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

FORM 10-Q

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

For the quarterly period ended September 30, 2020

OR

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

For the transition period from to

Commission File No. 001-38445

HELIUS MEDICAL TECHNOLOGIES, INC.

(Exact name of Registrant as specified in its charter)

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

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

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

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

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

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

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

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

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

As of November 6, 2020, the registrant had 51,922,480 shares of Class A common stock, $0.001 par value per share, outstanding.

HELIUS MEDICAL TECHNOLOGIES, INC.
INDEX

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

	September 30, 2020	December 31, 2019
ASSETS		
Current assets		
Cash	$ 2,680	$ 5,459
Accounts receivable, net	80	210
Other receivables	138	364
Inventory, net	572	598
Prepaid expenses	666	610
Total current assets	4,136	7,241
Property and equipment, net	463	712
Other assets		
Goodwill	725	1,242
Intangible assets, net	579	582
Operating lease right-of-use asset, net	105	552
Other assets	18	18
Total other assets	1,427	2,394
TOTAL ASSETS	**$ 6,026**	**$ 10,347**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 720	$ 1,676
Accrued liabilities	1,399	1,519
Operating lease liability	107	172
Derivative financial instruments	—	5
Deferred revenue	339	430
Total current liabilities	2,565	3,802
Non-current liabilities		
Operating lease liability	47	465
Deferred revenue	217	245
TOTAL LIABILITIES	**2,829**	**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 September 30, 2020 and December 31, 2019	—	—
Class A common stock, $0.001 par value; 150,000,000 shares authorized; 45,354,612 and 30,718,554 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	45	31
Additional paid-in capital	120,213	111,479
Accumulated other comprehensive loss	(693)	(902)
Accumulated deficit	(116,368)	(104,773)
TOTAL STOCKHOLDERS' EQUITY	**3,197**	**5,835**
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 6,026**	**$ 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
(Amounts in thousands except shares and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenue:				
Product sales, net	$ 124	$ 150	$ 441	$ 1,295
Fee revenue	—	—	9	49
License revenue	7	—	20	—
Total operating revenue	**131**	**150**	**470**	**1,344**
Cost of sales:				
Cost of product sales	22	89	187	538
Gross profit	**109**	**61**	**283**	**806**
Operating expenses:				
Research and development	1,327	1,506	3,755	6,462
Selling, general and administrative	2,370	4,291	7,625	12,715
Amortization expense	72	—	287	—
Total operating expenses	**3,769**	**5,797**	**11,667**	**19,177**
Operating loss	**(3,660)**	**(5,736)**	**(11,384)**	**(18,371)**
Other income (expense):				
Other income	—	11	63	35
Change in fair value of derivative financial instruments	1	196	4	14,033
Foreign exchange gain (loss)	182	(59)	(278)	(147)
Total other income (expense)	**183**	**148**	**(211)**	**13,921**
Net loss	**(3,477)**	**(5,588)**	**(11,595)**	**(4,450)**
Other comprehensive loss:				
Foreign currency translation adjustments	(172)	68	209	(168)
Comprehensive loss	**$ (3,649)**	**$ (5,520)**	**$ (11,386)**	**$ (4,618)**
Net loss per share				
Basic	**$ (0.08)**	**$ (0.22)**	**$ (0.30)**	**$ (0.17)**
Diluted	**$ (0.08)**	**$ (0.22)**	**$ (0.30)**	**$ (0.17)**
Weighted average shares outstanding				
Basic	**45,137,995**	**25,903,544**	**39,187,370**	**25,869,039**
Diluted	**45,137,995**	**25,903,544**	**39,187,370**	**25,869,039**

(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 September 30, 2020 and 2019
(Except share and per share data, amounts in thousands)

	Common Stock, $0.001 par value		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
Balance as of June 30, 2019	**25,903,544**	**$ 26**	**$ 107,437**	**$ (827)**	**$ (93,854)**	**$ 12,782**
Stock-based compensation	—	—	1,560	—	—	1,560
Foreign currency translation adjustments	—	—	—	68	—	68
Net loss	—	—	—	—	(5,588)	(5,588)
Balance as of September 30, 2019	**25,903,544**	**$ 26**	**$ 108,997**	**$ (759)**	**$ (99,442)**	**$ 8,822**

	Common Stock, $0.001 par value		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
Balance as of June 30, 2020	**45,114,506**	**$ 45**	**$ 119,763**	**$ (521)**	**$ (112,891)**	**$ 6,396**
Settlement of restricted stock units	240,106	—	—	—	—	—
Stock-based compensation	—	—	450	—	—	450
Foreign currency translation adjustments	—	—	—	(172)	—	(172)
Net loss	—	—	—	—	(3,477)	(3,477)
Balance as of September 30, 2020	**45,354,612**	**$ 45**	**$ 120,213**	**$ (693)**	**$ (116,368)**	**$ 3,197**

(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 Nine Months Ended September 30, 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 the exercise of stock options and warrants	74,720	—	215	—	—	215
Settlement of restricted stock units	964	—	—	—	—	—
Reclassification of derivative financial instruments from exercise of warrants	—	—	35	—	—	35
Stock-based compensation	—	—	3,336	—	—	3,336
Foreign currency translation adjustments	—	—	—	(168)	—	(168)
Net loss	—	—	—	—	(4,450)	(4,450)
Balance as of September 30, 2019	**25,903,544**	**$ 26**	**$ 108,997**	**$ (759)**	**$ (99,442)**	**$ 8,822**

	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	8,138,808	8	5,035	—	—	5,043
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	—	—	(506)	—	—	(506)
Settlement of restricted stock units	240,106	—	—	—	—	—
Stock-based compensation	—	—	2,021	—	—	2,021
Foreign currency translation adjustments	—	—	—	209	—	209
Net loss	—	—	—	—	(11,595)	(11,595)
Balance as of September 30, 2020	**45,354,612**	**$ 45**	**$ 120,213**	**$ (693)**	**$ (116,368)**	**$ 3,197**

(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)

	Nine Months Ended September 30,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (11,595)	$ (4,450)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of derivative financial instruments	(4)	(14,033)
Stock-based compensation expense	2,021	3,336
Unrealized foreign exchange loss	245	211
Depreciation expense	92	89
Amortization expense	287	—
Provision for doubtful accounts	160	—
Intangible asset impairment	182	—
Loss from disposal of property and equipment	110	—
Gain on lease modification	(56)	—
Changes in operating assets and liabilities:		
Accounts receivable	(30)	(380)
Other receivables	226	(123)
Inventory	26	(897)
Prepaid expenses	(56)	285
Other current assets	—	264
Operating lease liability	20	(9)
Accounts payable	(956)	(678)
Accrued liabilities	(120)	(75)
Deferred revenue	(119)	—
Net cash used in operating activities	**(9,567)**	**(16,460)**
Cash flows from investing activities:		
Purchase of property and equipment	(14)	(260)
Proceeds from sale of property and equipment	61	—
Internally developed software	(7)	—
Net cash provided by (used in) investing activities	**40**	**(260)**
Cash flows from financing activities:		
Proceeds from the issuances of common stock and warrants	7,233	—
Share issuance costs	(506)	(52)
Proceeds from the exercise of stock options and warrants	—	215
Proceeds from Paycheck Protection Program Loan	323	—
Repayment of Paycheck Protection Program Loan	(323)	—
Net cash provided by financing activities	**6,727**	**163**
Effect of foreign exchange rate changes on cash	21	(7)
Net decrease in cash	(2,779)	(16,564)
Cash at beginning of period	5,459	25,583
Cash at end of period	**$ 2,680**	**$ 9,019**

(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 ("PoNS™"), is authorized for sale in Canada as a class II, non-implantable medical device intended as a short term treatment (14 weeks) of gait deficit due to mild and moderate symptoms from multiple sclerosis ("MS",) and chronic balance deficit due to mild-to-moderate traumatic brain injury ("mmTBI") and is to be used in conjunction with physical therapy ("PoNS Treatment™"). It is an investigational medical device in the United States, the European Union ("EU"), and Australia ("AUS"). The device is currently under review for de novo classification and clearance by the U.S. Food and Drug Administration (the "FDA") as a potential treatment for gait deficit due to symptoms of MS. It is also under premarket review by the AUS Therapeutic Goods Administration. PoNS Treatment™ 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.

Going Concern Uncertainty

As of September 30, 2020, the Company had cash of $2.7 million. For the nine months ended September 30, 2020, the Company had an operating loss of $11.4 million, and as of September 30, 2020, its accumulated deficit was $116.4 million. For the nine months ended September 30, 2020, the Company had $0.5 million of revenue from the commercial sale of products or services. The Company expects to continue to incur operating losses and net cash outflows until such time as it generates a level of revenue to support its cost structure. There is no assurance that the Company will achieve profitable operations, and, if achieved, whether it will be sustained on a continued basis. These factors indicate substantial doubt about the Company's ability to continue as a going concern within one year after the date the financial statements are filed. The Company's condensed consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and satisfaction of liabilities in the ordinary course of business; no adjustments have been made relating to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company not continue as a going concern.

