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, 2019

OR

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

For the transition period to

Commission File No. 001-38445

HELIUS MEDICAL TECHNOLOGIES, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**36-4787690**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

642 Newtown Yardley Road Suite 100
Newtown, Pennsylvania, 18940
(Address of principal executive office) (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	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 8, 2019, the registrant had 25,903,544 shares of Class A common stock, $0.001 par value per share, outstanding.

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

	September 30, 2019	December 31, 2018
ASSETS		
Current assets		
Cash	$ 9,019	$ 25,583
Accounts receivable	557	177
Other receivables	201	98
Inventory	1,289	392
Prepaid expenses	162	447
Other current assets	—	264
Total current assets	11,228	26,961
Property and equipment, net	725	554
Other assets		
Operating lease right-of-use asset, net	586	—
Non-current receivables	323	294
Other assets	18	18
Total other assets	927	312
TOTAL ASSETS	**$ 12,880**	**$ 27,827**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,714	$ 2,392
Accrued liabilities	1,586	1,812
Operating lease liability	164	—
Derivative financial instruments	83	13,769
Total current liabilities	3,547	17,973
Non-current liabilities		
Operating lease liability	511	—
TOTAL LIABILITIES	**4,058**	**17,973**
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, 2019 and December 31, 2018	—	—
Class A common stock, $0.001 par value; 150,000,000 shares authorized; 25,903,544 and 25,827,860 shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively	26	26
Additional paid-in capital	108,997	105,411
Accumulated other comprehensive loss	(759)	(591)
Accumulated deficit	(99,442)	(94,992)
TOTAL STOCKHOLDERS' EQUITY	**8,822**	**9,854**
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 12,880**	**$ 27,827**

(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,	
	2019	2018	2019	2018
Revenue:				
Product sales, net	$ 150	$ —	$ 1,295	$ —
Fee revenue	—	—	49	—
Total operating revenue	**150**	**—**	**1,344**	**—**
Cost of sales:				
Cost of product sales	89	—	538	—
Gross profit	**61**	**—**	**806**	**—**
Operating expenses:				
Research and development	1,506	2,309	6,462	7,781
Selling, general and administrative	4,291	2,581	12,715	13,632
Total operating expenses	**5,797**	**4,890**	**19,177**	**21,413**
Operating loss	**(5,736)**	**(4,890)**	**(18,371)**	**(21,413)**
Other income (expense):				
Other income	11	4	35	63
Change in fair value of derivative financial instruments	196	368	14,033	(3,356)
Foreign exchange (loss) gain	(59)	1	(147)	1,198
Total other income (expense)	**148**	**373**	**13,921**	**(2,095)**
Net loss	**(5,588)**	**(4,517)**	**(4,450)**	**(23,508)**
Other comprehensive loss:				
Foreign currency translation adjustments	68	(96)	(168)	(930)
Comprehensive loss	**$ (5,520)**	**$ (4,613)**	**$ (4,618)**	**$ (24,438)**
Net loss per share				
Basic	**$ (0.22)**	**$ (0.19)**	**$ (0.17)**	**$ (1.06)**
Diluted	**$ (0.22)**	**$ (0.19)**	**$ (0.17)**	**$ (1.06)**
Weighted average shares outstanding				
Basic	**25,903,544**	**23,377,941**	**25,869,039**	**22,221,667**
Diluted	**25,903,544**	**23,845,498**	**25,869,039**	**22,221,667**

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

Helius Medical Technologies, Inc.
Unaudited Condensed Consolidated Statements of Stockholders' Equity (Deficit) for the Three Months Ended September 30, 2019 and 2018
(Except shares data, amounts in thousands)

	Common Stock, $0.001 par value		Common Stock, no par value		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount				
Balance as of June 30, 2018	**—**	**$ —**	**23,377,491**	**$ 70,512**	**$ 3,582**	**$ (787)**	**$ (85,360)**	**$ (12,053)**
Proceeds from exercise of stock options and warrants	—	—	50	1	—	—	—	1
Share issuance costs	—	—	—	(1)	—	—	—	(1)
Stock-based compensation	—	—	—	—	667	—	—	667
Settlement of vested restricted stock units, net of taxes	—	—	705	—	(2)	—	—	(2)
Reclassification of non-employee options recorded as derivative financial instruments due to modification of options	—	—	—	—	1,206	—	—	1,206
Reclassification of stock-based compensation due to modification of options	—	—	—	—	10,338	—	—	10,338
Reclassification upon change in corporate domicile	23,378,246	23	(23,378,246)	(70,512)	70,489	—	—	—
Foreign currency translation adjustments	—	—	—	—	—	(96)	—	(96)
Net loss	—	—	—	—	—	—	(4,517)	(4,517)
Balance as of September 30, 2018	**23,378,246**	**$ 23**	**—**	**$ —**	**$ 86,280**	**$ (883)**	**$ (89,877)**	**$ (4,457)**

