre-commercialization activities, our commercial launch in the U.S. could be impeded or delayed. The extent to which the COVID-19 pandemic will continue to impact our business, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted. We do not know yet the full extent of the impact of COVID-19 on our business, operations or the global economy as a whole.

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.

Results of Operations

Three Months Ended June 30, 2021 compared to the Three Months Ended June 30, 2020

The following table summarizes our results of operations for the three months ended June 30, 2021 and 2020 (amounts in thousands):

	Three Months Ended June 30,		
	2021	2020	Change
Revenue:			
Product sales	$ 63	$ 126	$ (63)
Fee revenue	—	—	—
License revenue	8	7	1
Total operating revenue	**71**	**133**	**(62)**
Cost of sales:			
Cost of product sales	67	64	3
Gross profit	**4**	**69**	**(65)**
Operating expenses:			
Research and development	1,377	1,308	69
Selling, general and administrative	4,744	2,394	2,350
Amortization expense	49	89	(40)
Total operating expenses	**6,170**	**3,791**	**2,379**
Operating loss	**(6,166)**	**(3,722)**	**(2,444)**
Other income:			
Other income	—	56	(56)
Change in fair value of derivative financial instruments	—	(1)	1
Foreign exchange gain	185	306	(121)
Total other income	**185**	**361**	**(176)**
Net loss	**$ (5,981)**	**$ (3,361)**	**$ (2,620)**

Revenue

For the three months ended June 30, 2021, we recognized revenue of $71 thousand, of which $63 thousand was generated through product sales of our PoNS device in Canada pursuant to our executed supply agreements with neuroplasticity clinics in Canada and $8 thousand was generated from license fee revenue related to our Co-Promotion Agreement with HTC. For the three months ended June 30, 2020 we recognized revenue of $133 thousand, of which $126 thousand was generated through product sales of our PoNS device in Canada pursuant to our executed supply agreements with neuroplasticity clinics in Canada and $7 thousand was generated from license fee revenue related to our Co-Promotion Agreement with HTC. The decrease year-over-year in revenue generated through product sales of our PoNS device in Canada is the result of lower clinic capacity in 2021 as a result of the COVID-19 pandemic combined with the impact of price changes focused on reducing the need for clinics and patients to pay large, upfront costs at the start of treatment.

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 June 30, 2021, we incurred $67 thousand in cost of sales. For the three months ended June 30, 2020, we incurred $64 thousand in cost of sales.

Research and Development Expense

Research and development, or R&D, expenses were $1.4 million for the three months ended June 30, 2021 compared to $1.3 million for the three months ended June 30, 2020, an increase of $0.1 million. The increase was primarily attributable to a $0.1 million increase in product development expenses.

Selling, General and Administrative Expense

Selling, general and administrative, or SG&A, expenses were $4.7 million for the three months ended June 30, 2021 compared to $2.4 million for the three months ended June 30, 2020, an increase of approximately $2.3 million. The increase was primarily due to a $2.0 million increase in our stock-based compensation expense, as well as a $0.3 million increase in legal and professional fees. Approximately $1.0 million of the increase in stock-based compensation expense related to the one-time fully vested stock option grant to our then Interim President and Chief Executive Officer in recognition of his service since August 2020 and election to take no additional compensation and continue to be compensated as a non-employee director of the Company while serving in that capacity. The remaining $1.0 million increase in stock-based compensation expense,

as well as a $0.1 million increase in salaries and wages, were both primarily the result of the addition of key management and sales executives in the second quarter of 2021.

Amortization Expense

Amortization expense consists of the periodic amortization of intangible assets, including customer relationships, 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 June 30, 2021, amortization expense was $49 thousand. For the three months ended June 30, 2020, amortization expense was $0.1 million. The decrease is primarily the result of the customer relationships becoming fully amortized during the first quarter of 2021.

Change in Fair Value of Derivative Financial Instruments

There was no change in fair value of derivative financial instruments for the three months ended June 30, 2021 because the warrants that qualified as derivatives required to be accounted for in accordance with ASC 815 (requiring the re-measurement of fair value at each balance sheet date) expired in April 2021 and had been valueless during the period. This compared to a loss of $1 thousand for the three months ended June 30, 2020.

