

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

FORM 10-Q

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

For the quarterly period ended March 31, 2020

OR

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

For the transition period to

Commission File No. 001-38445

HELIUS MEDICAL TECHNOLOGIES, INC.

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

642 Newtown Yardley Road, Suite 100
Newtown, Pennsylvania
(Address of principal executive offices)

36-4787690
(I.R.S. Employer
Identification No.)

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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of May 6, 2020, the registrant had 38,041,666 shares of Class A common stock, \$0.001 par value per share, outstanding.

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

	March 31, 2020	December 31, 2019
ASSETS		
Current assets		
Cash	\$ 4,360	\$ 5,459
Accounts receivable, net	110	210
Other receivables	124	364
Inventory, net of reserve	594	598
Prepaid expenses	687	610
Total current assets	5,875	7,241
Property and equipment, net	678	712
Other assets		
Goodwill	686	1,242
Intangible assets, net	687	582
Operating lease right-of-use asset, net	517	552
Other assets	18	18
Total other assets	1,908	2,394
TOTAL ASSETS	\$ 8,461	\$ 10,347
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 1,111	\$ 1,676
Accrued liabilities	1,005	1,519
Operating lease liability	180	172
Derivative financial instruments	—	5
Deferred revenue	321	430
Total current liabilities	2,617	3,802
Non-current liabilities		
Operating lease liability	417	465
Deferred revenue	218	245
TOTAL LIABILITIES	3,252	4,512
Commitments and contingencies (Note 6)		
STOCKHOLDERS' EQUITY		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding as of March 31, 2020 and December 31, 2019	—	—
Class A common stock, \$0.001 par value; 150,000,000 shares authorized; 38,041,666 and 30,718,554 shares issued and outstanding as of March 31, 2020 and December 31, 2019, respectively	38	31
Additional paid-in capital	114,967	111,479
Accumulated other comprehensive loss	(266)	(902)
Accumulated deficit	(109,530)	(104,773)
TOTAL STOCKHOLDERS' EQUITY	5,209	5,835
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 8,461	\$ 10,347

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

Helius Medical Technologies, Inc.
Unaudited Condensed Consolidated Statements of Operations and Comprehensive (Loss) Income

(Amounts in thousands except shares and per share data)

	Three Months Ended March 31,	
	2020	2019
Revenue:		
Product sales, net	\$ 191	\$ 677
Fee revenue	9	—
License revenue	7	—
Total operating revenue	207	677
Cost of sales:		
Cost of product sales	101	236
Gross profit	106	441
Operating expenses:		
Research and development	1,120	2,681
Selling, general and administrative	2,862	4,581
Amortization expense	126	—
Total operating expenses	4,108	7,262
Operating loss	(4,002)	(6,821)
Other income (expense):		
Other income	6	11
Change in fair value of derivative financial instruments	4	8,289
Foreign exchange loss	(765)	(155)
Total other income (expense)	(755)	8,145
Net income (loss)	(4,757)	1,324
Other comprehensive income (loss):		
Foreign currency translation adjustments	636	(112)
Comprehensive income (loss)	\$ (4,121)	\$ 1,212
Net income (loss) per share		
Basic	\$ (0.15)	\$ 0.05
Diluted	\$ (0.15)	\$ (0.06)
Weighted average shares outstanding		
Basic	30,972,064	25,832,190
Diluted	30,972,064	26,785,708

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

Helius Medical Technologies, Inc.
Unaudited Condensed Consolidated Statements of Stockholders' Equity for the Three Months Ended March 31, 2020 and 2019

(Except share and per 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, 2018	25,827,860	\$ 26	\$ 105,411	\$ (591)	\$ (94,992)	\$ 9,854
Proceeds from exercise of stock options and warrants	16,320	—	92	—	—	92
Stock-based compensation	—	—	835	—	—	835
Reclassification of derivative financial instruments from the exercise of warrants	—	—	25	—	—	25
Foreign currency translation adjustments	—	—	—	(112)	—	(112)
Net income	—	—	—	—	1,324	1,324
Balance as of March 31, 2019	25,844,180	\$ 26	\$ 106,363	\$ (703)	\$ (93,668)	\$ 12,018

	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	30,718,554	\$ 31	\$ 111,479	\$ (902)	\$ (104,773)	\$ 5,835
Proceeds from the issuance of common stock from At-the-Market program	1,065,968	1	802	—	—	803
Proceeds from issuance of common stock from the March 2020 Offering	6,257,144	6	1,342	—	—	1,348
Warrant issuance from the March 2020 Offering	—	—	842	—	—	842
Share issuance costs	—	—	(340)	—	—	(340)
Stock-based compensation	—	—	842	—	—	842
Foreign currency translation adjustments	—	—	—	636	—	636
Net loss	—	—	—	—	(4,757)	(4,757)
Balance as of March 31, 2020	38,041,666	\$ 38	\$ 114,967	\$ (266)	\$ (109,530)	\$ 5,209

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

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

	March 31,	
	2020	2019
Cash flows from operating activities:		
Net income (loss)	\$ (4,757)	\$ 1,324
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Change in fair value of derivative financial instruments	(4)	(8,289)
Stock-based compensation expense	842	835
Unrealized foreign exchange loss	738	176
Depreciation expense	37	22
Amortization expense	126	—
Provision for doubtful accounts	139	—
Intangible asset impairment	174	—
Changes in operating assets and liabilities:		
Accounts receivable	(39)	(740)
Other receivables	240	(84)
Inventory	4	(339)
Prepaid expenses	(77)	95
Other current assets	—	264
Operating lease liability	(5)	(3)
Accounts payable	(626)	83
Accrued liabilities	(459)	(144)
Deferred revenue	(84)	—
Net cash used in operating activities	(3,751)	(6,800)
Cash flows from investing activities:		
Purchase of property and equipment	(3)	(161)
Internally developed software	(7)	—
Net cash used in investing activities	(10)	(161)
Cash flows from financing activities:		
Proceeds from the issuances of common stock and warrants	2,992	—
Share issuance costs	(340)	(52)
Proceeds from the exercise of stock options and warrants	—	92
Net cash provided by financing activities	2,652	40
Effect of foreign exchange rate changes on cash	10	(6)
Net decrease in cash	(1,099)	(6,927)
Cash at beginning of period	5,459	25,583
Cash at end of period	\$ 4,360	\$ 18,656

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

1. DESCRIPTION OF BUSINESS

Helius Medical Technologies, Inc. (“we” or 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 (“PoNSTTM”), is an authorized class II, non-implantable medical device authorized for sale in Canada. PoNS is intended as a short term treatment (14 weeks) of chronic balance deficit due to mild-to-moderate traumatic brain injury (“mTBI”) and is to be used in conjunction with physical therapy (“PoNS TreatmentTM”), and is indicated as a short term treatment (14 weeks) of gait deficit due to mild and moderate symptoms from Multiple Sclerosis (“MS”) and is to be used in conjunction with physical therapy. It is an investigational medical device in the United States, the European Union (“EU”), and Australia (“AUS”), and it is currently under review for clearance by the AUS Therapeutic Goods Administration. PoNS TreatmentTM is not currently commercially available in the United States, the European Union or Australia.

The Company was incorporated in British Columbia, Canada on March 13, 2014. On May 28, 2014, we were reincorporated from British Columbia to the State of Wyoming, and on July 20, 2018, we were reincorporated from the State of Wyoming to the State of Delaware. We are 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.

The Company’s Class A common stock, par value \$0.001 per share (“common stock”), is listed on the Nasdaq Capital Market (“Nasdaq”) and the Toronto Stock Exchange (the “TSX”). The common stock began trading on the Canadian Securities Exchange on June 23, 2014, under the ticker symbol “HSM” and the trading was subsequently transferred to the TSX on April 18, 2016. On April 11, 2018, the common stock began trading on Nasdaq under the ticker symbol “HSDT” after having traded on the OTCQB in the United States under the ticker symbol “HSDT” since February 10, 2015.

Going Concern Uncertainty

As of March 31, 2020, the Company had cash of \$4.4 million. For the three months ended March 31, 2020, the Company had an operating loss of \$4.0 million, and as of March 31, 2020, its accumulated deficit was \$109.5 million. For the three months ended March 31, 2020, 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.