	Common Stock, $0.001 par value		Common Stock, no par value		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount				
Balance as of June 30, 2019	**25,903,544**	**$ 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**

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

Helius Medical Technologies, Inc.
Unaudited Condensed Consolidated Statements of Stockholders' Equity (Deficit) for the Nine Months Ended September 30, 2019 and 2018
(Except shares data, amounts in thousands)

	Common Stock, $0.001 par value		Common Stock, no par value		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2017	**—**	**$ —**	**20,178,226**	**$ 52,230**	**$ 6,602**	**$ 47**	**$ (66,369)**	**$ (7,490)**
Proceeds from the exercise of stock options and warrants	—	—	736,130	4,637	—	—	—	4,637
Proceeds from the issuance of common stock and accompanying warrants from April 2018 Offering	—	—	2,463,185	18,400	—	—	—	18,400
Fair value of liability-classified warrants issued in connection with April 2018 Offering	—	—	—	(7,372)	—	—	—	(7,372)
Share issuance costs	—	—	—	(1,273)	—	—	—	(1,273)
Stock-based compensation expense	—	—	—	—	1,047	—	—	1,047
Settlement of vested restricted stock units, net of taxes	—	—	705	—	(2)	—	—	(2)
Reclassification from other current liabilities due to exercise of stock options	—	—	—	32	—	—	—	32
Reclassification of liability-classified warrants upon exercise	—	—	—	3,748	—	—	—	3,748
Reclassification of exercised compensation options and warrants from additional paid-in capital	—	—	—	110	(110)	—	—	—
Reclassification of April 2016 compensation options and warrants from additional paid-in capital to derivative financial instruments due to change in functional currency	—	—	—	—	(1,586)	—	—	(1,586)
Reclassification of USD denominated warrants from derivative financial instruments to additional paid-in capital due to change in functional currency	—	—	—	—	2,478	—	—	2,478
Reclassification of equity-classified stock options to stock-based compensation liability due to change in functional currency	—	—	—	—	(4,182)	—	—	(4,182)
Reclassification of non-employee options recorded as derivative financial instruments due to modification of options	—	—	—	—	1,206	—	—	1,206
Reclassification of stock-based compensation due to modification of options	—	—	—	—	10,338	—	—	10,338
Reclassification upon change in corporate domicile	23,378,246	23	(23,378,246)	(70,512)	70,489	—	—	—
Foreign currency translation adjustments	—	—	—	—	—	(930)	—	(930)
Net loss	—	—	—	—	—	—	(23,508)	(23,508)
Balance as of September 30, 2018	**23,378,246**	**$ 23**	**—**	**$ —**	**$ 86,280**	**$ (883)**	**$ (89,877)**	**$ (4,457)**

	Common Stock, $0.001 par value		Common Stock, no par value		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Loss	Deficit	Total
Balance as of December 31, 2018	**25,827,860**	**$ 26**	**—**	**$ —**	**$ 105,411**	**$ (591)**	**$ (94,992)**	**$ 9,854**
Proceeds from exercise of stock options and warrants	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**

(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,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (4,450)	$ (23,508)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of derivative financial instruments	(14,033)	3,356
Stock-based compensation expense	3,336	7,245
Unrealized foreign exchange loss (gain)	211	(1,262)
Depreciation expense	89	40
Changes in operating assets and liabilities:		
Accounts receivable	(380)	—
Other receivables	(123)	663
Inventory	(897)	(197)
Prepaid expenses	285	252
Other assets	264	—
Operating lease liability	(9)	—
Accounts payable	(678)	(1,274)
Accrued liabilities	(75)	209
Net cash used in operating activities	**(16,460)**	**(14,476)**
Cash flows from investing activities:		
Purchase of property and equipment	(260)	(425)
Net cash used in investing activities	**(260)**	**(425)**
Cash flows from financing activities:		
Proceeds from the issuance of common stock and accompanying warrants	—	18,400
Share issuance costs	(52)	(1,345)
Proceeds from the exercise of stock options and warrants	215	4,637
Net cash provided by financing activities	**163**	**21,692**
Effect of foreign exchange rate changes on cash	(7)	44
Net (decrease) increase in cash	(16,564)	6,835
Cash at beginning of period	25,583	5,562
Cash at end of period	**$ 9,019**	**$ 12,397**

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

1. DESCRIPTION OF BUSINESS

Helius Medical Technologies, Inc. (the "Company"), is a neurotechnology company focused on neurological wellness. The Company's purpose is to develop, license or acquire non-invasive technologies targeted at reducing symptoms of neurological disease or trauma.