The Company intends to fund ongoing activities by utilizing its current cash on hand, cash received from the sale of its PoNS™ device in Canada and by raising additional capital through equity or debt financings. As discussed further in Note 8, on October 26, 2020, the Company closed a private placement and received net proceeds of approximately $3.2 million. There can be no assurance that the Company will be successful in raising that additional capital or that such capital, if available, will be on terms that are acceptable to the Company. If the Company is unable to raise sufficient additional capital, the Company may be compelled to reduce the scope of its operations and planned capital expenditures.

Risks and Uncertainties

COVID-19

On March 11, 2020, the World Health Organization declared the outbreak of a novel coronavirus ("COVID-19") as a global pandemic, which continues to spread throughout the United States and around the world. The Company's business, results of operations and financial condition have been and may continue to be adversely impacted by the COVID-19 pandemic and global economic conditions. The outbreak and spread of COVID-19 has significantly increased economic uncertainty. Authorities implemented numerous measures to try to contain COVID-19, such as travel bans and restrictions, quarantines, shelter in place orders, and business shutdowns. The COVID-19 pandemic initially led to the closure of PoNS Authorized clinic locations across Canada. While all clinics have re-opened, they are all currently operating at reduced capacity, and patients have been and may continue to be less willing to return to these clinics, impacting our commercial activities and our customer engagement efforts. Moreover, the Company's ability to conduct its ongoing clinical experience programs in Canada has been and may continue to be impaired due to trial participants' attendance being adversely affected by COVID-19, leading to further delays in the development and approval of the Company's product candidate. In addition, the COVID-19 pandemic has and may continue to cause delays in the Company's suppliers' ability to ship materials that the Company relies upon, and disruptions in business or governmental operations due to COVID-19 may delay the timing for the submission and approval of the Company's marketing applications with regulatory agencies. Further, the economic impact of the COVID-19 pandemic could affect the Company's ability to access the public markets and obtain necessary capital in order to properly capitalize and continue its operations.

The extent to which the COVID-19 pandemic will continue to impact the Company's business, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted. The Company does not know yet the full extent of the impact of COVID-19 on its business, operations or the global economy as a whole.

Nasdaq Delisting

On March 23, 2020, 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 Class A common stock (the "common stock") for the 30 consecutive business days preceding the Notice, 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 "Minimum Bid Price Requirement"). The Notice did 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 was provided a period of 180 calendar days in which to regain compliance.

On April 17, 2020, the Company received a second letter (the "Second Notice") for the Listing Qualifications staff of Nasdaq stating that the 180-day period to regain compliance with the Minimum Bid Price Requirement has been extended due to the global market impact caused by COVID-19. More specifically, Nasdaq has stated that compliance periods were suspended from April 16, 2020 until June 30, 2020. On July 1, 2020, companies received the balance of any pending compliance period to regain compliance with the Minimum Bid Price Requirement. As a result of this extension, the Company was given to until December 3, 2020 to regain compliance with the Minimum Bid Price Requirement. 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.

In the event that the Company does not regain compliance by December 3, 2020, the Company may be eligible to obtain an additional compliance period of 180 calendar days so long as the Company satisfies the continued listing requirement for market value of publicly held shares and all criteria for initial listing on the Nasdaq Capital Market, but for the Minimum Bid Price Requirement and market value of publicly held shares requirement, and provides written notice to Nasdaq of its intent to cure the deficiency during the second compliance period via the implementation of a reverse stock split if necessary. If the Company does not regain compliance with the Minimum Bid Price Requirement by the end of the applicable compliance period (either December 3, 2020 or June 1, 2021 in the event a second compliance period is requested and granted), the Company's common stock would be subject to delisting from Nasdaq. In that case, however, the Company would have the right to request a hearing before a Nasdaq Hearings Panel to address its plan to remedy the deficiency, which request would stay any delisting action by the Listing Qualifications staff pending the ultimate outcome of the hearing process.

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.

Concentrations of Credit Risk

The Company is subject to credit risk with respect to its cash. Amounts invested in such instruments are limited by credit rating, maturity, industry group, investment type and issuer. The Company is not currently exposed to any significant concentrations of credit risk from these financial

instruments. The Company seeks to maintain safety and preservation of principal and diversification of risk, liquidity of investments sufficient to meet cash flow requirements and a competitive after-tax rate of return.

Receivables

Accounts receivables are stated at their net realizable value. In determining the appropriate allowance for doubtful accounts, the Company considers a combination of factors, such as the aging of trade receivables, its customers' financial strength, and payment history. Changes in these factors, among others, may lead to adjustments in the Company's allowance for doubtful accounts. The calculation of the allowance required judgment by Company management. As of September 30, 2020, the Company's accounts receivable of $0.1 million, is net of an allowance for doubtful accounts of $0.4 million and is the result of revenue from product sales. As of December 31, 2019, the Company's accounts receivable of $0.2 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 September 30, 2020 and December 31, 2019 included refunds from research and development ("R&D") tax credits of $21 thousand and $0.2 million, respectively, and Goods and Services Tax ("GST") and Quebec Sales Tax ("QST") refunds of $0.1 million 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 $0 thousand and $2 thousand were recorded during the three and nine months ended September 30, 2020, respectively. No inventory markdowns to net realizable value were recorded during the three and nine months ended September 30, 2019.

As of September 30, 2020 and December 31, 2019, inventory consisted of the following (amounts in thousands):

	As of September 30, 2020	As of December 31, 2019
Raw materials	$ 159	$ 144
Work-in-process	446	375
Finished goods	19	129
Inventory	**$ 624**	**$ 648**
Inventory reserve	(52)	(50)
Total inventory, net of reserve	**$ 572**	**$ 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 September 30, 2020 and December 31, 2019, property and equipment consisted of the following (amounts in thousands):

	As of September 30, 2020	As of December 31, 2019
Leasehold improvement	$ 64	$ 182
Furniture and fixtures	93	247
Equipment	300	286
Computer software and hardware	182	182
Property and equipment	**639**	**897**
Less accumulated depreciation	(176)	(185)
Property and equipment, net	**$ 463**	**$ 712**

Depreciation expense was $26 thousand and $43 thousand for the three months ended September 30, 2020 and 2019, respectively. Depreciation expense was $92 thousand and $89 thousand for the nine months ended September 30, 2020 and 2019, respectively.

During the second quarter of 2020, the Company sold furniture and fixtures with a net book value of $118 thousand for $61 thousand. Additionally, the Company abandoned leasehold improvements with a net book value of $53 thousand. The loss on the disposal of the furniture

and fixtures and leasehold improvements of $110 thousand was recorded as selling, general and administrative expense in the condensed consolidated statements of operations and comprehensive loss.

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.

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 estimates and assumptions as of such date and are considered finalized. The Company recorded measurement adjustments of $0.4 million during the nine months ended September 30, 2020, all of which was recorded during the first quarter of 2020. The recorded adjustments related to the recognition of reacquired exclusivity rights.

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 $0.7 million is not expected to be deductible for tax purposes.

The fair value of 55 PoNS devices which we agreed to transfer to HTC pursuant to the SPA 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 September 30, 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 September 30, 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. The Company performed quantitative assessments at March 31, 2020, June 30, 2020 and September 30, 2020. As a result of these assessments, the Company determined that the estimated fair value of the reporting unit exceeded the carrying value of the reporting unit. Therefore, the Company concluded that goodwill was not impaired as of any of the aforementioned periods. The Company will continue to monitor the impacts of the COVID-19 pandemic in future periods.

The following is a summary of the activity for the period ended September 30, 2020 for goodwill:

Goodwill	2020
Carrying amount at beginning of period	$ 1,242
Business acquisition fair value allocation adjustment	(454)
Foreign currency translation	(63)
Carrying amount at end of period	$ 725

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 and $0.3 million during the three and nine months ended September 30, 2020, respectively. No amortization expense related to intangible assets was recorded during the three and nine months ended September 30, 2019. During the nine months ended September 30, 2020, the Company incurred an intangible asset impairment loss of $0.2 million related to the customer relationships, all of which was incurred during the first quarter of 2020, which is included in selling, general and administrative expenses in the accompanying condensed consolidated statement of operations and comprehensive loss.