The Company intends to fund ongoing activities by utilizing its current cash on hand, cash received from the sale of its PoNSTTM 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

The Company’s business, results of operations and financial condition may be adversely impacted by economic conditions, including the global health concerns relating to the coronavirus (“COVID-19”) pandemic. 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 has led to the closure of PoNS Authorized clinic locations across Canada. Timing for re-opening these clinics is uncertain at this time, and could result in a decrease of our commercial activities, and may have a negative impact on our customer engagement efforts. Moreover, the Company’s ability to conduct its ongoing clinical research may be impaired if trial participants or staff are adversely affected by COVID-19, leading to further delays in the development and approval of the Company’s product candidate. In addition, disruptions in business operations in the United States, Canada and China due to COVID-19 may delay the timing for the submission and approval of the Company’s marketing applications with regulatory agencies or limit the Company’s suppliers’ ability to ship materials that the Company relies upon due to delays or suspension of manufacturing operations. COVID-19 could also disrupt governmental operations or impair the Company’s ability to access the public markets to obtain the necessary capital and continue the Company’s operations. The extent to which the COVID-19 pandemic impacts 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 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, 2019, included in its Annual Report on Form 10-K that was filed with the Securities and Exchange Commission on March 12, 2020. 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. Certain prior period amounts have been reclassified to conform to the current period presentation.

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 required allowance required judgment by Company management. As of March 31, 2020, the Company’s accounts receivable of \$0.1 million, is net of an allowance for doubtful accounts of \$0.3 million and is the result of revenue from product sales. As of December 31, 2019, the Company’s accounts receivable of \$0.4 million, is net of an allowance for doubtful accounts of \$0.2 million and is the result of revenue from product sales.

Other receivables as of March 31, 2020 and December 31, 2019 included refunds from research and development (“R&D”) tax credits of \$44 thousand and \$0.2 million, respectively, and Goods and Services Tax (“GST”) and Quebec Sales Tax (“QST”) refunds of \$80 thousand and \$0.1 million, respectively, related to the Company’s Canadian expenditures.

Inventory

The Company’s inventory consists of raw materials, work in progress and finished goods of the PoNS device. Inventory is stated at the lower of cost (average cost method) or net realizable value. Adjustments to reduce the cost of inventory to its net realizable value are made if required. The Company calculates provisions for excess inventory based on inventory on hand compared to anticipated sales or usage. Management uses its judgment to forecast sales or usage and to determine what constitutes a reasonable period. There can be no assurance that the amount ultimately realized for inventories will not be materially different than that assumed in the calculation of the reserves. Inventory markdowns to net realizable value of \$2 thousand were recorded during the three months ended March 31, 2020. No inventory markdowns to net realizable value were recorded during the three months ended March 31, 2019.

As of March 31, 2020 and December 31, 2019, inventory consisted of the following (amounts in thousands):

	As of March 31, 2020	As of December 31, 2019
Raw materials	\$ 151	\$ 144
Work-in-process	466	375
Finished goods	29	129
Inventory	\$ 646	\$ 648
Inventory reserve	(52)	(50)
Total inventory, net of reserve	\$ 594	\$ 598

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; and equipment has an estimated useful life of 15 years, while computer software and hardware has an estimated useful life of 3 to 5 years.

As of March 31, 2020 and December 31, 2019, property and equipment consisted of the following (amounts in thousands):

	As of March 31, 2020	As of December 31, 2019
Leasehold improvement	\$ 182	\$ 182
Furniture and fixtures	247	247
Equipment	289	286
Computer software and hardware	182	182
Property and equipment	900	897
Less accumulated depreciation	(222)	(185)
Property and equipment, net	\$ 678	\$ 712

Depreciation expense of \$37 thousand and \$22 thousand for the three months ended March 31, 2020 and 2019, respectively.

Business Combinations

Transactions in which the Company obtains control of a business are accounted for according to the acquisition method as described in FASB ASC 805 – Business Combinations. The assets acquired and liabilities assumed are recognized and measured at their fair values as of the date control is obtained. Acquisition related costs in connection with a business combination are expensed as incurred. Contingent consideration is recognized and measured at fair value at the acquisition date and until paid re-measured on a recurring basis. It is classified as a liability based on appropriate GAAP.

On October 30, 2019, the Company and HTC entered into a Share Purchase Agreement (the "SPA") whereby the Company, through its wholly owned subsidiary, acquired Heuro from HTC. Under the terms of the SPA, total consideration of approximately CAD\$2.1 million (USD\$1.6 million) was transferred to HTC, which included (1) cash of CAD\$0.5 million (USD\$0.4 million), (2) delivery of 55 PoNS devices for which the fair value was determined to be CAD\$0.5 million (USD\$0.4 million), (3) the forgiveness of CAD\$750 thousand (USD\$0.5 million) 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 with a determined fair value of CAD\$0.4 million (USD\$0.3 million). The transaction has been accounted for as a business combination.

The acquisition related costs were \$0.1 million and were accounted for as selling, general and administrative expenses in the consolidated statement of operations and comprehensive loss for the year ended December 31, 2019.

Supplemental proforma financial information has not been presented here because the proforma effects of this acquisition are not material to the Company's reported results for any period presented.

The following table summarizes the recognized fair values of identifiable assets acquired and liabilities assumed as of October 30, 2019:

	October 30, 2019 Fair Value
Assets:	
Cash and cash equivalents	\$ 1
Other receivables	19
Fixed assets	7
Intangibles	1,053
Goodwill	737
Total assets	\$ 1,817
Liabilities:	
Accounts payable	\$ 186
Other current liabilities	9
Total liabilities	\$ 195
Net assets acquired	\$ 1,622

The fair values assigned to identifiable intangible assets assumed were based on management's current estimates and assumptions and is considered preliminary. The Company believes that the most recent information available provides a reasonable basis for assigning fair value, but anticipates receiving additional information, and as such, the provisional measurements of fair value are subject to change. The Company recorded measurement adjustments of \$0.4 million during the three months ended March 31, 2020. The recorded adjustments related to the recognition of reacquired exclusivity rights. The Company will finalize the amounts recognized as it obtains the information necessary to complete the analysis, but no later than one year from the acquisition date.

Acquired intangibles consisted of customer relationships, proprietary technology and reacquired rights. The remaining useful life at acquisition was 1.25 years, 5 years and 3.87 years, respectively, and the acquired intangibles are amortized using the straight-line method.

Factors considered by the Company in determination of goodwill include synergies, strategic fit and other benefits that do not meet the recognition criteria of acquired identifiable intangible assets. The recognized goodwill of \$0.6 million is not expected to be deductible for tax purposes.

The fair value of the 55 PoNS devices in the amount of CAD\$0.5 million will be recognized as revenue within the consolidated statements of operations and comprehensive loss once control has been transferred in accordance with ASC 606. As of December 31, 2019, the control had not been transferred resulting in the fair value being recorded as deferred revenue on the condensed consolidated balance sheet. As of March 31, 2020, the control of 11 devices had been transferred resulting in recognition of revenue for these devices. The fair value of the remaining 44 devices is still recorded as deferred revenue on the condensed consolidated balance sheet.

In connection with the SPA, on October 30, 2019, the Company entered into a Clinical Research and Co-Promotion Agreement with HTC (the "Co-Promotion Agreement"), whereby each company will promote the sales of the Company's PoNS Treatment and HTC's NeuroCatch™ device throughout Canada. This co-promotion arrangement terminates upon the earlier of the collection of data from 200 patients in Canada and December 31, 2020. Also, subject to certain terms and conditions, Helius 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 the Company and on terms no less favorable than the then-current standard terms and conditions. This exclusivity right has an initial term of ten (10) years, renewable by HTC for one additional ten (10) year term upon sixty (60) days' written notice to Helius. The Co-Promotion Agreement had a fair value of CAD\$360 thousand at the time of acquisition. License revenue will be recognized in connection with the Co-Promotion Agreement ratably over the ten-year term.