The change in fair value of our derivative financial instruments for the three months ended June 30, 2020 was primarily attributable to the change in our stock price, volatility and the number of derivative financial instruments being measured during the period. The change in the fair value of derivative financial instruments is a non-cash item.

Foreign Exchange Gain (Loss)

Foreign exchange gain was $0.2 million for the three months ended June 30, 2021, compared to a gain of $0.3 million for the three months ended June 30, 2020. 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.

Six Months Ended June 30, 2021 compared to the Six Months Ended June 30, 2020

The following table summarizes our results of operations for the six months ended June 30, 2021 and 2020 (amounts in thousands):

	Six Months Ended June 30,		
	2021	2020	Change
Revenue:			
Product sales	$ 140	$ 317	$ (177)
Fee revenue	—	9	$ (9)
License revenue	15	13	2
Total operating revenue	**155**	**339**	**(184)**
Cost of sales:			
Cost of product sales	83	165	(82)
Gross profit	**72**	**174**	**(102)**
Operating expenses:			
Research and development	2,694	2,428	266
Selling, general and administrative	6,939	5,255	1,684
Amortization expense	106	215	(109)
Total operating expenses	**9,739**	**7,898**	**1,841**
Operating loss	**(9,667)**	**(7,724)**	**(1,943)**
Other income (expense):			
Other income	—	63	(63)
Change in fair value of derivative financial instruments	—	3	(3)
Foreign exchange gain (loss)	324	(460)	784
Total other income (expense)	324	(394)	718
Net loss	**$ (9,343)**	**$ (8,118)**	**$ (1,225)**

Revenue

For the six months ended June 30, 2021, we recognized revenue of $0.2 million, of which $0.1 million was generated through product sales of our PoNS device in Canada pursuant to our executed supply agreements with neuroplasticity clinics in Canada and $15 thousand was generated from license fee revenue related to our Co-Promotion Agreement with HTC. For the six months ended June 30, 2020, we recognized revenue of $0.3 million, of which $0.3 million was generated through product sales of our PoNS device in Canada pursuant to our executed supply agreements with neuroplasticity clinics in Canada, $9 thousand was generated from fee revenue related to engaging new PoNS authorized clinics and $13 thousand was generated from license fee revenue related to our Co-Promotion Agreement with HTC. The decrease year-over-year in revenue generated through product sales of our PoNS device in Canada is the result of the COVID-19 pandemic negatively impacting our product sales beginning in March 2020 and the impact of price changes focused on reducing the need for clinics and patients to pay large, upfront costs at the start of treatment.

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 six months ended June 30, 2021, we incurred $0.1 million in cost of sales. For the six months ended June 30, 2020, we incurred $0.2 million in cost of sales.

Research and Development Expense

Research and development, or R&D, expenses were $2.7 million for the six months ended June 30, 2021, compared to $2.4 million for the six months ended June 30, 2020, an increase of $0.3 million. The increase was primarily attributable to a $0.4 million increase in product development expenses, partially offset by a $0.1 million decrease in stock-based compensation expense.

Selling, General and Administrative Expense

Selling, general and administrative, or SG&A, expenses were $6.9 million for the six months ended June 30, 2021, compared to $5.3 million for the six months ended June 30, 2020, a increase of approximately $1.6 million. The increase was primarily due to a $1.7 million increase in our stock-based compensation expense and a $0.2 million increase in salaries and wages, both resulting primarily from the addition of key management and sales executives in the second quarter of 2021. Approximately $1.0 million of the stock-based compensation expense during the six months ended June 30, 2021 related to the one-time fully vested stock option grant to our then Interim President and Chief Executive Officer in recognition of his service since August 2020 and election to take no additional compensation and continue to be compensated as a non-employee director of the Company while serving in that capacity. These increases were partially offset by a $0.3 million decrease in other operating expenses primarily as a result of the $0.2 million impairment of customer relationship intangible assets in the first quarter of 2020.