The Company's first product, known as the Portable Neuromodulation Stimulator ("PoNS™"), is an active, therapeutic, class II medical device authorized for sale in Canada intended as a short term treatment (14 weeks) of chronic balance deficit due to mild-to-moderate traumatic brain injury ("mmTBI") and is to be used in conjunction with therapeutic activities ("PoNS Treatment™"). It is an investigational medical device in the United States, the European Union ("EU"), and Australia ("AUS"), and it is currently under review for clearance by the AUS Therapeutic Goods Administration. PoNS Treatment™ is not currently commercially available in the United States, the European Union or Australia. The PoNS device, when combined with targeted therapeutic activities and/or cognitive therapy, or PoNS Treatment™, is the first and only treatment that combines neurostimulation of cranial nerves via the tongue to restore lost function. In April 2019, the Company announced that the U.S. Food and Drug Administration ("FDA") had completed its review and denied the Company's request for de novo classification of the PoNS device in the United States. A new FDA submission with additional supporting clinical data will be required for clearance in the United States. The Company is working with the FDA to define the scope of this ongoing clinical work. The Company has withdrawn its application from the EU marketing process due to uncertainty in Europe due to the switch from the Medical Device Directive (MDD) to the Medical Device Regulation (MDR) and the withdrawal of Lloyd's Register Quality Assurance, the Company's notified body, from the notified body business. The Company will reconsider submitting to the EU when conditions stabilize.

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, which will operate a clinical research site to collect data on the delivery of PoNS Treatment to patients with balance and gait disorders. 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 (see Note 9).

The Company's wholly owned subsidiaries are comprised of HMI, HMC, HCA and HNR.

The Company was incorporated in British Columbia, Canada on March 13, 2014. On May 28, 2014, the Company completed a continuation via a plan of arrangement whereby the Company moved from being a corporation governed by the British Columbia Corporations Act to a corporation governed by the Wyoming Business Corporations Act. On July 20, 2018, the Company completed its reincorporation from Wyoming to the state of Delaware. The Company is headquartered in Newtown, Pennsylvania.

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

Effective after the close of business on January 22, 2018, the Company completed a 1-for-5 reverse stock split of its common stock. All share and per share amounts in this quarterly report on Form 10-Q have been reflected on a post-split basis.

Going Concern Uncertainty

As of September 30, 2019, the Company had cash of $9.0 million. For the nine months ended September 30, 2019, the Company had an operating loss of $18.4 million, and as of September 30, 2019, its accumulated deficit was $99.4 million. The Company expects to continue to incur operating losses and net cash outflows until such time as it generates a level of revenue to support its cost structure. There is no assurance that the Company will achieve profitable operations, and, if achieved, whether it will be sustained on a continued basis. These factors indicate substantial doubt about the Company's ability to continue as a going concern within one year after the date the financial statements are filed. The Company's condensed consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and satisfaction of liabilities in the ordinary course of business.

The Company intends to fund ongoing activities by utilizing its current cash on hand, cash received from the sale of its PoNS device in Canada and by raising additional capital through equity or debt financings. There can be no assurance that the Company will be successful in raising that additional capital or that such capital, if available, will be on terms that are acceptable to the Company. If the Company is unable to raise sufficient additional capital, the Company may be compelled to reduce the scope of its operations and planned capital expenditures.

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, 2018, included in its Annual Report on Form 10-K that was filed with the Securities and Exchange Commission on March 14, 2019. 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 (see Note 7). All intercompany balances and transactions have been eliminated. Certain prior period amounts have been reclassified to conform to the current period presentation.

Concentrations of Credit Risk

The Company is subject to credit risk with respect to its cash. Amounts invested in such instruments are limited by credit rating, maturity, industry group, investment type and issuer. The Company is not currently exposed to any significant concentrations of credit risk from these financial instruments. The Company seeks to maintain safety and preservation of principal and diversification of risk, liquidity of investments sufficient to meet cash flow requirements and a competitive after-tax rate of return.