Goodwill and Other Intangible Assets

Goodwill represents the excess of purchase price over the fair values underlying net assets acquired in an acquisition. All of the Company's goodwill as of March 31, 2020 is the result of the Heuro acquisition discussed above. 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 COVID-19 pandemic was a triggering event for testing whether goodwill is impaired. As of March 31, 2020, the Company performed a quantitative assessment and 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 March 31, 2020. 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 March 31, 2020 for goodwill:

Goodwill	2020	
Carrying amount at beginning of period	\$	1,242
Business acquisition fair value allocation adjustment		(454)
Foreign currency translation		(102)
Carrying amount at end of period	<u>\$</u>	<u>686</u>

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 \$0.1 million during the three months ended March 31, 2020. No amortization expense related to intangible assets was recorded during the three months ended March 31, 2019. During the three months ended March 31, 2020, the Company incurred an intangible asset impairment loss of \$0.2 million related to the customer relationships, which is included in selling, general and administrative expenses in the accompanying consolidated statement of operations.

Intangible assets as of March 31, 2020 and December 31, 2019 consist of the following:

	Useful Life	As of March 31, 2020		As of December 31, 2019	
		Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Customer relationships	1.25 years	\$ 215	\$ (130)	\$ 423	\$ (55)
Acquired proprietary software	5 years	136	(11)	148	(5)
Reacquired rights	3.87 years	454	(49)	-	-
Internally developed software	3 years	82	(10)	75	(4)
Total intangible assets		<u>\$ 887</u>	<u>\$ (200)</u>	<u>\$ 646</u>	<u>\$ (64)</u>

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

For the Year Ending December 31,	
2020 (remaining 9 months)	\$ 206
2021	180
2022	168
2023	110
2024	23
	<u>\$ 687</u>

Leases

On January 1, 2019, the Company adopted ASU No. 2016-02, *Leases*, using the modified retrospective method. The Company elected the package of practical expedients permitted under the transition guidance within the new standard which allowed the Company to carry forward the historical lease classification. Adoption of this standard resulted in the recording of an operating lease right-of-use (“ROU”) asset and corresponding operating lease liabilities of \$0.7 million on January 1, 2019.

The Company does not record an operating lease ROU asset and corresponding lease liability for leases with an initial term of twelve months or less and recognizes lease expense for these leases as incurred over the lease term. As of March 31, 2020, the Company had only one operating lease, which was for its headquarters office in Newtown, Pennsylvania upon the adoption date. As of March 31, 2020, the Company has not entered into any additional lease arrangements. 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. As of March 31, 2020, approximately \$0.2 million of the Company's operating lease ROU asset had been amortized (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 (loss) gain.

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 (loss) gain, 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.

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 conditions.

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

During the first half of 2019, product sales were derived from the sale of the PoNS device and certain support services including services from the use of the NeuroCatch™ device, which is owned by HTC and assesses electroencephalogram brain waves related to cognition of patients participating in the PoNS Treatment at neuroplasticity clinics in Canada. The Company acted in an agency capacity for services performed using the NeuroCatch device and remitted CAD\$600 for each patient assessed with the NeuroCatch device. 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. Further, according to the Company's arrangement with HTC and Heuro, the Company shared 50/50 with Heuro in fees from support services excluding the CAD\$600 payment for an assessment using the NeuroCatch device. For the three months ended March 31, 2019, the Company recorded \$0.7 million in product sales net of \$25 thousand for HTC's portion related to services performed using the NeuroCatch device. As described above, the Company modified its arrangement with HTC on October 30, 2019 and product sales were derived from the sale of the PoNS device alone as the NeuroCatch is sold directly to the neuroplasticity clinics in Canada by HTC. For the three months ended March 31, 2020, the Company recorded \$0.2 million in product sales. As of March 31, 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 \$0.2 million in product sales. The fair value of the remaining 44 devices is recorded as deferred revenue of \$0.3 million on the condensed consolidated balance sheet. The only returns during the three months ended March 31, 2020 were the result of warranty returns for defective products. These returns were insignificant and any future replacements are expected to be immaterial.

Fee Revenue

During the three months ended March 31, 2020, the Company recognized \$9 thousand of fee revenue related to engaging new neuroplasticity clinics to provide the PoNS Treatment. During the three months ended March 31, 2019, the Company did not recognize any fee revenue associated with the Company's agreement with HTC and Heuro that entitled the Company to 50% of the franchise fees collected by Heuro from each executed franchise agreement. As of March 31, 2020 and December 31, 2019, the Company had no contract assets or liabilities on its consolidated balance sheets related to the supply agreements with each clinic.

License Revenue

The Company did not record any license revenue during the first quarter of 2019. As described above, the Company modified its arrangement with HTC on October 30, 2019. License revenue will be recognized ratably over the ten-year term as the performance obligation is met in connection with the Co-Promotion Agreement. During the three months ended March 31, 2020, the Company recognized revenues of \$7 thousand in license fees associated with the Co-Promotion Agreement. Revenue not yet recognized of \$0.2 million is recorded as deferred revenue on the condensed consolidated balance sheet.

Cost of Sales

Cost of product sales includes the cost to manufacture the PoNS device, 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 and certain support services provided by Heuro on the Company's behalf.

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. Currently, we do not believe the CARES Act will have 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*. 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 March 31, 2020 and December 31, 2019, the Company’s derivative financial instruments 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.

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, operating lease ROU asset and non-current receivables 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 March 31, 2020 and December 31, 2019 and the roll forward of the Company's derivative financial instruments. The Company's derivative financial instruments are comprised of warrants which are classified as liabilities.

The following table summarizes the Company's recurring fair value measurements for derivative financial instruments and stock-based compensation liability within the fair value hierarchy as of March 31, 2020 and December 31, 2019 (amounts in thousands):

	<u>Fair Value</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
March 31, 2020				
Liabilities:				
Derivative financial instruments	\$ —	—	—	\$ —
December 31, 2019				
Liabilities:				
Derivative financial instruments	\$ 5	—	—	\$ 5

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 three months ended March 31, 2020 of \$0.2 million and has a remaining net book value of \$0.1 million as of March 31, 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.

Basic and Diluted 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) income per share for the periods noted below is as follows (amounts in thousands except shares and per share data):

	Three Months Ended	
	March 31,	
	2020	2019
Basic		
Numerator:		
Net income (loss)	\$ (4,757)	\$ 1,324
Denominator:		
Weighted average common shares outstanding	30,972,064	25,832,190
Basic net income (loss) per share	\$ (0.15)	\$ 0.05
Diluted		
Numerator:		
Net income (loss), basic	\$ (4,757)	\$ 1,324
Effect of dilutive securities: warrants	—	(2,809)
Net loss, diluted	\$ (4,757)	\$ (1,485)
Denominator:		
Weighted average common shares outstanding - basic	30,972,064	25,832,190
<i>Potential common share issuances:</i>		
Incremental dilutive shares from equity instruments (treasury stock method)	—	953,518
Weighted average common shares outstanding	30,972,064	26,785,708
Diluted net loss per share	\$ (0.15)	\$ (0.06)

The following outstanding securities have been excluded from the computation of diluted weighted shares outstanding for the periods noted below, as they would have been anti-dilutive due to the Company's (losses) earnings for the three months ended March 31, 2020 and 2019 and because the exercise price of certain of these outstanding securities was greater than the average closing price of the Company's common stock.

	Three Months Ended March 31,	
	2020	2019
Stock options outstanding	3,807,417	1,799,795
RSUs	111,305	—
Warrants outstanding	9,300,749	3,043,605
Total	13,219,471	4,843,400

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 Small 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 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*, which adds disclosure requirements to Topic 820 for the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. This ASU is effective for interim and annual reporting periods beginning after December 15, 2019. The Company adopted this standard as of January 1, 2020 and the adoption did not have a material impact on the Company's condensed consolidated financial statements.

In November 2018, FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606*, which, among other things, provides guidance on how to assess whether certain collaborative arrangement transactions should be accounted for under Topic 606. The amendments in this ASU are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted. The Company adopted this standard on January 1, 2020 and the adoption did not have a material impact on the Company's condensed consolidated financial statements.

3. COMMON STOCK AND WARRANTS

The Company's authorized capital stock pursuant to its Delaware charter consists of 150,000,000 authorized shares of common stock, at a par value per share of \$0.001 and 10,000,000 authorized shares of preferred stock at a par value per share of \$0.001. Holders of common stock are entitled to vote at any meeting of the Company's stockholders on the basis of one vote per share of common stock owned as of the record date of such meeting. Each share of common stock entitles the holder to receive dividends, if any, as declared by the Company's Board of Directors.