Intangible assets as of September 30, 2020 and December 31, 2019 consist of the following:

		As of September 30, 2020		As of December 31, 2019	
	Useful Life	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Customer relationships	1.25 years	$ 227	$ (191)	$ 423	$ (55)
Acquired proprietary software	5 years	143	(26)	148	(5)
Reacquired rights	3.87 years	480	(113)	—	—
Internally developed software	3 years	82	(23)	75	(4)
Total intangible assets		$ 932	$ (353)	$ 646	$ (64)

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

For the Year Ending December 31,	
2020 (remaining 3 months)	$ 73
2021	189
2022	176
2023	117
2024	24
	$ 579

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. The Company had only one operating lease, which was for its headquarters office in Newtown, Pennsylvania upon the adoption date. As of September 30, 2020, the Company has not entered into any additional lease arrangements, but did modify the existing lease arrangement. Operating lease ROU assets and operating lease liabilities are recognized upon the adoption date based on the present value of lease payments over the lease term. The Company does not have a public credit rating and as such used a corporate yield with a "CCC" rating by S&P Capital IQ with a term commensurate with the term of its lease as its incremental borrowing rate in determining the present value of lease payments. Lease expense is recognized on a straight-line basis over the lease term. The Company's lease arrangement does not have lease and non-lease components which are to be accounted for separately (see Note 6).

Foreign Currency

The Company's functional currency is the U.S. dollar. Monetary assets and liabilities denominated in foreign currencies are translated into U.S. dollars using exchange rates in effect at the balance sheet date. Opening balances related to non-monetary assets and liabilities are based on prior period translated amounts, and non-monetary assets acquired, and non-monetary liabilities incurred are translated at the approximate exchange rate prevailing at the date of the transaction. Revenue and expense transactions are translated at the approximate exchange rate in effect at the time of the transaction. Foreign exchange gains and losses are included in the condensed consolidated statement of operations and comprehensive loss as foreign exchange (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. Compensation cost is not adjusted for estimated forfeitures, but instead is adjusted upon an actual forfeiture of a stock option.

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

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

The Company uses the Black-Scholes option pricing model to calculate the fair value of stock options. The use of the Black-Scholes option pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common

stock consistent with the expected term of the option, risk-free interest rates, the value of the common stock and expected dividend yield of the common stock. Changes in these assumptions can materially affect the fair value estimate.

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

Revenue Recognition

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

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

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

Product Sales, net

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 and nine months ended September 30, 2019, the Company recorded $0.2 million and $1.3 million, respectively, in product sales net of $0 and $11 thousand, respectively, 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 and nine months ended September 30, 2020, the Company recorded $0.1 million and $0.4 million, respectively, in product sales. As of September 30, 2020, the control of 11 of the 55 PoNS devices included as consideration in the Heuro acquisition had been transferred resulting in revenue of $0.1 million being recognized which is included in the aforementioned $0.4 million in product sales for the nine months ended September 30, 2020. 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 and nine months ended September 30, 2020 were the result of warranty returns for defective products. These returns were insignificant and any future replacements are expected to be insignificant.

Fee Revenue

During the three and nine months ended September 30, 2020, the Company recognized $0 and $9 thousand, respectively, of fee revenue related to engaging new neuroplasticity clinics to provide the PoNS Treatment. During the three and nine months ended September 30, 2019, the Company recognized $0 and $49 thousand, respectively, of 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 September 30, 2020 and December 31, 2019, the Company had no contract assets or liabilities on its condensed consolidated balance sheets related to the supply agreements with each clinic.

License Revenue

The Company did not record any license revenue during the nine months ended September 30, 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 and nine months ended September 30, 2020, the Company recognized

revenues of $7 thousand and $20 thousand, respectively, in license fees associated with the Co-Promotion Agreement. Revenue not yet recognized of $0.2 million is recorded as deferred revenue on the condensed consolidated balance sheet.

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* ("ASC 815"). The result of this accounting treatment is that the fair value of the derivative is re-measured at each balance sheet date and recorded as a liability or asset and the change in fair value is recorded in the condensed consolidated statements of operations and comprehensive loss. As of September 30, 2020 and December 31, 2019, the Company's derivative financial instruments accounted for in accordance with ASC 815 were comprised of warrants issued in connection with both public and/or private securities offerings. Upon settlement of a derivative financial instrument, the instrument is re-measured at the settlement date and the fair value of the underlying instrument is reclassified to equity.

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

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 September 30, 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 September 30, 2020 and December 31, 2019 (amounts in thousands):

	Fair Value	Level 1	Level 2	Level 3
September 30, 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 nine months ended September 30, 2020 of $0.2 million, all of which was recorded during the first quarter of 2020, and has a remaining net book value of $0.1 million as of September 30, 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 per share for the periods noted below is as follows (amounts in thousands except shares and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Basic				
Numerator:				
Net loss	$ (3,477)	$ (5,588)	$ (11,595)	$ (4,450)
Denominator:				
Weighted average common shares outstanding	45,137,995	25,903,544	39,187,370	25,869,039
Basic net loss per share	**$ (0.08)**	**$ (0.22)**	**$ (0.30)**	**$ (0.17)**
Diluted				
Numerator:				
Net loss, basic	$ (3,477)	$ (5,588)	$ (11,595)	$ (4,450)
Effect of dilutive securities	—	—	—	—
Net loss, diluted	$ (3,477)	$ (5,588)	$ (11,595)	$ (4,450)
Denominator:				
Weighted average common shares outstanding - basic	45,137,995	25,903,544	39,187,370	25,869,039
Potential common share issuances:				
Incremental dilutive shares from equity instruments (treasury stock method)	—	—	—	—
Weighted average common shares outstanding	45,137,995	25,903,544	39,187,370	25,869,039
Diluted net loss per share	**$ (0.08)**	**$ (0.22)**	**$ (0.30)**	**$ (0.17)**

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 for the three and nine months ended September 30, 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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Stock options outstanding	3,929,944	3,629,288	3,929,944	3,629,288
RSUs	5,752	—	5,752	—
Warrants outstanding	9,295,445	3,043,605	9,295,445	3,043,605
Total	**13,231,141**	**6,672,893**	**13,231,141**	**6,672,893**

Recent Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which requires measurement and recognition of expected credit losses for financial assets held and requires enhanced disclosures regarding significant estimates and judgments used in estimating credit losses. In November 2019, the FASB issued ASU 2019-10, *Financial Instruments – Credit Losses (Topic 326), Derivatives and Hedging (Topic 815) and Leases (Topic 842): Effective Dates*, which amends the effective date of ASU 2016-13. Public business entities that meeting the definition of an SEC filer, excluding entities eligible to be a Smaller Reporting Company ("SRC") as defined by the SEC, are required to adopt the standard for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. All other entities are required to adopt the standard for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The Company meets the definition of an SRC and therefore the standard will not be effective until the beginning of 2023. The Company is evaluating the effect that ASU 2016-13 will have on its consolidated financial statements.

In August 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, C*ollaborative 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 September 30, 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. On April 24, 2018, the Company closed on the sale of an additional 321,285 shares of its common stock and warrants to purchase 321,285 shares of the Company's common stock pursuant to the exercise of the underwriters' over-allotment option (collectively the "April 2018 Offering"). The Company received net proceeds of $16.3 million from the April 2018 Offering. The fair value of these warrants at issuance was approximately $7.4 million.

Each warrant issued in connection with the April 2018 Offering 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 September 30, 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 issued in the April 2018 Offering using the Black-Scholes option pricing model as of the date of the initial closing of the offering and the date of the closing of the over-allotment option and September 30, 2020.

	September 30, 2020	April 24, 2018	April 13, 2018
Stock price	CAD$ 0.53	CAD$ 10.76	CAD$ 9.85
Exercise price	CAD$ 12.25	CAD$ 12.25	CAD$ 12.25
Warrant term	0.53 years	3.00 years	3.00 years
Expected volatility	107.16%	64.49%	64.20%
Risk-free interest rate	0.16%	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. The Company received net proceeds of $1.1 million.

On January 27, 2020, the Company filed a Form S-3 shelf registration under the Securities Act which was declared effective by the SEC on February 6, 2020 (the "2020 Shelf"). In conjunction with the 2020 Shelf, on January 27, 2020, the Company entered into an At The Market Offering Agreement (the "2020 ATM") with H.C. Wainwright & Co., LLC ("Wainwright") under which the Company may offer and sell, from time to time at its sole discretion, to or through Wainwright, acting as agent and/or principal, shares of its common stock having an aggregate offering price of up to $11.34 million, which, in March 2020, was subsequently reduced to $9.15 million, including the shares previously sold under the 2020 ATM. For the nine months ended September 30, 2020, under the 2020 ATM, the Company sold and issued 8,138,808 shares of its common stock with an aggregated market value of $5.0 million at an average price of $0.62 per share and paid Wainwright a sales commission of approximately $181 thousand related to those shares.

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 an exercise price of $0.46 per share. Gross proceeds from the offering (the "March 2020 Offering") were approximately $2.2 million. The underwriting discounts and commissions and offering expenses of $0.3 million were recorded to share issuance costs.