Receivables

Accounts receivables are stated at their net realizable value. As of each of September 30, 2019 and December 31, 2018, the Company's accounts receivable were comprised of amounts owed related to license revenue of approximately $0.5 million recognized in 2018 resulting from the Company's arrangement with HTC and Heuro, of which $0.3 million was classified as a non-current receivable. As of September 30, 2019, accounts receivable included revenue from product sales and fee revenue of approximately $0.4 million. As described in Note 9, the Company modified its arrangement with HTC on October 30, 2019.

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. No inventory write-offs were recorded during the nine months ended September 30, 2019.

As of September 30, 2019 and December 31, 2018, inventory consisted of the following (amounts in thousands):

	As of September 30, 2019	As of December 31, 2018
Raw materials	$ 1,046	$ 392
Work-in-process	74	—
Finished goods	169	—
Total	**$ 1,289**	**$ 392**

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, 2019 and December 31, 2018, property and equipment consisted of the following (amounts in thousands):

	As of September 30, 2019	As of December 31, 2018
Leasehold improvement	$ 182	$ 182
Furniture and fixtures	248	185
Equipment	219	219
Computer software and hardware	241	44
Property and equipment	**890**	**630**
Less accumulated depreciation	(165)	(76)
Property and equipment, net	**$ 725**	**$ 554**

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. The Company's condensed consolidated balance sheets for reporting periods beginning on or after January 1, 2019 are presented under the new guidance, while prior period amounts were not adjusted and continue to be reported in accordance with previous guidance.

The Company does not record an operating lease ROU asset and corresponding lease liability for leases with an initial term of twelve months or less and recognizes lease expense for these leases as incurred over the lease term. As of September 30, 2019, the Company had only one operating lease, which was for its headquarters office in Newtown, Pennsylvania upon the adoption date. As of September 30, 2019, the Company has not entered into any additional lease arrangements. Operating lease ROU assets and operating lease liabilities are recognized upon the adoption date based on the present value of lease payments over the lease term. The Company does not have a public credit rating and as such used a corporate yield with a "CCC" rating by S&P Capital IQ with a term commensurate with the term of its lease as its incremental borrowing rate in determining the present value of lease payments. Lease expense is recognized on a straight-line basis over the lease term. The Company's lease arrangement does not have lease and non-lease components which are to be accounted for separately. As of September 30, 2019, approximately $0.1 million of the Company's operating lease ROU asset had been amortized (see Note 6).

Foreign Currency

Prior to April 1, 2018, the Company's functional currency was the Canadian dollar ("CAD$"). Translation gains and losses from the application of the USD$ as the reporting currency during the period that the Canadian dollar was the functional currency were included as part of cumulative currency translation adjustment, which is reported as a component of stockholders' equity (deficit) as accumulated other comprehensive income (loss).

The Company re-assessed its functional currency and determined that, as of April 1, 2018, its functional currency had changed from the CAD$ to the USD$ based on management's analysis of changes in the primary economic environment in which the Company operates. The change in functional currency was accounted for prospectively from April 1, 2018 and condensed consolidated financial statements prior to and including the period ended March 31, 2018 were not restated for the change in functional currency.

For periods commencing April 1, 2018, 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 after April 1, 2018 are translated at the approximate exchange rate prevailing at the date of the transaction. Revenue and expense transactions are translated at the approximate exchange rate in effect at the time of the transaction. Foreign exchange gains and losses are included in the condensed consolidated statement of operations and comprehensive loss as foreign exchange (loss) gain.

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

Stock-Based Compensation

The Company accounts for all stock-based payments and awards under the fair value-based method. The Company recognizes its stock-based compensation expense using the straight-line method.

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

Prior to the adoption of ASU No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"), during the third quarter of 2018, stock-based payments to non-employees were measured at the fair value of the consideration received, or the fair value of the equity instruments issued, or liabilities incurred, whichever was more reliably measurable, and the fair value of stock-based payments to non-employees was re-measured at the end of each reporting period until the counterparty performance was completed, with any change therein recognized over the vesting period of the award and in the same manner as if the Company had paid cash instead of paying with or using equity-based instruments. The fair value of the stock-based payments to non-employees that was fully vested and non-forfeitable as of the grant date were measured and recognized at that date. Following the adoption of 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. The change in the Company's functional currency, effective April 1, 2018, resulted in the reclassification of outstanding stock options that were previously denominated in CAD$ from equity to liability-classified options. Liability-classified options are re-measured to their fair values at the end of each reporting date with changes in the fair value recognized in stock-based compensation expense or additional paid-in capital until settlement or cancellation. Under FASB's ASC 718, *Compensation – Stock Compensation*, when an award is reclassified from equity to liability, if at the reclassification date the original vesting conditions are expected to be satisfied, then the minimum amount of compensation cost to be recognized is based on the grant date fair value of the original award. Fair value changes below this minimum amount are recorded in additional paid-in capital. In June 2018, the Company's Board of Directors approved, subject to the consent of the holders of such options the modification of outstanding stock options with exercise prices denominated in CAD$ to convert the exercise prices of such options to USD$ based on the prevailing USD$/CAD$ exchange rates on the dates of the grants for such modified stock options. During the third quarter of 2018, employee and non-employee option holders owning stock options representing an aggregate of 2,741,146 shares of common stock consented to the modification. Employee stock options with a fair value of $10.3 million on August 8, 2018, which were previously classified as stock-based compensation liabilities, were reclassified to equity during the third quarter of 2018. Following these reclassifications, the Company no longer has any liability-classified stock options.