No dividends have been declared since inception of the Company through March 31, 2020. 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 2,141,900 shares of its common stock and warrants to purchase 2,141,900 shares of the Company's common stock in an underwritten public offering at a price of \$7.47 per share and accompanying warrant. Gross proceeds from the offering were approximately \$16.0 million. On April 24, 2018, the Company closed on the sale of an additional 321,285 shares of its common stock and warrants pursuant to the exercise of the over-allotment option (collectively the “April 2018 Offering”) granted to the underwriters in connection with the offering at a price of \$7.47 per share and accompanying warrants. Gross proceeds from the exercise of the over-allotment option was \$2.4 million. BTIG, LLC and Echelon Wealth Partners acted as joint book-running managers for the April 2018 Offering. The Company paid approximately \$1.1 million in underwriting discounts and commissions and incurred offering expenses of approximately \$1.0 million in connection with the April 2018 Offering, resulting in net proceeds of \$16.3 million from the April 2018 Offering. The underwriting discounts and commissions and offering expenses were allocated between share issuance costs and expenses based on the relative fair values of common stock and warrants issued in connection with the April 2018 Offering, resulting in the recording of approximately \$0.8 million of expenses in the Company's condensed consolidated statement of operations and comprehensive loss. The fair value of these warrants at issuance was approximately \$7.4 million.

Each warrant issued in connection with the April 2018 Offering entitles the holder to acquire one additional share of common stock at an exercise price of CAD\$12.25 per share on or before April 10, 2021. Pursuant to the guidance of ASC 815 *Derivatives and Hedging*, the Company has 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 is outside of the Company's control and that it may be required to settle the exercise of the warrants in cash and because, as

a result of the change in the Company's functional currency (see Note 2), the exercise prices of these warrants are 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 March 31, 2020, 70,900 warrants had been exercised, all during 2018, for gross proceeds of CAD\$0.9 million.

The following table summarizes the weighted average assumptions used in estimating the fair value of the warrants granted 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 and March 31, 2020.

	March 31, 2020	April 24, 2018	April 13, 2018
Stock price	CAD\$ 0.46	CAD\$ 10.76	CAD\$ 9.85
Exercise price	CAD\$ 12.25	CAD\$ 12.25	CAD\$ 12.25
Warrant term	1.03 years	3.00 years	3.00 years
Expected volatility	91.69%	64.49%	64.20%
Risk-free interest rate	0.38%	2.02%	1.99%
Dividend rate	0.00%	0.00%	0.00%

On November 22, 2019, the Company issued 4,815,010 shares of its common stock in an underwritten public offering at a price of \$0.35 per share. Gross proceeds from the offering (the "November 2019 Offering") were approximately \$1.7 million. H.C. Wainwright & Co., LLC ("Wainwright") acted as book-running manager for the November 2019 Offering. The Company paid approximately \$0.1 million in underwriting discounts and commissions and incurred offering expenses of approximately \$0.5 million, resulting in net proceeds of \$1.1 million, in connection with the November 2019 Offering.

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"). The 2020 Shelf provides for the public offer and sale of certain securities of the Company from time to time, at its discretion, up to an aggregate offering amount of \$100 million. In conjunction with the 2020 Shelf, on January 27, 2020, the Company entered into an At The Market Offering Agreement (the "2020 ATM") with 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. For three months ended March 31, 2020, under the 2020 ATM, the Company sold and issued 1,065,968 shares of its common stock with an aggregated market value of \$0.8 million at an average price of \$0.75 per share and paid Wainwright a sales commission of approximately \$28 thousand related to those shares.

On March 18, 2020, the Company filed a Prospectus Supplement which amended and supplemented the information in the 2020 Shelf to decrease the amount of common stock offered pursuant to the 2020 ATM to \$9.15 million, including the shares previously sold under the 2020 ATM.

On March 20, 2020, the Company, in a registered direct offering, issued an aggregate of 6,257,144 shares of its common stock at a price of \$0.35 per share. Additionally, the Company issued unregistered warrants in a concurrent private placement to purchase up to 6,257,144 shares of its common stock at a price of \$0.46 per share. Gross proceeds from the offering (the "March 2020 Offering") were approximately \$2.2 million. H.C. Wainwright & Co. acted as book-running manager for the March 2020 Offering. 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 \$0.46 per share, which will be 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 the warrants can be settled with unregistered shares. The relative fair value of these warrants at issuance was approximately \$0.8 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 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	\$ 0.35
Exercise price	\$ 0.46
Warrant term	5.50 years
Expected volatility	82.41%
Risk-free interest rate	0.52%
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 three months ended March 31, 2020 and 2019 (amounts in thousands):

	Three Months Ended March 31,	
	2020	2019
Fair value of warrants at beginning of period	\$ 5	\$ 13,769
Exercise of warrants	—	(25)
Foreign exchange losses	—	288
Change in fair value of warrants during the period	(5)	(8,289)
Fair value of warrants at end of period	\$ —	\$ 5,743

These warrants which are classified as derivative financial instruments in the Company's condensed consolidated balance sheets are 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 will continue to be classified as a liability until such time as they are exercised, expire or there is an amendment to the respective agreements that renders these financial instruments to be no longer classified as such.

The fair value of all warrants classified as derivative financial instruments outstanding as of March 31, 2020 and December 31, 2019 were estimated using the Black-Scholes option pricing model with the following weighted average assumptions:

	March 31, 2020	December 31, 2019
Stock price	CAD\$ 0.46	CAD\$ 1.23
Exercise price	CAD\$ 12.25	CAD\$ 12.25
Warrant term	1.03 years	1.28 years
Expected volatility	91.69%	72.43%
Risk-free interest rate	0.38%	1.72%
Dividend rate	0.00%	0.00%

The following is a summary of the Company's warrant activity during the three months ended March 31, 2020:

	Number of Warrants		Weighted Average Exercise Price	
	CAD	US	CAD\$	USD\$
Outstanding as of December 31, 2019	2,392,285	651,320	\$ 12.25	\$ 12.24
Granted	—	6,257,144	—	0.46
Cancelled/Expired	—	—	—	—
Exercised	—	—	—	—
Outstanding as of March 31, 2020	2,392,285	6,908,464	\$ 12.25	\$ 1.57

The Company's warrants outstanding and exercisable as of March 31, 2020 were as follows:

Number of Warrants Outstanding	Exercise Price	Expiration Date
3,795	USD\$10.75	June 26, 2020
1,509	USD\$10.75	July 17, 2020
270,915	USD\$12.25	December 22, 2020
171,020	USD\$12.25	December 28, 2020
204,081	USD\$12.25	December 29, 2020
2,392,285	CAD\$12.25	April 10, 2021
6,257,144	USD\$0.46	March 20, 2025
9,300,749		

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 ("2018 Plan"), under which an aggregate of 5,356,114 shares may be issued. This share reserve is the sum of 3,000,000 new shares, plus the remaining 2,356,114 shares that remained available for issuance 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. 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 ("RSU"), stock equivalent units and performance-based cash awards. These awards may be granted to directors, officers, employees and eligible consultants. Vesting and the term of

an option is determined at the discretion of the Company's Board of Directors. Subsequent to the adoption of the 2018 Plan, the Company ceased granting awards under the 2016 Plan, the predecessor incentive plan. However, outstanding stock options granted prior to the effective date of the 2018 Plan are still governed by the 2016 Plan or the Company's 2014 Stock Incentive Plan, which preceded the 2016 Plan.

As of March 31, 2020, there was an aggregate of 3,645,038 shares of common stock remaining available for grant under the Company's 2018 Plan.

For the three months ended March 31, 2020, the Company issued 368,000 stock options to employees. The Company issued no stock options to consultants and non-employees during the three months ended March 31, 2020.

The following is a summary of the Company's stock option activity during the three months ended March 31, 2020:

	<u>Number of Stock Options</u>	<u>Weighted Average Exercise Price</u>	<u>Aggregate Intrinsic Value (in thousands)</u>
Outstanding as of December 31, 2019	3,467,292	\$ 6.76	\$ —
Granted	368,000	0.32	
Forfeited/Cancelled	(27,875)	(5.28)	
Exercised	—	—	
Outstanding as of March 31, 2020	<u>3,807,417</u>	<u>\$ 6.15</u>	<u>\$ —</u>
Exercisable as of March 31, 2020	<u>2,032,782</u>	<u>\$ 3.79</u>	<u>\$ —</u>

As of March 31, 2020, the unrecognized compensation cost related to non-vested stock options outstanding for employees and directors, was \$5.0 million which will be recognized over a weighted-average remaining vesting period of approximately 2.8 years. Compensation cost is not adjusted for estimated forfeitures, but instead is adjusted upon an actual forfeiture of a stock option.