Each warrant issued in connection with the March 2020 Offering entitles the holder to acquire one additional share of common stock at an exercise price of $0.46 per share, which became exercisable on September 20, 2020 and will expire on March 20, 2025. Pursuant to the guidance of ASC 480 *Distinguishing Liabilities from Equity* and ASC 815 *Derivatives and Hedging*, the Company has determined that warrants issued in connection with the March 2020 Offering should be classified as equity as 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 nine months ended September 30, 2020 and 2019 (amounts in thousands):

	Nine Months Ended September 30,	
	2020	2019
Fair value of warrants at beginning of period	**$ 5**	**$ 13,769**
Exercise of warrants	—	(35)
Foreign exchange losses	(1)	382
Change in fair value of warrants during the period	(4)	(14,033)
Fair value of warrants at end of period	**$ —**	**$ 83**

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 September 30, 2020 and December 31, 2019 were estimated using the Black-Scholes option pricing model with the following weighted average assumptions:

	September 30, 2020	December 31, 2019
Stock price	CAD$ 0.53	CAD$ 1.23
Exercise price	CAD$ 12.25	CAD$ 12.25
Warrant term	0.53 years	1.28 years
Expected volatility	107.16%	72.43%
Risk-free interest rate	0.16%	1.72%
Dividend rate	0.00%	0.00%

The following is a summary of the Company's warrant activity during the nine months ended September 30, 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	—	(5,304)	—	10.75
Exercised	—	—	—	—
Outstanding as of September 30, 2020	**2,392,285**	**6,903,160**	**$ 12.25**	**$ 1.56**

The Company's warrants outstanding and exercisable as of September 30, 2020 were as follows:

Number of Warrants Outstanding	Exercise Price	Expiration Date
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
9,295,445		

4. STOCK-BASED PAYMENTS

On May 15, 2018, the Company's Board of Directors authorized and approved the adoption of the 2018 Omnibus Incentive Plan, (as amended, the "2018 Plan"), which was effective upon approval by the stockholders of the Company on June 28, 2018 and under which an aggregate of 5,356,114 shares may be issued. This share reserve is the sum of 3,000,000 new shares, plus the 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 ("RSUs"), stock equivalent units and performance-based cash awards. These awards may be granted to directors, officers, employees and eligible consultants. Vesting and the term of an option is determined at the discretion of the Company's Board of Directors. Subsequent to the adoption of the 2018 Plan, the Company ceased granting awards under the 2016 Plan, the predecessor incentive plan. However, outstanding stock options granted prior to the effective date of the 2018 Plan are still governed by the 2016 Plan or the Company's 2014 Stock Incentive Plan, which preceded the 2016 Plan.

As of September 30, 2020, there was an aggregate of 3,387,958 shares of common stock remaining available for grant under the Company's 2018 Plan.

For the nine months ended September 30, 2020, the Company issued 809,590 stock options to employees and directors. The Company issued no stock options to consultants during the nine months ended September 30, 2020.

The following is a summary of the Company's stock option activity during the nine months ended September 30, 2020:

	Number of Stock Options	Weighted Average Exercise Price	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2019	**3,467,292**	**$ 6.76**	**$ —**
Granted	809,590	0.47	—
Forfeited/Cancelled	(346,938)	(5.66)	—
Exercised	—	—	—
Outstanding as of September 30, 2020	**3,929,944**	**$ 5.56**	**$ —**
Exercisable as of September 30, 2020	**2,449,829**	**$ 4.27**	**$ —**

As of September 30, 2020, the unrecognized compensation cost related to non-vested stock options outstanding for employees and directors, was $4.1 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 nine months ended September 30, 2020 was $0.30 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:

	Nine Months Ended September 30, 2020
Stock price	$ 0.47
Exercise price	$ 0.47
Expected term	5.26 years
Expected volatility	77.35%
Risk-free interest rate	0.58%
Dividend rate	0.00%

As of September 30, 2020, the unrecognized compensation cost related to non-vested stock options outstanding for non-employees was $15 thousand which will be recognized over a weighted-average remaining vesting period of approximately 0.9 years. Compensation cost is not adjusted for estimated forfeitures, but instead is adjusted upon an actual forfeiture of a stock option.

Restricted Stock Awards

Beginning in 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 is based on the closing price of the Company's common stock on the day of the grant.

The following is a summary of the Company's restricted stock award activity for the nine months ended September 30, 2020:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value per Unit
Outstanding as of December 31, 2019	27,697	$ 0.61
Granted	218,161	0.50
Settled	(240,106)	0.52
Outstanding as of September 30, 2020	5,752	$ 0.39

Stock-Based Compensation Expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Research and development	$ 245	$ 233	$ 727	$ 643
Cost of sales	—	(6)	(1)	—
Selling, general and administrative	205	1,333	1,295	2,693
Total	**$ 450**	**$ 1,560**	**$ 2,021**	**$ 3,336**

Stock-based compensation expense for the three and nine months ended September 30, 2020 includes the reversal of $125 thousand of expense as a result of forfeitures due to the departure of our former chief executive officer in August 2020.

5. ACCRUED EXPENSES

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

	As of	
	September 30, 2020	December 31, 2019
Employees benefits	$ 557	$ 722
Professional services	6	67
Legal fees	163	81
Royalty fees	5	13
Franchise fees	40	28
Severance	550	606
Other	78	2
Total	**$ 1,399**	**$ 1,519**

Accrued severance expenses as of September 30, 2020 included $0.5 million in severance costs related to the departure of our former chief executive officer in August 2020.

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 and nine months ended September 30, 2020, the Company recorded approximately $5 thousand and $15 thousand, respectively, in royalty expenses in its condensed consolidated statement of operations and comprehensive loss. For the three and nine months ended September 30, 2019, the Company recorded approximately $6 thousand and $52 thousand, respectively, in royalty expenses in its condensed consolidated statement of operations and comprehensive loss.

(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 was from July 1, 2017 through December 31, 2022, with an option to extend until 2027. In July 2017, the Company amended the contract to commence the lease on July 17, 2017 through January 16, 2023, with an option to extend until January 2028. Lease extension options were not included in the lease term as it was not reasonably certain that the Company would elect to utilize the option to extend. Monthly rent plus utilities were approximately $20 thousand per month beginning in January 2018 with a 3% annual increase. In May 2020, the Company terminated its lease and entered into a new lease (the "Lease Amendment") for a smaller footprint of the current office space in Newtown, Pennsylvania. Lease payments under the original contract will be made through December 2020. The Lease Amendment was determined to be a partial termination that qualified as a change of accounting of the existing lease and not a separate contract. As such, the ROU assets and operating lease liabilities were remeasured using an incremental borrowing rate at the date of modification. The carrying value of the ROU asset decreased on a basis proportionate to the partial termination by approximately $0.4 million and the related lease liability decreased by approximately $0.4 million. The Company recorded a gain of approximately $0.1 million resulting from the difference between the reduction in the lease liability and the proportionate reduction of the ROU asset. This amount is recorded as a component of other income in the condensed consolidated statement of operations and comprehensive loss for the nine months ended September 30, 2020. The initial lease term of the Lease Amendment is from July 1, 2020 through June 30, 2021, with options to extend for successive six month periods. Two lease extension options were included in the lease term as it was reasonably certain that the Company would elect to utilize the option to extend for this period of time. Monthly rent plus utilities will be approximately $5 thousand per month beginning in January 2021 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 September 30, 2020 (amounts in thousands).

For the Nine Months Ended September 30, 2020		
Operating lease cost	$	57
Operating lease - operating cash flows	$	189
Weighted average remaining lease term		1.75 years
Weighted average discount rate		7.2%
Future minimum lease payments under non-cancellable lease as of September 30, 2020 were as follows:		
For the Period Ending December 31,		
2020 (remaining three months)	$	63
2021		63
2022		32
Total future minimum lease payments		**158**
Less imputed interest		(4)
Total liability	**$**	**154**
Reported as of September 30, 2020		
Current operating lease liability		107
Non-current operating lease liability		47
Total	**$**	**154**

(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. On June 1, 2020, HMI extended the existing manufacturing agreement with Key Tronic for a second three year term from December 29, 2020 until December 31, 2023. As of September 30, 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 thousand 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 publicly traded companies may not be eligible for a PPP loan, the Company returned the PPP Loan proceeds in May 2020 and paid interest for the period of time the loan was outstanding.

Legal Contingencies

Caramahai v. Helius Medical Technologies, Inc. et al.

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 clearance 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.

During the second quarter of 2020, the plaintiffs voluntarily dismissed the lawsuit without prejudice, ending the case. The U.S. District Judge signed the final order dismissing the litigation on July 1, 2020.