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

Prior to July 1, 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. Further, according to the Company's arrangement with HTC and Heuro, the Company shared 50/50 with Heuro in fees from support services excluding the CAD$600 payment for an assessment using the NeuroCatch device. For the three months ended September 30, 2019, product sales were derived from the sale of the PoNS device alone as the NeuroCatch is sold directly to the neuroplasticity clinics in Canada. 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 $11,100, respectively, for HTC's portion related to assessments using the NeuroCatch device. As described in Note 9, the Company modified its arrangement with HTC on October 30, 2019.

Fee Revenue

Prior to July 1, 2019, the Company's agreement with HTC and Heuro also entitled the Company to 50% of the franchise fees collected by Heuro from each franchise agreement Heuro executed with neuroplasticity clinics engaged in providing the PoNS Treatment as a result of the Company's 50% share in Heuro profit/loss. For the three and nine months ended September 30, 2019, the Company recognized $0 and $49,000, respectively, as its 50% portion of the franchise fees. For the three months ended September 30, 2019, there were no new franchise agreements entered into and 3 franchise agreements were entered into for the nine months ended September 30, 2019.

As of September 30, 2019, the Company had recorded $0.4 million in current receivables and had no contract assets or liabilities on its condensed consolidated balance sheet related to these supply agreements. As of September 30, 2019 and December 31, 2018, the Company had recorded $0.2 million and $0.3 million in current and non-current receivables, respectively, and had no contract assets or liabilities on its condensed consolidated balance sheets related to license revenue pursuant to the Company's arrangement with HTC and Heuro.

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.

Research and Development Expenses

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

Segment Information

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

Derivative Financial Instruments

The Company evaluates its financial instruments and other contracts to determine if those contracts or embedded components of those contracts qualify as derivatives to be separately accounted for in accordance with ASC 815, *Derivatives and Hedging*. The result of this accounting treatment is that the fair value of the derivative is re-measured at each balance sheet date and recorded as a liability or asset and the change in fair value is recorded in the condensed consolidated statements of operations and comprehensive loss. As of September 30, 2019 and December 31, 2018, the Company's derivative financial instruments were comprised of warrants issued in connection with both public and/or private securities offerings. During the third quarter of 2018, these non-employee stock options were classified to equity following the modification of these stock options. 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, 2019 and December 31, 2018 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 derivative financial instruments and stock-based compensation liability within the fair value hierarchy as of September 30, 2019 and December 31, 2018 (amounts in thousands):

	Fair Value	Level 1	Level 2	Level 3
September 30, 2019				
Liabilities:				
Derivative financial instruments	$ 83	—	—	$ 83
December 31, 2018				
Liabilities:				
Derivative financial instruments	$ 13,769	—	—	$ 13,769

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

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,	
	2019	2018	2019	2018
Basic				
Numerator				
Net loss	$ (5,588)	$ (4,517)	$ (4,450)	$ (23,508)
Denominator				
Weighted average common shares outstanding	25,903,544	23,377,941	25,869,039	22,221,667
Basic net loss per share	**$ (0.22)**	**$ (0.19)**	**$ (0.17)**	**$ (1.06)**
Diluted				
Numerator:				
Net loss, basic	$ (5,588)	$ (4,517)	$ (4,450)	$ (23,508)
Effect of dilutive securities: warrants	—	(93)	—	—
Net loss, diluted	$ (5,588)	$ (4,610)	$ (4,450)	$ (23,508)
Denominator:				
Weighted average common shares outstanding - basic	25,903,544	23,377,941	25,869,039	22,221,667
Potential common share issuances:				
Incremental dilutive shares from equity instruments (treasury stock method)	—	467,557	—	—
Weighted average common shares outstanding	25,903,544	23,845,498	25,869,039	22,221,667
Diluted net loss per share	**$ (0.22)**	**$ (0.19)**	**$ (0.17)**	**$ (1.06)**