The weighted average grant date fair value of employee and director stock options granted for the three months ended March 31, 2020 was \$0.22 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:

	<u>Three Months Ended March 31, 2020</u>
Stock price	\$ 0.32
Exercise price	\$ 0.32
Expected term	6.25 years
Expected volatility	80.46%
Risk-free interest rate	0.85%
Dividend rate	0.00%

As of March 31, 2020, the unrecognized compensation cost related to non-vested stock options outstanding for non-employees was \$33 thousand which will be recognized over a weighted-average remaining vesting period of approximately 1.3 years. Compensation cost is not adjusted for estimated forfeitures, but instead is adjusted upon an actual forfeiture of a stock option.

Restricted Stock Awards

During the fourth quarter of 2019, certain members of the Company's executive management team elected to receive restricted stock awards in lieu of cash compensation under the 2018 Plan that vest upon issuance. The fair value of the restricted stock awards was 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 restricted stock award activity for the three months ended March 31, 2020:

	<u>Number of Restricted Stock Units</u>	<u>Weighted Average Grant Date Fair Value per Unit</u>
Outstanding as of December 31, 2019	27,697	\$ 0.61
Granted	83,608	\$ 0.64
Outstanding as of March 31, 2020	<u>111,305</u>	<u>\$ 0.63</u>

Stock-Based Compensation Expense

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

	Three Months Ended March 31,	
	2020	2019
Research and development	\$ 239	\$ 195
Cost of sales	1	3
Selling, general and administrative	602	637
Total	\$ 842	\$ 835

5. ACCRUED EXPENSES

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

	As of	
	March 31, 2020	December 31, 2019
Employees benefits	\$ 247	\$ 722
Professional services	37	67
Legal fees	108	81
Royalty fees	17	13
Franchise fees	33	28
Severance	412	606
Other	151	2
Total	\$ 1,005	\$ 1,519

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 3,207,005 shares of common stock to ANR, the Company agreed to pay a 4% royalty on net revenue on the sales of devices covered by the patent-pending technology and services related to the therapy or use of devices covered by the patent-pending technology. For the three months ended March 31, 2020 and March 31, 2019, the Company recorded approximately \$5 thousand and \$27 thousand, respectively, in royalty expenses in its condensed consolidated statement of operations.
- (b) On October 30, 2017, HMI amended the Asset Purchase Agreement with A&B (HK) Company Ltd. (“A&B”) which specified that if the Company fails to obtain FDA marketing authorization for commercialization of or otherwise fails to ensure that the PoNS device is available for purchase by the U.S. Government by December 31, 2021, the Company would be subject to a \$2.0 million contract penalty payable to A&B, unless the Company receives an exemption for the requirement of FDA marketing authorization from the U.S. Army Medical Material Agency. In December 2018, the U.S. Army notified the Company that it was amending the Agreement such that the satisfaction of the obligation of the contract was changed from FDA marketing authorization of the PoNS device to submitting of an application for marketing authorization of the PoNS device with the FDA. As the Company submitted its application for marketing authorization of the PoNS device to the FDA on August 31, 2018, and with copies of the submission documents provided to the U.S. Army, the Company has met its obligation under the amended agreement. Based on this amendment the Company has determined that the possibility of a payment under this contractual penalty is remote.
- (c) In March 2017, the Company entered into a lease for office space in Newtown, Pennsylvania. The initial term of the lease is 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 will be approximately \$20 thousand per month beginning in January 2018 with a 3% annual increase.

The following table summarizes the Company's operating lease information including future minimum lease payments under a non-cancellable lease as of March 31, 2020 (amounts in thousands).

<u>For the Three Months Ended March 31, 2020</u>	
Operating lease cost	\$ 50
Operating lease - operating cash flows	\$ 63
Weighted average remaining lease term	2.80 years
Weighted average discount rate	15.1%
Future minimum lease payments under non-cancellable lease as of March 31, 2020 were as follows:	
<u>For the Period Ending December 31,</u>	
2020 (remaining nine months)	\$ 190
2021	260
2022	267
2023	10
Total future minimum lease payments	727
Less imputed interest	(130)
Total liability	\$ 597
<u>Reported as of March 31, 2020</u>	
Current operating lease liability	180
Non-current operating lease liability	417
Total	\$ 597

- (d) 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. As of March 31, 2020, 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.
- (e) The Company was granted a \$323,000 loan on April 13, 2020 under the Paycheck Protection Program (the “PPP Loan”) established under the CARES Act. The Company planned to use the proceeds from the PPP Loan for covered payroll costs, rent and utilities in accordance with the relevant terms and conditions of the CARES Act. However, based upon subsequent guidance issued by the Federal Government, including a presumption that no publicly traded companies are eligible for a PPP loan, the Company intends to return the PPP Loan proceeds within the time period imposed under these new guidelines out of an abundance of caution, subject to any additional guidance that may be issued by the Federal Government on eligibility criteria for public companies who have already been granted PPP loans.

Legal Contingencies

On or about July 9, 2019, a putative shareholder class action lawsuit, *Caramahai v. Helius Medical Technologies, Inc. et al.*, Case No. 1:19-cv-06365 (S.D.N.Y.), was filed against the Company and three of its individual officers in the Southern District of New York (“the *Caramahai* Action”). The lawsuit alleges that the Company made materially false and misleading statements regarding the prospects for FDA approval of Helius’ application for de novo classification and marketing authorization of its PoNS device in the United States. As a result of these alleged misstatements, the *Caramahai* Action asserts claims on behalf of shareholders who bought or sold Helius common stock between from November 9, 2017 to April 10, 2019 for alleged violations of the federal securities laws, specifically Section 10(b) and Rule 10b-5 of the Securities Exchange Act of 1934, as amended.

On or about July 31, 2019, a putative shareholder class action lawsuit, *Evans v. Helius Medical Technologies, Inc. et al.*, Case No. 1:19-cv-07171 (S.D.N.Y.), was filed against the Company and three of its individual officers in the Southern District of New York (the “*Evans* Action”). The *Evans* Action alleges similar claims as the *Caramahai* Action.

On September 9, 2019, three Helius shareholders each filed motions in the *Caramahai* and *Evans* cases seeking to consolidate the two proceedings into a single putative class action. The individual motions also sought to have the movant appointed as Lead Plaintiff (the plaintiff responsible for prosecuting the class’s claims and has the power to settle and release claims of all class members) and have the movant’s attorneys appointed as Lead Counsel. On September 13 and 17, 2019, respectively, two of the movants filed notices withdrawing their motions on the ground that they did not appear to have “the largest financial interest in the relief sought by the class.” The third movant was appointed Lead Plaintiff on April 28, 2020 and movant’s attorneys were appointed as Lead Counsel.

While the Company believes that each of the *Caramahai* Action and the *Evans* Action is without merit and intends to vigorously defend its position in each case, it recognizes that additional putative class actions or related proceedings may be filed. Given that each of these legal proceedings is in its early stages, the Company is unable to predict the probable outcomes at this time.

7. RELATED PARTY TRANSACTIONS

During the three months ended March 31, 2020 and 2019, the Company paid approximately \$5 thousand and \$10 thousand respectively, in consulting fees to a director of the Company. As of March 31, 2020, the Company did not have an accrued liability for consulting fees to a director of the Company.

8. SUBSEQUENT EVENTS

The Company received a letter (the “Notice”) from the Listing Qualifications staff of Nasdaq indicating that, based on the closing bid price of the Company’s common stock for the last 30 consecutive business days, the Company no longer meets the requirement to maintain a minimum bid price of \$1.00 per share, as set forth in Nasdaq Listing Rule 5550(a)(2). The Notice does not result in the immediate delisting of the Company’s common stock from Nasdaq. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company has been provided a period of 180 calendar days, or until September 21, 2020, in which to regain compliance. In order to regain compliance with the minimum bid price requirement, the closing bid price of the Company’s common stock must be at least \$1.00 for a minimum of ten consecutive business days during this 180-day period. In the event that the Company does not regain compliance within this 180-day period, the Company may be eligible to see an additional compliance period of 180 calendar days if it meets the continued listing requirement for market value of publicly held shares and all other initial listing standard for Nasdaq, with the exception of the bid price requirement, and provides written notice to Nasdaq of its intent to cure the deficiency during this second compliance period, by effecting a reverse stock split, if necessary.