7. RELATED PARTY TRANSACTIONS

During the three and nine months ended September 30, 2020, the Company paid $0 and approximately $5 thousand, respectively, in consulting fees to a director of the Company. During the three and nine months ended September 30, 2019, the Company paid approximately $2 thousand and $25 thousand, respectively, in consulting fees to a director of the Company. As of September 30, 2020, the Company did not have an accrued liability for consulting fees to a director of the Company.

8. SUBSEQUENT EVENTS

On October 26, 2020, the Company closed on a private placement of an aggregate of 6,567,868 shares of common stock and warrants to purchase an aggregate of 3,283,936 shares of common stock at a purchase price of $0.52 per unit, consisting of one share and a warrant to purchase 0.50 shares of common stock, resulting in gross proceeds of approximately $3.4 million, excluding the proceeds, if any, that the Company may receive in the future from the exercise of the warrants. The Company incurred $0.2 million in share issuance costs, including placement agent fees. The warrants have an initial exercise price of $0.452 per share and are exercisable for a period of three years from the date of issuance. The Company also issued warrants to the placement agent to purchase 33,654 shares of common stock, with an exercise price of $0.565 per share. An officer of the Company and affiliates of an officer and director of the Company participated in the private placement on the same terms and conditions as all other purchasers, except that they paid $0.5244 per unit and their warrants have an exercise price of $0.4619 per share.

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

The following table sets forth the Company's total stockholders' equity as reported as of September 30, 2020 and as adjusted on a pro forma basis to reflect the recently completed private placement (amounts in thousands):

Total stockholders' equity as of September 30, 2020	$	3,197
Net proceeds from October 2020 private placement		3,254
Pro forma total stockholders' equity as of September 30, 2020	**$**	**6,451**

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Unless otherwise specified or the context otherwise requires, references to "we", "us" or "our" mean Helius Medical Technologies, Inc. and its wholly owned subsidiaries, Helius Medical, Inc., or HMI, Helius Medical Technologies (Canada), Inc., or HMC, Helius Canada Acquisition Ltd., or HCA, and Helius NeuroRehab, Inc., or HNR. The interim financial statements and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 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. 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. 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. 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. 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, we cannot guarantee future results, events, levels of activity, performance or achievement and our actual results will almost always vary, sometimes materially, from any estimates, predictions, projections, assumptions or other future performance suggested herein. We do not intend, and undertake no obligation, to update or revise any of the forward-looking statements as a result of new information, future events or otherwise or to conform these statements to actual results, except as required by applicable law, including the securities laws of the United States.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q.

Overview

We are a neurotechnology company focused on neurological wellness. Our purpose is to develop, license or acquire non-invasive technologies targeted at reducing symptoms of neurological disease or trauma.

Our first product, known as the Portable Neuromodulation Stimulator (PoNS™), is authorized for sale in Canada as a class II, non-implantable medical device intended as a short term treatment (14 weeks) of gait deficit due to mild and moderate symptoms from multiple sclerosis (MS) and chronic balance deficit due to mild-to-moderate traumatic brain injury (mmTBI) and is to be used in conjunction with physical therapy (PoNS Treatment™). It is an investigational medical device in the United States, the European Union (EU), and Australia (AUS). The device is currently under review for de novo classification and clearance by the U.S. Food and Drug Administration (the FDA) as a potential treatment for gait deficit due to symptoms of MS. It is also under premarket review by the AUS Therapeutic Goods Administration. PoNS Treatment™ is not currently commercially available in the United States, the European Union or Australia.

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 and clearance to enable US marketability. Novel treatments for MS are highlighted as a specific target of the FDA as a high unmet medical need disease.

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

The Breakthrough Devices Program replaces the Expedited Access Pathway and Priority Review for medical devices. The FDA considers devices granted designation under the Expedited Access Pathway to be part of the Breakthrough Devices Program.

The Breakthrough Devices Program offers manufacturers an opportunity to interact with the FDA's experts through several different program options to efficiently address topics as they arise during the premarket review phase, which can help manufacturers receive feedback from the FDA and identify areas of agreement in a timely way. Manufacturers can also expect prioritized review of their submission.

Breakthrough Device Designation does not change the requirements for approval of an application for a marketing authorization under section 510(k) of the Food, Drug, and Cosmetic Act.

On August 4, 2020, we submitted our request to the FDA for de novo classification and clearance of the PoNS device for the treatment of gait deficit due to symptoms from MS, to be used as an adjunct to a supervised therapeutic exercise program in patients over 18 years of age.

On October 19, 2020, we announced that we received a request for additional information from the FDA related to the Company's request for de novo classification and clearance of the PoNS device. During the substantive review phase of a request for de novo classification and clearance, FDA may request additional information in order to obtain information necessary for the FDA to continue or complete its review and, in such instances, places its review on hold until the requested information is submitted. The FDA's request for additional information was received approximately 75 days from the submission date, which is consistent with FDA's expected timing for review of a Breakthrough Designated product, such as the PoNS device. The FDA's request for additional information includes requests for additional analysis of clinical data and proposes certain labeling modifications.

US Regulatory Status: mmTBI

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

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

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

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

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

TBI-002 will proceed in two phases: a run-in phase, followed by a treatment phase. During the run-in phase, all subjects will receive 5 weeks of physical therapy alone. Subjects will then be randomized and assigned to one of two groups in the treatment phase where subjects will either

receive up to 10 weeks of physical therapy with the PoNS device or 10 weeks of physical therapy without the PoNS device. The primary effectiveness endpoint of TBI-002 will be a responder analysis.

Prior to the COVID-19 pandemic, our expectation was that we would move forward with the revised protocol and estimated that enrollment would begin in April 2020 with the completion of the trial and submission to the FDA in the second quarter of 2021. However, the launch of the TBI-002 trial has been temporarily suspended, and we are evaluating our options for funding and timing to commence the trial.

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 with additional data based on questions supplied to date and provided responses to additional questions during the third quarter of 2020. We are currently awaiting additional feedback from TGA on our application.

Canada Commercialization Efforts

From a real-world results perspective, in Canada thus far, the collective experience of our patients that have completed the 14-week PoNS Treatment have been encouraging. Consistent with what we saw in our two clinical trials, one for 5 weeks and the other for 14 weeks, commercial 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.

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

Following in-depth market analysis and field intelligence, our Canadian commercial team began an expansion plan to increase the number of authorized PoNS clinics. 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. As of June 30, 2020, we had 20 clinic locations which we increased to 22 clinic locations as of September 30, 2020 and to 27 clinic locations as of November 4, 2020, including a clinical experience program through University Health Network Toronto at 3 private clinic locations which have transitioned 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. Our commercialization efforts in Canada were negatively affected by the impact of the COVID-19 pandemic as described below.

In addition to pursuing this expansion plan, we continue to improve our go-to-market pricing model in 2020 based on direct market feedback. Our modified pricing approach is focused on reducing the need for clinics and patients to pay large, upfront costs at the start of treatment. We have also experimented with various promotional pricing programs resulting in lower unit prices for both PoNS system purchases and mouthpieces in order to increase access to the PoNS treatment and drive market awareness which we expect to result in an increase in the volume of units sold.

In parallel with our commercialization efforts, we, in concert with input from insurers, have created value dossiers for mmTBI and MS on behalf of the clinics and patients to fully demonstrate in both scientific and financial terms, the merits of PoNS Treatment for claimants. The dossier is 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. Our reimbursement strategy for MS is focused on commercial insurers.

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.

COVID-19 Pandemic

On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 as a global pandemic, which continues to spread throughout the United States and around the world. The Company's business, results of operations and financial condition have been adversely impacted by the COVID-19 pandemic and global economic conditions. The outbreak and spread of COVID-19 has significantly increased economic uncertainty. Authorities implemented numerous measures to try to contain the virus, such as travel bans and restrictions, quarantines, shelter in place orders, and business shutdowns. The COVID-19 pandemic initially led to the closure of PoNS Authorized clinic locations across Canada from March until June 2020. Patients who completed their initial training in the clinics prior to the closures have been able to continue working independently in the at-home portion of the treatment, with remote check-ins with their certified therapists. While all clinics have re-opened, they are all currently operating at reduced capacity within provincial guidelines, which limited operations to 50% capacity during the third quarter of 2020. Some patients have begun to return to these clinics for treatment, but patients have been and may continue to be less willing to return to the clinics due to COVID-19, impacting our commercial activities and our customer engagement efforts. We have expanded our services to include remote training and treatment, but the long-term viability of these remote programs is still being assessed.