Amortization Expense

Amortization expense consists of the periodic amortization of intangible assets, including customer relationships, proprietary software and reacquired rights recognized in connection with the acquisition of Heuro on October 30, 2019 and internally developed software. For the six months ended June 30, 2021, amortization expense was $0.1 million. For the six months ended June 30, 2020, amortization expense was $0.2 million. The decrease is primarily the result of the customer relationships becoming fully amortized during the first quarter of 2021.

Change in Fair Value of Derivative Financial Instruments

There was no change in fair value of derivative financial instruments for the six months ended June 30, 2021 because the warrants that qualified as derivatives required to be accounted for in accordance with ASC 815 (requiring the re-measurement of fair value at each balance sheet date) expired in April 2021 and had been valueless during the period. This compared to a gain of $3 thousand for the six months ended June 30, 2020.

The change in fair value of our derivative financial instruments for the six months ended June 30, 2020 was primarily attributable to the change in our stock price, volatility and the number of derivative financial instruments being measured during the period. The change in the fair value of derivative financial instruments is a non-cash item.

Foreign Exchange Gain (Loss)

Foreign exchange gain was $0.3 million for the six months ended June 30, 2021, compared to a loss of $0.5 million for the six months ended June 30, 2020. 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 six months ended June 30, 2021 and 2020 (amounts in thousands):

	Six Months Ended June 30,		
	2021	2020	Change
Net cash used in operating activities	$ (6,690)	$ (6,979)	$ 289
Net cash (used in) provided by investing activities	(21)	51	(72)
Net cash provided by financing activities	10,834	6,727	4,107
Effect of exchange rate changes on cash	(29)	6	(35)
Net increase (decrease) in cash	$ 4,094	$ (195)	$ 4,289

Net Cash Used in Operating Activities

Net cash used in operating activities during the six months ended June 30, 2021 was $6.7 million. This was comprised of net loss of $9.3 million, unrealized foreign exchange gains of $0.3 million, recovery of doubtful accounts of $11 thousand and $361 thousand net cash used resulting from changes in operating assets and liabilities, partially offset by certain adjustments for non-cash items of $3.3 million comprised mainly of stock-based compensation of $3.2 million and depreciation and amortization of $0.2 million.

Net cash used in operating activities during the six months ended June 30, 2020 was $7.0 million. This was comprised of net loss of $8.1 million and $1.5 million net cash used resulting from changes in operating assets and liabilities, partially offset by certain adjustments for non-cash items of $2.7 million comprised mainly of stock-based compensation of $1.6 million, unrealized foreign exchange losses of $0.4 million, depreciation and amortization of $0.3 million, impairment loss on intangible assets of $0.2 million, provision for doubtful accounts of $0.2 million, loss on disposal of office furniture of $0.1 million and gain on lease modification of $0.1 million.

Net Cash Used in Investing Activities

Net cash used in investing activities during the six months ended June 30, 2021 was $21 thousand, which was primarily related to the purchase of equipment.

Net cash provided by investing activities during the six months ended June 30, 2020 was $51 thousand, which was primarily related to the sale of office furniture.

Net Cash Provided by Financing Activities

Net cash provided by financing activities during the six months ended June 30, 2021 was $10.8 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 and stock options.

Net cash provided by financing activities during the six months ended June 30, 2020 was $6.7 million, which consisted of proceeds from the issuance of common stock from the 2020 ATM and March 2020 Offering, net of share issuance costs.

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 June 30, 2021, we raised approximately $118.9 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 excluding derivative financial instruments) as of June 30, 2021 and December 31, 2020 (amounts in thousands):

	June 30, 2021	December 31, 2020
Cash	$ 7,425	$ 3,331
Working capital	$ 6,848	$ 2,261

While we have started generating revenue from the commercial sale of our PoNS device in Canada, we expect to incur significant losses until any such time as our revenue exceeds our expenses and will require additional funding. Based on our cash burn rate during the first six months of

2021, our existing capital resources would be sufficient to fund our operations into the first quarter of 2022. However, in light of the receipt of marketing authorization from the FDA for the PoNS device in March 2021, we expect our expenses to increase throughout the remainder of 2021 in connection with our pre-commercialization activities, particularly as we invest in marketing and distribution capabilities, make improvements to our manufacturing process and product design, and add additional personnel. We also expect our expenses to increase if and as we decide to launch the TBI-002 trial or conduct other trials of the PoNS device without nondilutive funding, or if and as we decide to pursue further regulatory approvals, or maintain, expand and protect our intellectual property portfolio. 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.