On April 17, 2020, the Company received a second letter (the “Second Notice”) for the Listing Qualifications staff of Nasdaq stating that due to unprecedented turmoil in U.S. and world financial markets resulting from the COVID-19 pandemic, investor confidence has been diminished resulting in depressed prices for companies that otherwise remain suitable for continued listing. Given these extraordinary market conditions, Nasdaq has determined to toll the compliance periods for bid price and market value of publicly held shares (“MVPHS”) requirements (collectively, the “Price-based Requirements”) through June 30, 2020. As a result, companies presently in compliance periods for any Price-based Requirements will remain at that same stage of the process and will not be subject to being delisted for these concerns. Starting on July 1, 2020, companies will receive the balance of any pending compliance period in effect at the start of the tolling period to regain compliance.

Accordingly, since the Company had 158 calendar days remaining in its Bid compliance period as of April 16, 2020, it will, upon reinstatement of the Price-based Requirements, still have 158 calendar days from July 1, 2020, or until December 3, 2020, to regain compliance. The Company can regain compliance, either during the suspension or during the compliance period resuming after the suspension, by evidencing compliance with the Price-based Requirements for a minimum of 10 consecutive trading days.

If the Company’s common stock is delisted from Nasdaq, its ability to raise capital through public offerings of the Company’s securities and to finance its operations could be adversely affected. The Company also believes that delisting would likely result in decreased liquidity and/or increased volatility in its common stock and could harm the Company’s business and future prospects. In addition, the Company believes that, if its common stock is delisted, the Company’s stockholders would likely find it more difficult to obtain accurate quotations as to the price of the common stock and it may be more difficult for stockholders to buy or sell the Company’s common stock at competitive market prices, or at all.

On April 13, 2020, the Company was granted a \$323,000 loan under the Paycheck Protection Program (the “PPP Loan”) established under the CARES Act. The Company planned to use the proceeds from the PPP Loan for covered payroll costs, rent and utilities in accordance with the relevant terms and conditions of the CARES Act. However, based upon subsequent guidance issued by the Federal Government, including a presumption that no publicly traded companies are eligible for a PPP loan, the Company intends to return the PPP Loan proceeds within the time period imposed under these new guidelines out of an abundance of caution, subject to any additional guidance that may be issued by the Federal Government on eligibility criteria for public companies who have already been granted PPP loans.

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 Heliuss Medical Technologies, Inc. and its wholly owned subsidiaries, Heliuss Medical, Inc, or HMI, Heliuss Medical Technologies (Canada), Inc., or HMC, Heliuss Canada Acquisition Ltd., or HCA, and Heliuss 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, 2019, 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, 2019 filed with the Securities and Exchange Commission, or the SEC, on March 12, 2020, or our 2019 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. Such forward-looking statements involve risks and uncertainties regarding 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, operating costs, and our ability to achieve significant revenues and other factors. Forward-looking statements are made, without limitation, in relation to operating plans, availability of funds and operating costs. 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. Actual events or results may differ materially. In evaluating these statements, you should consider various factors, including the risks outlined in the "Risk Factors" sections of our 2019 Annual Report and this report. These factors may cause our actual results to differ materially from any forward-looking statements. 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, 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 to update any of the forward-looking statements to conform these statements to actual results, except as required by applicable law, including the securities laws of the United States. The forward-looking statements are subject to a number of risks and uncertainties which are discussed in the section entitled "Item 1A. Risk Factors" in this Quarterly Report on Form 10-Q and in our 2019 Annual Report and those described from time to time in our future reports filed with the SEC. Although we believe that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee future results, events, levels of activity, performance or achievement. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

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.

The Company's first product, known as the Portable Neuromodulation Stimulator ("PoNSTM"), is an authorized class II, non-implantable medical device authorized for sale in Canada. PoNS is intended as a short term treatment (14 weeks) of chronic balance deficit due to mild-to-moderate traumatic brain injury ("mmTBI") and is to be used in conjunction with physical therapy ("PoNS TreatmentTM"), and is indicated as a short term treatment (14 weeks) of gait deficit due to mild and moderate symptoms from Multiple Sclerosis ("MS") and is to be used in conjunction with physical therapy. It is an investigational medical device in the United States, the European Union ("EU"), and Australia ("AUS"), and it is currently under review for clearance by the AUS Therapeutic Goods Administration. PoNS TreatmentTM is not currently commercially available in the United States, the European Union or Australia.

Business Update

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

In March 2020, we announced that based on the quality of the data included in our MS submission package to Health Canada and the significant unmet needs of those afflicted with MS, we are prioritizing the MS indication as the pathway to pursue our first U.S. clearance of the PoNS device. We believe the existing published data and real-world evidence with use of the PoNS for the treatment of gait disorder in patients with mild and moderate MS are sufficient to demonstrate a favorable risk/benefit profile, as required for de novo classification to enable US marketability. Novel treatments for MS are highlighted as a specific target of the FDA as a high unmet medical need disease. We plan to submit to the FDA for this high unmet medical need in the second half of 2020.

US Regulatory Status: mmTBI

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

We submitted a request for de novo classification 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 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 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. As clinical trial activity across the U.S. and Canada has been halted, our launch of the TBI002 trial has been temporarily suspended and we are evaluating our options and timing for restarting the trial.

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 new notified body 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 and have received and answered all the questions supplied to date and wait for the TGA's decision.

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 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 PoNS Treatment in Canada.

In March 2019, we began the initial commercialization of our PoNS Treatment in Canada, where our PoNS device is the first and only device authorized 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.

Following in-depth market analysis and field intelligence, our Canadian commercial team began an expansion plan to increase the number of authorized PoNS clinics. In the first two months of 2020, we authorized 7 new clinic locations for a total of 14 clinic locations to provide PoNS Treatment across Canada. In addition, we launched a clinical experience program through University Health Network Toronto at 3 private clinic locations with an opportunity to transition to commercial treatment centers. We expect that it will take the newly authorized clinics time to work the PoNS Treatment into the clinic rotation but are confident that our focus on authorizing clinics which meet our refined criteria will drive efficiency and PoNS sales performance.

In addition to pursuing this expansion plan, we modified our go-to-market pricing model in 2020 based on direct market feedback. Our modified pricing model is focused on reducing the need for clinics and patients to pay large, upfront costs at the start of treatment.

In parallel with our commercialization efforts, we, in concert with input from insurers, have created a value dossier on behalf of the clinics and patients to fully demonstrate in both scientific and financial terms, the merits of PoNS Treatment for claimants. We are currently expanding the value dossier to add MS detail based on the March 18, 2020 Canadian MS label expansion. The dossier will be 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 in the auto accident insurance and workers compensation, or WC, market as well as long-term disability cases.

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.

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 was successful and received marketing authorization for PoNS from Health Canada.

In March 2020, the COVID-19 pandemic led to the closure of the PoNS Authorized clinic locations across Canada. 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. Timing for re-opening the clinics will be determined on a provincial basis, which continues to be uncertain at this time.

The Company's business, results of operations and financial condition may be adversely impacted by economic conditions, including the global health concerns relating to the COVID-19 pandemic. 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. Moreover, the Company's ability to conduct its ongoing clinical research may be impaired if trial participants or staff are adversely affected by COVID-19, leading to further delays in the development and approval of the Company's product candidate. In addition, disruptions in business operations in the United States, Canada and China due to COVID-19 may delay the timing for the submission and approval of the Company's marketing applications with regulatory agencies or limit the Company's suppliers' ability to ship materials that the Company relies upon due to delays or suspension of manufacturing operations. COVID-19 could also disrupt governmental operations or impair the Company's ability to access the public markets to obtain the necessary capital and continue the Company's operations. The extent to which the COVID-19 pandemic impacts 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 business, operations or the global economy as a whole.