The following outstanding securities have been excluded from the computation of diluted weighted shares outstanding for the periods noted below, as they would have been anti-dilutive due to the Company's losses for the three and nine months ended September 30, 2019 and 2018 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,	
	2019	2018	2019	2018
Stock options outstanding	3,629,288	3,133,552	3,629,288	3,133,552
Warrants outstanding	3,043,605	651,320	3,043,605	4,004,304
Restricted stock units	—	963	—	963
Total	**6,672,893**	**3,785,835**	**6,672,893**	**7,138,819**

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. This ASU is effective for annual periods beginning after December 15, 2019, and early adoption is permitted for annual periods beginning after December 15, 2018. The Company is evaluating the effect that ASU 2016-13 will have on its condensed 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 is evaluating the effect that ASU 2018-13 will have on its 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 is in the process of evaluating the impact the standard will have on its condensed consolidated financial statements.

3. COMMON STOCK AND WARRANTS

On June 28, 2018, at the Company's 2018 Annual Meeting of Shareholders, the Company's shareholders approved the Company's reincorporation from the state of Wyoming to the state of Delaware. On July 20, 2018, the Company completed its reincorporation from Wyoming to the state of Delaware.

As a result, following the Company's reincorporation in the state of Delaware, 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, 2019. 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 18, 2016, the Company closed its short form prospectus offering in Canada and a concurrent U.S. private placement (the "April 2016 Offering") of units (the "Units") with gross proceeds to the Company of $7.2 million through the issuance of Units at a price of CAD$5.00 per Unit. Each Unit consists of one share of common stock of the Company (a "Common Share') and one-half of one Common Share purchase warrant (each whole warrant, a "Warrant"). Each Warrant entitled the holder thereof to acquire one additional Common Share at an exercise price of CAD$7.50 on or before April 18, 2019. Mackie Research Capital Corporation (the "Agent") acted as agent and sole bookrunner in connection with the April 2016 Offering. The Company paid the Agent a cash commission of $0.3 million and granted to the Agent compensation options exercisable to purchase 87,210 Units at an exercise price of CAD$5.00 per Unit for a period of 24 months from the closing of the April 2016 Offering. The Company incurred other cash issuance costs of $1.1 million related to this offering. During the third quarter of 2019, no warrants were exercised. On April 18, 2019, 922,348 warrants were cancelled due to their expiration.

On April 13, 2018, the Company issued 2,141,900 shares of its common stock and warrants to purchase 2,141,900 shares of the Company's common stock in an underwritten public offering at a price of $7.47 per share and accompanying warrant. Gross proceeds from the offering were approximately $16.0 million. On April 24, 2018, the Company closed on the sale of an additional 321,285 shares of its common stock and warrants pursuant to the exercise of the over-allotment option (collectively the "April 2018 Offering") granted to the underwriters in connection with the offering at a price of $7.47 per share and accompanying warrants. Gross proceeds from the exercise of the over-allotment option was $2.4 million. BTIG, LLC and Echelon Wealth Partners acted as joint book-running managers for the April 2018 Offering. The Company paid approximately $1.1 million in underwriting discounts and commissions and incurred offering expenses of approximately $1.0 million in connection with the April 2018 Offering, resulting in net proceeds of $16.3 million from the April 2018 Offering. The underwriting discounts and commissions and offering expenses were allocated between share issuance costs and expenses based on the relative fair values of common stock and warrants issued in connection with the April 2018 Offering, resulting in the recording of approximately $0.8 million of expenses in the Company's condensed consolidated statement of operations and comprehensive loss. The fair value of these warrants at issuance was approximately $7.4 million.

Each warrant issued in connection with the April 2018 Offering entitles the holder to acquire one additional share of common stock at an exercise price of CAD$12.25 per share on or before April 10, 2021. Pursuant to the guidance of ASC 815 *Derivatives and Hedging*, the Company has determined that warrants issued in connection with the April 2018 Offering should be accounted for as liabilities as the ability to maintain an effective registration is outside of the Company's control and that it may be required to settle the exercise of the warrants in cash and because, as a result of the change in the Company's functional currency (see Note 2), the exercise prices of these warrants are in a currency other than the Company's functional currency. Consequently, the Company determined the fair value of each warrant issuance using the Black-Scholes option pricing model, with the remainder of the proceeds allocated to the common shares. As of September 30, 2019, 70,900 warrants had been exercised, all during 2018, for gross proceeds of CAD$0.9 million.