Additionally, while we do not currently have any clinical trials underway, we are running clinical experience programs in Canada and have experienced delays in the programs as trial participant attendance has generally decreased as a result of the pandemic, and clinics and clinical research sites have experienced delays and difficulties in recruiting and re-hiring clinical site staff, leading to further delays in the development and approval of the Company's product candidate. As noted above, prior to the COVID-19 pandemic, our expectation was that we would move forward with the launch of our TBI-002 trial and we had estimated that enrollment would begin in April 2020 with the completion of the trial and submission to the FDA in the second quarter of 2021. However, the launch of the TBI-002 trial has been temporarily suspended and we are evaluating our options and timing for funding and starting the trial.

The COVID-19 pandemic and other outbreaks may cause delays in or the suspension of our business partners manufacturing operations, our research and product development activities, our regulatory workstreams, our research and development activities and other important commercial functions. We are also dependent upon our suppliers for the manufacture of our PoNS device, and in the second quarter of 2020, two of our business partners diverted resources towards other activities related to COVID-19, resulting in delays in the development and manufacturing of our product. Such diversion of suppliers' resources may occur again in the future, and the pandemic could limit our suppliers' ability to travel or ship materials or force temporary closure of facilities that we rely upon. Disruptions in business operations or governmental operations due to COVID-19 may delay the timing for the submission and approval of the Company's marketing applications with regulatory agencies. Further, the economic impact of the COVID-19 pandemic could affect our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

The extent to which the COVID-19 pandemic will continue to impact our business, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted. We do not know yet the full extent of the impact of COVID-19 on its business, operations or the global economy as a whole.

Nasdaq Delisting

On March 23, 2020, we received a Notice from the Listing Qualifications staff of Nasdaq indicating that, based on the closing bid price of the common stock for the 30 consecutive business days preceding the Notice, we no longer meet the Minimum Bid Price Requirement. The Notice does not result in the immediate delisting of our common stock from Nasdaq. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were provided a period of 180 calendar days in which to regain compliance.

On April 17, 2020, the Company the Second Notice for the Listing Qualifications staff of Nasdaq stating that the 180-day period to regain compliance with the Minimum Bid Price Requirement has been extended due to the global market impact caused by COVID-19. More specifically, Nasdaq has stated that compliance periods were suspended from April 16, 2020 until June 30, 2020. On July 1, 2020, companies received the balance of any pending compliance period to regain compliance with the Minimum Bid Price Requirement. As a result of this extension, we were given to until December 3, 2020 to regain compliance with the Minimum Bid Price Requirement. In order to regain compliance with the Minimum Bid Price Requirement, the closing bid price of our common stock must be at least $1.00 for a minimum of ten consecutive business days.

In the event that we do not regain compliance by December 3, 2020, we may be eligible to obtain an additional compliance period of 180 calendar days so long as we satisfy the continued listing requirement for market value of publicly held shares and all criteria for initial listing on the Nasdaq Capital Market, but for the Minimum Bid Price Requirement and market value of publicly held shares requirement, and provide written notice to

Nasdaq of our intent to cure the deficiency during the second compliance period via the implementation of a reverse stock split if necessary. We plan to timely submit our request to Nasdaq for the additional 180-day extension, if necessary. If we do not regain compliance with the Minimum Bid Price Requirement by the end of the applicable compliance period (either December 3, 2020 or June 1, 2021 in the event a second compliance period is requested and granted), our common stock would be subject to delisting from Nasdaq. In that case, however, we would have the right to request a hearing before a Nasdaq Hearings Panel to address our plan to remedy the deficiency, which request would stay any delisting action by the Listing Qualifications staff pending the ultimate outcome of the hearing process.

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. We anticipate that the co-promotion arrangement will terminate on December 31, 2020 and do not expect such termination to have a material impact to our results of operations. Also, subject to certain terms and conditions, we granted to HTC the exclusive right to provide the PoNS Treatment in the Fraser Valley and Vancouver metro regions of British Columbia, where HTC has operated a PoNS authorized clinic since February 2019. HTC will purchase the PoNS devices for use in these regions exclusively from us and on terms no less favorable than the then-current standard terms and conditions. This exclusivity right has an initial term of ten years, renewable by HTC for one additional ten year term upon sixty days' written notice to us.

Results of Operations

Three Months Ended September 30, 2020 compared to the Three Months Ended September 30, 2019

The following table summarizes our results of operations for the three months ended September 30, 2020 and 2019 (amounts in thousands):

	Three Months Ended September 30,		
	2020	2019	Change
Revenue:			
Product sales, net	$ 124	$ 150	$ (26)
Fee revenue	—	—	—
License revenue	7	—	7
Total operating revenue	**131**	**150**	**(19)**
Cost of sales:			
Cost of product sales	22	89	(67)
Gross profit	**109**	**61**	**48**
Operating expenses:			
Research and development	1,327	1,506	(179)
Selling, general and administrative	2,370	4,291	(1,921)
Amortization expense	72	—	72
Total operating expenses	**3,769**	**5,797**	**(2,028)**
Operating loss	**(3,660)**	**(5,736)**	**2,076**
Other income:			
Other income	—	11	(11)
Change in fair value of derivative financial instruments	1	196	(195)
Foreign exchange gain (loss)	182	(59)	241
Total other income	**183**	**148**	**35**
Net loss	**$ (3,477)**	**$ (5,588)**	**$ 2,111**

Revenue

For the three months ended September 30, 2020, we recognized revenue of $0.1 million, of which $0.1 million was generated through product sales of our PoNS device in Canada pursuant to our executed supply agreements with neuroplasticity clinics in Canada and $7 thousand was generated from license fee revenue related to our Co-Promotion Agreement with HTC. For the three months ended September 30, 2019 we recognized revenue of $0.2 million, all of which was generated through product sales of our PoNS device in Canada pursuant to our executed supply agreements with neuroplasticity clinics in Canada and none of which was generated from license fee revenue as the Co-Promotion Agreement with HTC did not go into effect until October 2019.

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 September 30, 2020, we incurred $22 thousand in our cost of sales. For the three months ended September 30, 2019, we incurred $0.1 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 $1.3 million for the three months ended September 30, 2020 compared to $1.5 million for the three months ended September 30, 2019, a decrease of $0.2 million. The decrease was primarily attributable to a $0.2 million reduction in medical affairs expenses due to the effort in 2019 to create awareness of the PoNS device by delivery of clinical and scientific data to key opinion leaders, professional societies and practitioners combined with a $0.2 million reduction in professional services expenses. These decreases were partially offset by a $0.2 million increase in legal expenses as a result of the submission of our request to the FDA on August 4, 2020 for de novo classification and clearance of the PoNS device for the treatment of gait deficit due to symptoms from MS, to be used as an adjunct to a supervised therapeutic exercise program in patients over 18 years of age.

Selling, General and Administrative Expense

Selling, general and administrative, or SG&A, expenses were $2.4 million for the three months ended September 30, 2020 compared to $4.3 million for the three months ended September 30, 2019, an decrease of approximately $1.9 million. The decrease was primarily due to a $1.1 million decrease in stock compensation expense, a $0.4 million reduction in commercial operations expense due to our investments in marketing and distribution capabilities in 2019 in support of a potential U.S. launch prior to receiving denial for clearance from the FDA coupled with a $0.2 million decrease in wages and salaries due to higher headcount in 2019.

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 September 30, 2020, amortization expense was $0.1 million. No amortization expense was recorded during the three months ended September 30, 2019.

Change in Fair Value of Derivative Financial Instruments

The change in fair value of derivative financial instruments was a gain of $1 thousand for the three months ended September 30, 2020 compared to a gain of $0.2 million for the three months ended September 30, 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 Gain (Loss)

Foreign exchange gain was $0.2 million for the three months ended September 30, 2020, compared to a loss of $0.1 million for the three months ended September 30, 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.

Nine Months Ended September 30, 2020 compared to the Nine Months Ended September 30, 2019

The following table summarizes our results of operations for the nine months ended September 30, 2020 and 2019 (amounts in thousands):

	Nine Months Ended September 30,		
	2020	2019	Change
Revenue:			
Product sales, net	$ 441	$ 1,295	$ (854)
Fee revenue	9	49	$ (40)
License revenue	20	—	20
Total operating revenue	**470**	**1,344**	**(874)**
Cost of sales:			
Cost of product sales	187	538	(351)
Gross profit	**283**	**806**	**(523)**
Operating expenses:			
Research and development	3,755	6,462	(2,707)
Selling, general and administrative	7,625	12,715	(5,090)
Amortization expense	287	—	287
Total operating expenses	**11,667**	**19,177**	**(7,510)**
Operating loss	**(11,384)**	**(18,371)**	**6,987**
Other (expense) income:			
Other income	63	35	28
Change in fair value of derivative financial instruments	4	14,033	(14,029)
Foreign exchange loss	(278)	(147)	(131)
Total other (expense) income	(211)	13,921	(14,132)
Net loss	**$ (11,595)**	**$ (4,450)**	**$ (7,145)**

Revenue

For the nine months ended September 30, 2020, we recognized revenue of $0.5 million, of which $0.4 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 $20 thousand was generated from license fee revenue related to our co-promotion agreement with HTC. For the nine months ended September 30, 2019, we recognized revenue of $1.3 million, of which $1.3 million was generated through product sales of our PoNS device in Canada pursuant to our executed supply agreements with neuroplasticity clinics in Canada and $49 thousand was generated from fee revenue related to engaging new PoNS authorized clinics. The decrease year-over-year in revenue generated through product sales of our PoNS device in Canada is primarily due to pent up demand positively impacting our product sales for the first six months of 2019, the COVID-19 pandemic negatively impacting our product sales beginning in March 2020 and, to a lesser extent, the impact of price changes, focused on reducing the need for clinics and patients to pay large, upfront costs at the start of treatment, that we began implementing in September 2019.