Our ability to raise additional capital may be adversely impacted by global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic.

Off-Balance Sheet Arrangements

To the best of management's knowledge, there are no off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our results of operations or financial condition.

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 2020 Annual Report. There have been no changes in critical accounting policies in the current year from those described in our 2020 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. 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 2020 Annual Report. You should carefully consider the risk factors discussed below and in Part I, "Item 1A. Risk Factors" in our 2020 Annual Report. The risks described below and in our 2020 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.

The COVID-19 pandemic has adversely impacted, and may continue to materially and adversely impact, our business, financial condition and results of operations.

On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 as a global pandemic, which continues to spread throughout the United States and around the world. The Company's business, results of operations and financial condition have been 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 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 have been 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, they are all currently operating at reduced capacity within provincial guidelines, which during the second quarter of 2021 limited operations to 25% capacity, with capacity as low as 15% in Ontario. 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 is 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. However, the rate of vaccination has increased throughout all provinces during the end of the second quarter of 2021 facilitating the lifting of some of the previously imposed restrictions.

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 or could 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. As noted above, prior to the COVID-19 pandemic, our expectation was that we would move forward with the launch of our TBI-002 trial and we had estimated that enrollment would begin in April 2020 with the completion of the trial and submission to the FDA in the second quarter of 2021. However, the launch of the TBI-002 trial has been suspended and we are evaluating our options and timing for funding and timing to commence the trial or potentially look at other indications.

The COVID-19 pandemic and other outbreaks may 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, and 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. Disruptions in business operations or governmental operations due to COVID-19 may delay the timing for the submission and approval of the 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.

As the COVID-19 pandemic continues, we may experience additional disruptions that could severely impact our business, including:

- Changes in local regulations as part of a response to the COVID-19 pandemic may require us to change the way PoNS Authorized clinic locations operate or our clinical experience programs or clinical trials are conducted and may result in unexpected costs;
- Some patients may be unable, or continue to be unwilling, to visit or return to our PoNS Authorized clinic locations;
- Necessary interactions with local regulators, ethics committees and other important agencies and contractors may be delayed due to limitations in employee resources or forced furlough of government employees;
- The timing of our interactions with the FDA may be delayed due to absenteeism by federal employees or the diversion of their efforts and attention to approval of other therapeutics or other activities related to COVID-19;
- Our ability to complete necessary pre-commercialization activities may be impeded, which could delay our commercial launch in the U.S.;

- Healthcare resources may be diverted away from PoNS Authorized clinic locations, our clinical experience programs and the conduct of clinical trials;
- We may experience delays in receiving approval from local regulatory authorities to initiate future clinical trials; and
- Future key clinical trial activities may be delayed, such as clinical trial site monitoring, due to limitation on travel imposed or recommended by federal or state governments, employers and others.

In addition to the risks specifically described above, the COVID-19 pandemic has exacerbated and precipitated the other risks described in our 2020 Annual Report, and may continue to do so. The extent to which the COVID-19 pandemic will continue to impact the our business, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted. We do not know yet the full extent of the impact of COVID-19 on our business, operations or the global economy as a whole.

Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements. We may be unable to operate without the threat of liquidation for the foreseeable future.