The following table summarizes the weighted average assumptions used in estimating the fair value of the warrants granted in the April 2018 Offering using the Black-Scholes option pricing model as of the date of the initial closing of the offering and the date of the closing of the over-allotment option and September 30, 2019.

	September 30, 2019	April 24, 2018	April 13, 2018
Stock price	CAD$ 2.20	CAD$ 10.76	CAD$ 9.85
Exercise price	CAD$ 12.25	CAD$ 12.25	CAD$ 12.25
Warrant term	1.53 years	3.00 years	3.00 years
Expected volatility	71.76%	64.49%	64.20%
Risk-free interest rate	1.65%	2.02%	1.99%
Dividend rate	0.00%	0.00%	0.00%

On November 19, 2018, the Company issued 2,121,212 shares of its common stock in an underwritten public offering at a price of $8.25 per share. Gross proceeds from the offering were $17.5 million. On November 30, 2018, the Company closed on the sale of an additional 318,182 shares of its common stock pursuant to the exercise of the over-allotment option (collectively the "November 2018 Offering") granted to the underwriters in connection with the offering at a price of $8.25 per share. Gross proceeds from the exercise of the over-allotment option was $2.6 million. BTIG, LLC and Oppenheimer & Co. Inc. acted as joint book-running managers for the November 2018 Offering. The Company paid approximately $1.2 million in underwriting discounts and commissions and incurred offering expenses of approximately $0.7 million, resulting in net proceeds of $18.3 million.

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, 2019 and 2018 (amounts in thousands):

	Nine Months Ended September 30,	
	2019	2018
Fair value of warrants at beginning of period	**$ 13,769**	**$ 6,941**
Issuance of warrants	—	7,372
Exercise of warrants	(35)	(3,012)
Fair value of previously equity-classified warrants	—	5,049
Fair value of previously liability-classified warrants reclassified to additional paid-in capital	—	(2,478)
Foreign exchange losses (gains)	382	(142)
Change in fair value of warrants during the period	(14,033)	548
Fair value of warrants at end of period	**$ 83**	**$ 14,278**

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, 2019 and December 31, 2018 were estimated using the Black-Scholes option pricing model with the following weighted average assumptions:

	September 30, 2019	December 31, 2018
Stock price	CAD$ 2.20	CAD$ 12.80
Exercise price	CAD$ 12.25	CAD$ 10.89
Warrant term	1.53 years	1.71 years
Expected volatility	71.76%	75.31%
Risk-free interest rate	1.65%	1.80%
Dividend rate	0.00%	0.00%

The following is a summary of the Company's warrant activity during the nine months ended September 30, 2019:

	Number of Warrants		Weighted Average Exercise Price	
	CAD	US	CAD$	USD$
Outstanding as of December 31, 2018	**3,352,984**	**651,320**	**$ 10.89**	**$ 12.24**
Granted	—	—	—	—
Cancelled/Expired	(922,348)	—	7.50	—
Exercised	(38,351)	—	7.50	—
Outstanding as of September 30, 2019	**2,392,285**	**651,320**	**$ 12.25**	**$ 12.24**

The Company's warrants outstanding and exercisable as of September 30, 2019 were as follows:

Number of Warrants Outstanding	Exercise Price	Expiration Date
3,795	USD$10.75	June 26, 2020
1,509	USD$10.75	July 17, 2020
270,915	USD$12.25	December 22, 2020
171,020	USD$12.25	December 28, 2020
204,081	USD$12.25	December 29, 2020
2,392,285	CAD$12.25	April 10, 2021
3,043,605		

4. STOCK-BASED PAYMENTS

On May 15, 2018, the Company's Board of Directors authorized and approved the adoption of the 2018 Omnibus Incentive Plan ("2018 Plan"), under which an aggregate of 5,356,114 shares may be issued. This share reserve is the sum of 3,000,000 new shares, plus the remaining 2,356,114 shares that remained available for issuance under the Company's 2016 Omnibus Incentive Plan (the "2016 Plan"), the predecessor incentive plan at the time of the adoption of the 2018 Plan. Pursuant to the terms of the 2018 Plan, the Company is authorized to grant stock options, as well as awards of stock appreciation rights, restricted stock, unrestricted shares, restricted stock units ("RSU"), stock equivalent units and performance-based cash awards. These awards may be granted to directors, officers, employees and eligible consultants. Vesting and the term of an option is determined at the discretion of the Company's Board of Directors. Subsequent to the adoption of the 2018 Plan, the Company ceased granting awards under the 2016 Plan, the predecessor incentive plan. However, outstanding stock options granted prior to the effective date of the 2018 Plan are still governed by the 2016 Plan or the Company's 2014 Stock Incentive Plan, which preceded the 2016 Plan.