Share Purchase Agreement and Co-Promotion Agreement

During the third quarter of 2019, we engaged with HTC through the joint steering committee in discussions regarding the future development of the commercialization of the PoNS device and PoNS Treatment in Canada. As we worked with Heuro to expand the commercial infrastructure, the complexity and feasibility of using a franchise model to build a market for PoNS including the physical therapy component became challenging. By acquiring Heuro, as noted below, we were able 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 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 paid 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 CAD\$750,000 receivable from the September 2018 strategic alliance agreement and (4) the sale of 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 will promote the sales of the PoNS Treatment and the NeuroCatch™ device throughout Canada. This co-promotion arrangement terminates upon the earlier of the collection of data from 200 patients in Canada and December 31, 2020. 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 (10) years, renewable by HTC for one additional ten (10) year term upon sixty (60) days' written notice to us.

Results of Operations

Three Months Ended March 31, 2020 compared to the Three Months Ended March 31, 2019

The following table summarizes our results of operations for the three months ended March 31, 2020 and 2019 (amounts in thousands):

	Three Months Ended		
	March 31,		
	2020	2019	Change
Revenue:			
Product sales, net	\$ 191	\$ 677	\$ (486)
Fee revenue	9	—	9
License revenue	7	—	7
Total operating revenue	207	677	(470)
Cost of sales:			
Cost of product sales	101	236	(135)
Gross profit	106	441	(335)
Operating expenses:			
Research and development	1,120	2,681	(1,561)
Selling, general and administrative	2,862	4,581	(1,719)
Amortization expense	126	—	126
Total operating expenses	4,108	7,262	(3,154)
Operating loss	(4,002)	(6,821)	2,819
Other income (expense):			
Other income	6	11	(5)
Change in fair value of derivative financial instruments	4	8,289	(8,285)
Foreign exchange loss	(765)	(155)	(610)
Total other income (expense)	(755)	8,145	(8,900)
Net income (loss)	\$ (4,757)	\$ 1,324	\$ (6,081)

Revenue

For the three months ended March 31, 2020, we recognized revenue of \$0.2 million, of which \$0.2 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 \$7 thousand was generated from license fee revenue related to our co-promotion agreement with HTC. For the three months ended March 31, 2019 we recognized revenue of \$0.7 million, of which all was generated through product sales of our PoNS device in Canada pursuant to our executed supply agreements with neuroplasticity clinics in Canada.

Cost of Sales

Cost of product sales includes the cost to manufacture the PoNS device, royalty expense, freight charges, customs duties as well as wages and salaries of employees involved in the management of the supply chain and logistics of fulfilling our sales orders. For the three months ended March 31, 2020, we incurred \$0.1 million in our cost of sales. For the three months ended March 31, 2019, we incurred \$0.2 million in our cost of sales which also included certain support services provided by Heuro on our behalf.

Research and Development Expense

Research and development, or R&D, expenses were \$1.1 million for the three months ended March 31, 2020 compared to \$2.7 million for the three months ended March 31, 2019, a decrease of \$1.6 million. The decrease was primarily attributable to a \$0.7 million reduction in product development costs due to completion of the PoNS device development in 2019 and a \$0.4 million decrease in salary, wages and other employee expense from an increased headcount in 2019 to support our Canadian launch. Medical affairs expenses decreased by \$0.2 million due to the effort in 2019 to create awareness of the PoNS device by delivery clinical and scientific data to key opinion leaders, professional societies and practitioners. There was also a reduction of \$0.1 million in regulatory expenses.

Selling, General and Administrative Expense

Selling, general and administrative, or SG&A, expenses were \$2.9 million for the three months ended March 31, 2020 compared to \$4.6 million for the three months ended March 31, 2019, an decrease of approximately \$1.7 million. The decrease was primarily due to \$1.0 million in less wages and salaries due to higher headcount in 2019 and a \$0.7 million reduction in commercial operations expense as in 2019 we invested in marketing and distribution capabilities in support of our US launch prior to receiving denial for clearance from the FDA. Office and computer expenses also decreased by \$0.2 million. These decreases were partially offset by a \$0.2 million impairment loss related to intangible assets.

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 March 31, 2020, amortization expense was \$0.1 million. No amortization expense was recorded during the three months ended March 31, 2019.

Change in Fair Value of Derivative Financial Instruments

The change in fair value of derivative financial instruments was a gain of \$4 thousand for the three months ended March 31, 2020 compared to a gain of \$8.3 million for the three months ended March 31, 2019.

The change in fair value of our derivative financial instruments 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 Loss

Foreign exchange loss was \$0.8 million for the three months ended March 31, 2020, compared to a loss of \$0.2 million for the three months ended March 31, 2019. This was primarily due to fluctuations in the foreign exchange rate as it relates to the amount of Canadian dollars held at the end of each reporting period.

Statement of Cash Flows

The following table summarizes our cash flows for the three months ended March 31, 2020 and 2019 (amounts in thousands):

	Three Months Ended March 31,		
	2020	2019	Change
Net cash used in operating activities	\$ (3,751)	\$ (6,800)	\$ 3,049
Net cash used in investing activities	(10)	(161)	151
Net cash provided by financing activities	2,652	40	2,612
Effect of exchange rate changes on cash	10	(6)	16
Net decrease in cash	\$ (1,099)	\$ (6,927)	\$ 5,828

Net Cash Used in Operating Activities

Net cash used in operating activities during the three months ended March 31, 2020 was \$3.8 million. This was comprised of a loss from operations of \$4.0 million and \$1.0 million net cash used resulting from changes in operating assets and liabilities, partially offset by certain adjustments for non-cash items of \$2.0 million comprised mainly of stock-based compensation of \$0.8 million, unrealized foreign exchange

losses of \$0.7 million, depreciation and amortization of \$0.2 million, impairment loss on intangible assets of \$0.2 million and provision for doubtful accounts of \$0.1 million.

Net cash used in operating activities during the three months ended March 31, 2019 was \$6.8 million. This was comprised of a loss from operations of \$6.8 million and \$0.9 million net cash used resulting from changes in operating assets and liabilities, partially offset by certain adjustments for non-cash items comprised of stock-based compensation of \$0.8 million and depreciation expense of \$22,000.

Net Cash Used in Investing Activities

Net cash used in investing activities during the three months ended March 31, 2020 was \$10 thousand, which was primarily related to the purchase of equipment for our office and internally developed software.

Net cash used in investing activities during the three months ended March 31, 2019 was \$0.2 million, which was primarily related to the purchase of furniture and fixtures for our office as well as laser marking equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities during the three months ended March 31, 2020 was \$2.7 million, which consisted of proceeds from the issuance of common stock from the 2020 ATM and March 2020 Offering, net of share issuance costs.

Net cash provided by financing activities during the three months ended March 31, 2019 was \$40,000, which was comprised of \$0.1 million in proceeds from the exercise of warrants. This amount was partially offset by \$52,000 in share issuance costs incurred in connection with the November 2018 public offering.

Liquidity and Capital Resources

Our condensed consolidated financial statements have been prepared assuming that we will continue as a going concern and, accordingly, do not include adjustments relating to the recoverability and realization of assets and classification of liabilities that might be necessary should we be unable to continue in operation. Our major sources of cash have been proceeds from various public and private offerings of our common stock and exercises of stock options and warrants. From June 2014 through March 31, 2020, we raised approximately \$98.9 million in gross proceeds from various public and private offerings of our common stock as well as the exercise of stock options and warrants.

The following table summarizes our cash and working capital (which we define as current assets less current liabilities excluding derivative financial instruments) as of March 31, 2020 and December 31, 2019 (amounts in thousands):

	<u>March 31, 2020</u>	<u>December 31, 2019</u>
Cash	\$ 4,360	\$ 5,459
Working capital	\$ 3,258	\$ 3,444

We currently have limited working capital and liquid assets. Our cash as of March 31, 2020 was approximately \$4.4 million. While we have started generating revenue from the commercial sale of our PoNS device in Canada, we expect to incur significant losses until such time as our revenue exceeds our expenses and during this time, we will require additional funding to fund our ongoing activities. We believe that our existing capital resources will be sufficient to fund our operations through the second quarter of 2020. 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 potential worsening 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 2019 Annual Report. There have been no changes in critical accounting policies in the current year from those described in our 2019 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.