In connection with our management's assessment, our report from our independent registered public accounting firm for the fiscal year ended December 31, 2020 includes an explanatory paragraph stating that our recurring losses from operations and net capital deficiency raise substantial doubt about our ability to continue as a going concern. We will require additional funding and, if we are unable to obtain sufficient funding, our business, prospects, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. Future reports from our independent registered public accounting firm may also contain statements expressing substantial doubt about our ability to continue as a going concern. Based on our cash burn rate during the first six months of 2021, our existing capital resources would be sufficient to fund our operations into the first quarter of 2022. However, in light of the receipt of marketing authorization from the FDA for the PoNS device in March 2021, we expect our expenses to increase throughout the remainder of 2021 in connection with our pre-commercialization activities, particularly as we invest in marketing and distribution capabilities, make improvements to our manufacturing process and product design, and add additional personnel. We also expect our expenses to increase if and as we decide to launch the TBI-002 trial or conduct other trials of the PoNS device without nondilutive funding, or if and as we decide to pursue further regulatory approvals, or maintain, expand and protect our intellectual property portfolio. 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 continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our consolidated financial statements, and investors will likely lose all or a part of their investment. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all.

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)
10.1†	2018 Omnibus Incentive Plan Form of Stock Grant Notice and Award Agreement (incorporated by reference to Exhibit 10.1 to the Form 8-K filed April 7, 2021)
10.2†	Second Amendment to Employment Agreement between Helius Medical Technologies, Inc. and Joyce LaViscount dated April 1, 2021 (incorporated by reference to Exhibit 10.2 to the Form 8-K filed April 7, 2021)
10.3†	Non-employee Director Compensation Policy (incorporated by reference to Exhibit 10.7 to the Form 10-Q filed May 17, 2021)
10.4†	Amendment to the Helius Medical Technologies, Inc. 2018 Omnibus Incentive Plan, effective May 25, 2021 (incorporated by reference to Exhibit 10.1 to the Form 8-K filed May 27, 2021)
10.5†	2018 Omnibus Incentive Plan Form of Option Grant Agreement (incorporated by reference to Exhibit 10.3 to the Form 10-Q filed November 8, 2018)
10.6†	Employment Agreement by and between Helius Medical Technologies, Inc. and Dane C. Andreeff effective as of June 14, 2021 (incorporated by reference to Exhibit 10.1 to the Form 8-K filed June 15, 2021)
10.7†	Employment Agreement by and between Helius Medical Technologies, Inc. and Jeffrey S. Mathiesen effective as of June 14, 2021 (incorporated by reference to Exhibit 10.2 to the Form 8-K filed June 15, 2021)
10.8†	2018 Omnibus Incentive Plan Form of Option Agreement – Initial Grants to Dane C. Andreeff and Jeffrey S. Mathiesen (incorporated by reference to Exhibit 10.3 to the Form 8-K filed June 15, 2021)
10.9†	Helius Medical Technologies, Inc. 2021 Inducement Plan (incorporated by reference to Exhibit 4.5 to the Form S-8 filed July 7, 2021)
10.10†	Form of Stock Option Grant Notice, Option Agreement and Notice of Exercise under the Helius Medical Technologies, Inc. 2021 Inducement Plan (incorporated by reference to Exhibit 4.6 to the Form S-8 filed July 7, 2021)
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	Coverage 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: August 12, 2021

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

Dated: August 12, 2021

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 of Helius Medical Technologies, Inc.

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

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

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

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

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

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

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

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

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

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

Date: August 12, 2021

/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 of Helius Medical Technologies, Inc.

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

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

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

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

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

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

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

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

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

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

Date: August 12, 2021

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

EXHIBIT 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
HELIUS MEDICAL TECHNOLOGIES, INC.
FORM 10-Q FOR THE QUARTER ENDED JUNE 30, 2021
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I am the Chief Executive Officer of Helius Medical Technologies, Inc., a Delaware corporation (the "Company"). I am delivering this certificate in connection with the Form 10-Q of the Company for the quarter ended June 30, 2021 and filed with the Securities and Exchange Commission ("Form 10-Q").

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

Date: August 12, 2021

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

EXHIBIT 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
HELIUS MEDICAL TECHNOLOGIES, INC.
FORM 10-Q FOR THE QUARTER ENDED JUNE 30, 2021
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I am the Chief Financial Officer of Helius Medical Technologies, Inc., a Delaware corporation (the "Company"). I am delivering this certificate in connection with the Form 10-Q of the Company for the quarter ended June 30, 2021 and filed with the Securities and Exchange Commission ("Form 10-Q").

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

Date: August 12, 2021

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