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 nine months ended September 30, 2020, we incurred $0.2 million in our cost of sales. For the nine months ended September 30, 2019, we incurred $0.5 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 $3.8 million for the nine months ended September 30, 2020 compared to $6.5 million for the nine months ended September 30, 2019, a decrease of $2.7 million. The decrease was attributable to a $0.9 million reduction in product development costs due to completion of the PoNS device development in 2019 and a $0.5 million reduction in wages and salaries. Medical affairs expenses also decreased by $1.0 million due to the effort in 2019 to create awareness of the PoNS device by delivery of clinical and scientific data to key opinion leaders, professional societies and practitioners. There was also a reduction of $0.3 million in professional services expenses.

Selling, General and Administrative Expense

Selling, general and administrative, or SG&A, expenses were $7.6 million for the nine months ended September 30, 2020 compared to $12.7 million for the nine months ended September 30, 2019, a decrease of approximately $5.1 million. The decrease was primarily due to $1.7 million

in less wages and salaries due to higher headcount in 2019 and a $1.9 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. Stock-based compensation expense also decreased by $1.4 million and legal expenses decreased by $0.5 million. These decreases were partially offset by a $0.2 million impairment loss related to intangible assets in 2020 and a $0.1 million loss as the result of the disposal of property and equipment.

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 nine months ended September 30, 2020, amortization expense was $0.3 million. No amortization expense was recorded during the nine months ended September 30, 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 nine months ended September 30, 2020 compared to a gain of $14.0 million for the nine months ended September 30, 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 $0.3 million for the nine months ended September 30, 2020, compared to a loss of $0.1 million for the nine months ended September 30, 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 nine months ended September 30, 2020 and 2019 (amounts in thousands):

	Nine Months Ended September 30,		
	2020	2019	Change
Net cash used in operating activities	$ (9,567)	$ (16,460)	$ 6,893
Net cash provided by (used in) investing activities	40	(260)	300
Net cash provided by financing activities	6,727	163	6,564
Effect of exchange rate changes on cash	21	(7)	28
Net decrease in cash	$ (2,779)	$ (16,564)	$ 13,785

Net Cash Used in Operating Activities

Net cash used in operating activities during the nine months ended September 30, 2020 was $9.6 million. This was comprised of a loss from operations of $11.6 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 $3.0 million comprised mainly of stock-based compensation of $2.0 million, unrealized foreign exchange losses of $0.2 million, depreciation and amortization of $0.4 million, impairment loss on intangible assets of $0.2 million, provision for doubtful accounts of $0.2 million, loss on disposal of office furniture of $0.1 million and gain on lease modification of $0.1 million.

Net cash used in operating activities during the nine months ended September 30, 2019 was $16.5 million. This was comprised of a loss from operations of $18.4 million and $1.6 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 $3.3 million and unrealized foreign exchange losses of $0.2 million.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities during the nine months ended September 30, 2020 was $40 thousand, which was primarily related to the sale of office furniture, offset partially by the purchase of equipment.

Net cash used in investing activities during the nine months ended September 30, 2019 was $0.3 million, which was primarily related to the purchase of computer software, furniture and fixtures for our office.

Net Cash Provided by Financing Activities

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

Net cash provided by financing activities during the nine months ended September 30, 2019 was $0.2 million, which consisted primarily of proceeds from the exercise of our April 2016 warrants.

Liquidity and Capital Resources

Our condensed consolidated financial statements have been prepared assuming that we will continue as a going concern and, accordingly, do not include adjustments relating to the recoverability and realization of assets and classification of liabilities that might be necessary should we be unable to continue in operation. Our major sources of cash have been proceeds from various public and private offerings of our common stock and exercises of stock options and warrants. From June 2014 through September 30, 2020, we raised approximately $103.2 million in gross proceeds from various public and private offerings of our common stock as well as the exercise of stock options and warrants. As described below, on October 26, 2020, we closed a private placement of shares of common stock and warrants for total gross proceeds of approximately $3.4 million.

The following table summarizes our cash and working capital (which we define as current assets less current liabilities excluding derivative financial instruments) as of September 30, 2020 and December 31, 2019 (amounts in thousands):

	September 30, 2020	December 31, 2019
Cash	$ 2,680	$ 5,459
Working capital	$ 1,571	$ 3,444

We currently have limited working capital and liquid assets. Our cash as of September 30, 2020 was approximately $2.7 million. As noted above, subsequent to the date of our latest balance sheet, on October 26, 2020, we closed a private placement of an aggregate of 6,567,868 shares of common stock and warrants to purchase an aggregate of 3,283,936 shares of common stock at purchase price of $0.52 per unit ($0.5244 per unit for certain participating affiliates), consisting of one share and a warrant to purchase 0.50 shares of common stock, resulting in net proceeds of approximately $3.2 million after deducting placement agents fees and estimated expenses and excluding the proceeds, if any, that we may receive in the future from the exercise of the warrants. The warrants have an initial exercise price of $0.452 per share ($0.4619 per share for certain participating affiliates) and are exercisable for three years from the date of issuance. The Company also issued warrants to the placement agent to purchase 33,654 shares of common stock, with an exercise price of $0.565 per share.

Pursuant to the securities purchase agreement for the private placement, if we issue any shares of common stock or common stock equivalents for cash consideration, indebtedness or a combination thereof, with certain exceptions, within twelve months of the closing of the private placement, each purchaser who subscribed for at least $250,000 in the private placement has the right to participate in up to such purchaser’s pro rata portion of 30% of the such subsequent financing on the same terms, conditions and price provided for in the subsequent financing. In connection with the private placement, the Company agreed to file a registration statement covering the resale of the shares of common stock and the shares of common stock issuable upon exercise of the warrants within 30 days of the closing.

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, including the net proceeds from the October 2020 private placement, will be sufficient to fund our operations throughout most of the first quarter of 2021. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. We expect our expenses to increase over time in connection with our ongoing activities, particularly if and as we: invest in marketing and distribution capabilities in support of potentially commercializing our PoNS device in the U.S., if approved; make improvements to our manufacturing process and product design; launch the TBI-002 trial or conduct other trials of the PoNS device; pursue further regulatory approvals; maintain, expand and protect our intellectual property portfolio; and add additional personnel. There can be no assurance that we will be successful in raising additional capital or that such capital, if available, will be on terms that are acceptable to us. If we are unable to raise sufficient additional capital, we may be compelled to reduce the scope of our operations and planned capital expenditure or sell certain assets, including intellectual property, and we may be forced to cease or wind down operations, seek protection under the provisions of the U.S. Bankruptcy Code, or liquidate and dissolve our Company.

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

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based upon our condensed consolidated financial statements that have been prepared in accordance with U.S. GAAP. This preparation requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and the disclosure of contingent assets and liabilities.

Our critical accounting policies and estimates are described in Item 7 “Management’s Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Policies and Estimates” of our 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. We will remain an “emerging growth company” until December 31, 2020.

ITEM 3. Quantitative and Qualitative Disclosures about Market Risk

Not applicable.

ITEM 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

Changes in Internal Control over Financial Reporting

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

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

Our business is subject to risks and events that, if they occur, could adversely affect our financial condition and results of operations and the trading price of our securities. Except for the updated risk factors set forth immediately below, our risk factors have not changed materially from those risk factors previously disclosed in our 2019 Annual Report. You should carefully consider the risk factors discussed below and 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.