JOBS Act

In April 2012, the Jumpstart Our Business Startups Act of 2012, or JOBS Act, was enacted in the United States. Section 107 of the JOBS Act provides that an “emerging growth company” can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth public companies.

ITEM 3. Quantitative and Qualitative Disclosures about Market Risk

We are exposed to foreign currency exchange risk from the transfer of funds between the United States and Canada to satisfy obligations as we do not hedge our foreign exchange exposure.

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 the Chief Executive Officer and the 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 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. Other than as set forth below, 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.

On or about July 9, 2019, a putative shareholder class action lawsuit, *Caramahai v. Helius Medical Technologies, Inc. et al.*, Case No. 1:19-cv-06365 (S.D.N.Y.), was filed against the Company and three of our individual officers in the Southern District of New York, or the *Caramahai* Action. The lawsuit alleges that the Company made materially false and misleading statements regarding the prospects for FDA approval of Helius' application for de novo classification and marketing authorization of its PoNS device in the United States. As a result of these alleged misstatements, the *Caramahai* Action asserts claims on behalf of shareholders who bought or sold Helius common stock between from November 9, 2017 to April 10, 2019 for alleged violations of the federal securities laws, specifically Section 10(b) and Rule 10b-5 of the Securities Exchange Act of 1934, as amended.

On or about July 31, 2019, a putative shareholder class action lawsuit, *Evans v. Helius Medical Technologies, Inc. et al.*, Case No. 1:19-cv-07171 (S.D.N.Y.), was filed against the Company and three of our individual officers in the Southern District of New York, or the *Evans* Action. The *Evans* Action alleges similar claims as the *Caramahai* Action.

On September 9, 2019, three Helius shareholders each filed motions in the *Caramahai* and *Evans* cases seeking to consolidate the two proceedings into a single putative class action. The individual motions also sought to have the movant appointed as Lead Plaintiff (the plaintiff responsible for prosecuting the class's claims and has the power to settle and release claims of all class members) and have the movant's attorneys appointed as Lead Counsel. On September 13 and 17, 2019, respectively, two of the movants filed notices withdrawing their motions on the ground that they did not appear to have "the largest financial interest in the relief sought by the class." The third movant was appointed Lead Plaintiff on April 28, 2020 and movant's attorneys were appointed as Lead Counsel.

While we believe that each of the *Caramahai* Action and the *Evans* Action is without merit and intend to vigorously defend our position in each case, we recognize that additional putative class actions or related proceedings may be filed. Given that each of these legal proceedings is in its early stages, we are unable to predict the probable outcomes at this time.

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 Annual Report on Form 10-K for the year ended December 31, 2019. You should carefully consider the risk factors discussed in Part I, "Item 1A. Risk Factors" in our 2019 Annual Report. The risks described below and in our 2019 Annual Report are not the only risks facing us. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially and adversely affect our business, financial condition and/or operating results.

We could be delisted from Nasdaq, which could seriously harm the liquidity of our stock and our ability to raise capital.

On March 23, 2020, we received a written notice from Nasdaq staff indicating that, based upon the closing bid price of our common stock for the last 30 consecutive business days, we no longer met the requirement to maintain a minimum bid price of \$1 per share, as set forth in Nasdaq Listing Rule 5550(a)(1). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were provided a period of 180 calendar days, or until September 21, 2020, in which to regain compliance. On April 17, 2020, we received a second notice from Nasdaq stating that due to unprecedented turmoil in U.S. and world financial markets resulting from the COVID-19 pandemic, Nasdaq has tolled the compliance period for bid price requirements through June 30, 2020, and accordingly, we have until December 3, 2020, to regain compliance. However, we may be unable to regain compliance with our current minimum bid price obligation or other listing requirements, which could cause us to lose eligibility for continued listing on the Nasdaq Capital Market or any comparable trading market.

If we cease to be eligible to trade on Nasdaq:

- We may have to pursue trading on a less recognized or accepted market, such as the OTC Bulletin Board or the "pink sheets."
- Shares of our common stock could be less liquid and marketable, thereby reducing the ability of stockholders to purchase or sell our shares as quickly and as inexpensively as they have done historically. If our stock is traded as a "penny stock," transactions in our stock would be more difficult and cumbersome.
- We may be unable to access capital on favorable terms or at all, as companies trading on alternative markets may be viewed as less attractive investments with higher associated risks, such that existing or prospective institutional investors may be less interested in, or prohibited from, investing in our common stock. This may also cause the market price of our common stock to decline.

Outbreaks of communicable diseases may materially and adversely affect our business, financial condition and results of operations.

We face risks related to health pandemics and outbreaks of communicable diseases, and in particular, the recent outbreak around the world of the highly transmissible and pathogenic COVID-19 coronavirus. The COVID-19 pandemic has led to the closure of PoNS Authorized clinic locations across Canada. Timing for re-opening these clinics is uncertain at this time, and has resulted/is expected to result in a decrease of our commercial activities, and may have a negative impact on our customer engagement efforts. Moreover, our ability to conduct our ongoing clinical research if trial participant attendance at requisite study visits is substantially reduced or if a significant percentage of study participants and study staff are adversely affected by COVID-19, the resulting disease course and corresponding government or community shutdowns, may be impaired, and our ability to analyze and submit the results from our clinical trials may also be impaired, leading to further delays in the development and approval of our product candidate.

Since our business operations are in the United States and Canada, and some of our business partners' operations are in China, the continued impact resulting from the COVID-19 outbreak in these areas, where we and our business partners have operations, and the measures taken by the governments of countries affected, could adversely affect our business, financial condition, revenues, and results of operations, and may delay the timing for the submission and approval of our marketing applications with regulatory agencies.

Such outbreaks could also result in delays in or the suspension of our business partners manufacturing operations, our research and product development activities, our regulatory work streams, 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 the COVID-19 pandemic could significantly disrupt our business by limiting our suppliers' ability to travel or ship materials or force temporary closure of facilities that we rely upon.

Further, in our operations as a public company, prolonged government disruptions, global pandemics and other natural disasters or geopolitical actions could affect our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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	Bylaws as amended and restated (incorporated by reference to Exhibit 3.3 to the Form 10-Q filed August 9, 2018)
31.1#	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2#	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1#*	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2#*	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS#	XBRL Instance Document
101.SCH#	XBRL Taxonomy Extension Schema Document
101.CAL#	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB#	XBRL Taxonomy Extension Label Linkbase Document
101.PRE#	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF#	XBRL Taxonomy Extension Definition Linkbase Document

Filed herewith.

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

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

HELIUS MEDICAL TECHNOLOGIES, INC.

Dated: May 11, 2020

By: /s/ Philippe Deschamps
Philippe Deschamps
President, Chief Executive Officer and a Director

Dated: May 11, 2020

By: /s/ Joyce LaViscount
Joyce LaViscount
Chief Financial Officer (Principal Accounting Officer)

CERTIFICATIONS

I, Phillippe Deschamps, 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: May 11, 2020

/s/ Phillippe Deschamps

Phillippe Deschamps

Chief Executive Officer and Director

CERTIFICATIONS

I, Joyce LaViscount, 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: May 11, 2020

/s/ Joyce LaViscount
Joyce LaViscount
Chief Financial Officer
(Principal Financial Officer)

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER
HELIUS MEDICAL TECHNOLOGIES, INC.
FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 2020
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I am the Chief Executive Officer of Helius Medical Technologies, Inc., a Delaware corporation (the “Company”). I am delivering this certificate in connection with the Form 10-Q of the Company for the quarter ended March 31, 2020 and filed with the Securities and Exchange Commission (“Form 10-Q”).

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

Date: May 11, 2020

/s/ Philippe Deschamps

Phillippe Deschamps
Chief Executive Officer and Director
(Principal Executive Officer)

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
HELIUS MEDICAL TECHNOLOGIES, INC.
FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 2020
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I am the Chief Financial Officer of Helius Medical Technologies, Inc., a Delaware corporation (the “Company”). I am delivering this certificate in connection with the Form 10-Q of the Company for the quarter ended March 31, 2020 and filed with the Securities and Exchange Commission (“Form 10-Q”).

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

Date: May 11, 2020

/s/ Joyce LaViscount

Joyce LaViscount

Chief Financial Officer

(Principal Financial Officer)