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

On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 as a global pandemic, which continues to spread throughout the United States and around the world. The Company's business, results of operations and financial condition have been adversely impacted by the COVID-19 pandemic and global economic conditions. The outbreak and spread of COVID-19 has significantly increased economic uncertainty. Authorities implemented numerous measures to try to contain the virus, such as travel bans and restrictions, quarantines, shelter in place orders, and business shutdowns. The COVID-19 pandemic initially led to the closure of PoNS Authorized clinic locations across Canada from March until June 2020. Patients who completed their initial training in the clinics prior to the closures have been able to continue working independently in the at-home portion of the treatment, with remote check-ins with their certified therapists. While all clinics have re-opened, they are all currently operating at reduced capacity within provincial guidelines, which limits operations to 50% capacity. Some patients have begun to return to these clinics for treatment, but patients have been and may continue to be less willing to return to the clinics due to COVID-19, impacting our commercial activities and our customer engagement efforts. We have expanded our services to include remote training and treatment, but the long-term viability of these remote programs is still being assessed. Additionally, while we do not currently have any clinical trials underway, we are running clinical experience programs in Canada and have experienced delays in the programs as trial participant attendance has generally decreased as a result of the pandemic, and clinics and clinical research sites have experienced delays and difficulties in recruiting and re-hiring clinical site staff, leading to further delays in the development and approval of the Company's product candidate. As noted above, prior to the COVID-19 pandemic, our expectation was that we would move forward with the launch of our TBI-002 trial and we had estimated that enrollment would begin in April 2020 with the completion of the trial and submission to the FDA in the second quarter of 2021. However, the launch of the TBI-002 trial has been temporarily suspended and we are evaluating our options and timing for funding and starting the trial.

The COVID-19 pandemic and other outbreaks may cause delays in or the suspension of our business partners manufacturing operations, our research and product development activities, our regulatory workstreams, our research and development activities and other important commercial functions. We are also dependent upon our suppliers for the manufacture of our PoNS device, and in the second quarter of 2020, two of our business partners diverted resources towards other activities related to COVID-19, resulting in delays in the development and manufacturing of our product. Such diversion of suppliers' resources may occur again in the future, and the pandemic could limit our suppliers' ability to travel or ship materials or force temporary closure of facilities that we rely upon. Disruptions in business operations or governmental operations due to COVID-19 may delay the timing for the submission and approval of the Company's marketing applications with regulatory agencies. Further, the economic impact of the COVID-19 pandemic could affect our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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

- Diversion of healthcare resources away from the conduct on clinical trials, including the diversion of hospitals serving as clinical trial sites and hospital staff supporting the conduct of clinical trials;
- Interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitation on travel imposed or recommended by federal or state governments, employers and others;
- Delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- Changes in local regulations as part of a response to the COVID-19 pandemic which may require us to change the way in which clinical trials are conducted and may result in unexpected costs;
- Delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and
- Delay in the timing of our interactions with the FDA due to absenteeism by federal employees or the diversion of their efforts and attention to approval of other therapeutics or other activities related to COVID-19.

In addition to the risks specifically described above, the COVID-19 pandemic has exacerbated and precipitated the other risks described in our 2019 Annual Report, and may continue to do so. The extent to which the COVID-19 pandemic will continue to impact the Company's business, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted. The Company does not know yet the full extent of the impact of COVID-19 on its business, operations or the global economy as a whole.

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 Notice from the Listing Qualifications staff of Nasdaq indicating that, based on the closing bid price of the common stock for the 30 consecutive business days preceding the Notice, we no longer meet the Minimum Bid Price Requirement. The Notice does not result in the immediate delisting of our common stock from Nasdaq. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were provided a period of 180 calendar days in which to regain compliance.

On April 17, 2020, the Company the Second Notice for the Listing Qualifications staff of Nasdaq stating that the 180-day period to regain compliance with the Minimum Bid Price Requirement has been extended due to the global market impact caused by COVID-19. More specifically, Nasdaq has stated that compliance periods were suspended from April 16, 2020 until June 30, 2020. On July 1, 2020, companies received the balance of any pending compliance period to regain compliance with the Minimum Bid Price Requirement. As a result of this extension, we were given to until December 3, 2020 to regain compliance with the Minimum Bid Price Requirement. In order to regain compliance with the Minimum Bid Price Requirement, the closing bid price of our common stock must be at least $1.00 for a minimum of ten consecutive business days.

In the event that we do not regain compliance by December 3, 2020, we may be eligible to obtain an additional compliance period of 180 calendar days so long as we satisfy the continued listing requirement for market value of publicly held shares and all criteria for initial listing on the Nasdaq Capital Market, but for the Minimum Bid Price Requirement and market value of publicly held shares requirement, and provide written notice to Nasdaq of our intent to cure the deficiency during the second compliance period via the implementation of a reverse stock split if necessary. We plan to timely submit our request to Nasdaq for the additional 180-day extension, if necessary. If we do not regain compliance with the Minimum Bid Price Requirement by the end of the applicable compliance period (either December 3, 2020 or June 1, 2021 in the event a second compliance period is requested and granted), our common stock would be subject to delisting from Nasdaq. In that case, however, we would have the right to request a hearing before a Nasdaq Hearings Panel to address our plan to remedy the deficiency, which request would stay any delisting action by the Listing Qualifications staff pending the ultimate outcome of the hearing process.

If our common stock is delisted from Nasdaq, our ability to raise capital through public offerings of our securities and to finance our operations could be adversely affected. We also believe that delisting would likely result in decreased liquidity and/or increased volatility in our common stock and could harm our business and future prospects. In addition, we believe that, if our common stock is delisted, our 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 our common stock at competitive market prices, or at all.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Not applicable.

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)
4.1	Form of Warrant to Purchase Common Stock issued pursuant to the Securities Purchase Agreement, dated October 21, 2020 (incorporated by reference to Exhibit 4.1 to the Form 8-K filed on October 26, 2020)
10.1	Interim President and CEO Employment Letter Agreement with Dane C. Andreeff dated August 23, 2020 (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on August 25, 2020)
10.2	Separation and Release Agreement with Philippe Deschamps dated August 23, 2020 (incorporated by reference to Exhibit 10.2 to the Form 8-K filed on August 25, 2020)
10.3	2018 Omnibus Incentive Plan Form of Option Grant Agreement – 2020 Retention Grant (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on October 7, 2020)
10.4+	Form of Securities Purchase Agreement dated October 21, 2020 (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on October 26, 2020)
10.5#	Non-Employee Director Compensation Policy, effective as of June 10, 2020
31.1#	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2#	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a), as adopted pursuant to Section302 of the Sarbanes-Oxley Act of 2002
32.1#*	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2#*	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS#	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.

+Schedules and exhibits to this agreement have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Company agrees to furnish any omitted schedules or exhibits upon the request of the Securities and Exchange Commission. A list of the omitted schedules and exhibits to this agreement is as follows: Exhibit A: Schedule of Purchasers; Exhibit B: Form of Warrant; Exhibit C: Accredited Investor Qualification Questionnaire; Exhibit D: Bad Actor Questionnaire; and Exhibit E: Selling Stockholder Questionnaire.

SIGNATURES

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

HELIUS MEDICAL TECHNOLOGIES, INC.

Dated: November 12, 2020

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

Dated: November 12, 2020

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

Exhibit 10.5

HELIUS MEDICAL TECHNOLOGIES, INC.

SUMMARY OF NON-EMPLOYEE DIRECTOR COMPENSATION

Non-employee directors of the Board receive a mix of cash and equity compensation, as provided herein. The compensation described herein will have effect starting June 10, 2020.

In addition to reimbursement for reasonable expenses incurred in connection with attending Board and committee meetings, non-employee directors receive the following:

- an annual cash retainer of $10,000 for the chair of the Audit Committee, payable quarterly;
- an annual cash retainer of $5,000 for the chair of the Compensation Committee, payable quarterly;
- an annual cash retainer of $2,500 for the chair of the Nominating and Corporate Governance Committee, payable quarterly; and
- $20,000 worth of non-statutory stock option awards, as determined by the BlackScholes value of the options on the grant date, granted to each non-employee director on the date of the Company's annual meeting of shareholders without any further action by the Board, with such options vesting in 12 equal monthly installments on each of the first 12 month anniversaries of the grant date, expiring 10 years from date of issuance and having an exercise price per share equal to the closing price of the Company's Class A common stock on the Nasdaq Capital Market on the grant date.

EXHIBIT 31.1

CERTIFICATIONS

I, Dane C. Andreeff, certify that:

1) I have reviewed this report on Form 10-Q of Helius Medical Technologies, Inc.

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

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

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

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

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

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

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

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

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

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

Date: November 12, 2020

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

(Principal Executive Officer)

EXHIBIT 31.2

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: November 12, 2020

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

EXHIBIT 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
HELIUS MEDICAL TECHNOLOGIES, INC.
FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 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 Interim Chief Executive Officer of Helius Medical Technologies, Inc., a Delaware corporation (the "Company"). I am delivering this certificate in connection with the Form 10-Q of the Company for the quarter ended September 30, 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: November 12, 2020

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

EXHIBIT 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
HELIUS MEDICAL TECHNOLOGIES, INC.
FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 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 September 30, 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: November 12, 2020

/s/ Joyce LaViscount
Joyce LaViscount
Chief Financial Officer