As of September 30, 2019, there was an aggregate of 3,934,473 shares of common stock remaining available for grant under the Company's 2018 Plan.

For the nine months ended September 30, 2019, the Company issued 1,132,658 stock options to employees and directors. The Company issued no stock options to consultants and non-employees during the nine months ended September 30, 2019.

The following is a summary of the Company's stock option activity during the nine months ended September 30, 2019:

	Number of Stock Options	Weighted Average Exercise Price	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2018	**3,308,049**	**$ 7.14**	**$ 8,308**
Granted	1,132,659	4.74	
Forfeited/Cancelled	(291,420)	8.28	
Exercised [1]	(520,000)	2.77	108
Outstanding as of September 30, 2019	**3,629,288**	**$ 6.93**	**$ —**
Exercisable as of September 30, 2019	**1,907,349**	**$ 3.79**	**$ —**

1. For the nine months ended September 30, 2019, 520,000 stock options were exercised on a cashless basis resulting in 483,631 shares being withheld in satisfaction of their exercise prices.

The following table summarizes stock options outstanding and exercisable by employees and directors as of September 30, 2019:

Number of Stock Options Outstanding	Expiration Date	Stock Options Outstanding Remaining Contractual Life (In Years)	Exercise Price	Fair Value Post Modification [1]	Grant Date Fair Value	Number of Stock Options Exercisable
20,000	December 8, 2019	0.19	$ 12.72	$ 2.18	$ —	20,000
80,000	December 8, 2019	0.19	$ 12.72	$ 2.18	$ —	80,000
20,000	March 16, 2020	0.46	$ 12.52	$ 2.43	$ —	20,000
150,000	October 21, 2020	1.06	$ 3.20	$ 6.57	$ —	150,000
20,000	December 31, 2020	1.25	$ 4.48	$ 5.86	$ —	20,000
595,000	July 13, 2020	0.79	$ 5.35	$ 5.18	$ —	595,000
20,000	August 8, 2020	0.86	$ 4.98	$ 5.42	$ —	20,000
617,000	April 17, 2027	7.54	$ 8.13	$ 7.54	$ —	308,500
6,146	May 18, 2027	7.63	$ 7.35	$ 4.75	$ —	6,146
10,000	May 18, 2027	7.63	$ 7.35	$ 7.65	$ —	5,000
25,000	August 8, 2027	7.85	$ 10.38	$ 7.38	$ —	15,000
20,000	April 9, 2028	8.52	$ 9.03	$ 8.01	$ —	5,000
337,500	May 15, 2028	8.62	$ 10.99	$ 7.89	$ —	167,500
150,000	July 9, 2028	8.77	$ 9.69	$ —	$ 6.83	150,000
59,584	August 22, 2028	8.89	$ 10.23	$ —	$ 7.21	17,949
4,000	September 4, 2028	8.92	$ 10.19	$ —	$ 7.19	2,875
50,000	September 10, 2028	8.94	$ 10.34	$ —	$ 7.30	12,500
50,000	September 24, 2028	8.98	$ 9.71	$ —	$ 6.79	12,500
75,000	October 15, 2028	9.04	$ 8.75	$ —	$ 6.19	—
10,000	October 29, 2028	9.08	$ 9.71	$ —	$ 6.87	—
20,000	November 19, 2028	9.13	$ 8.00	$ —	$ 5.66	—
7,500	January 22, 2029	9.31	$ 7.65	$ —	$ 5.30	—
7,500	February 4, 2029	9.34	$ 7.26	$ —	$ 5.03	—
545,558	March 28, 2029	9.49	$ 6.76	$ —	$ 4.62	51,129
232,500	August 7, 2029	9.85	$ 2.03	$ —	$ 1.37	—
40,000	August 19, 2029	9.88	$ 1.93	$ —	$ 1.30	—
150,000	September 23, 2029	9.98	$ 1.73	$ —	$ 1.20	—
30,000	September 30, 2029	9.99	$ 1.65	$ —	$ 1.11	—
3,352,288						**1,659,099**

1. Reflects fair value of modified stock options on August 8, 2018.

As of September 30, 2019, the unrecognized compensation cost related to non-vested stock options outstanding for employees and directors, was $7.3 million which will be recognized over a weighted-average remaining vesting period of approximately 3.0 years. The Company recognizes compensation expense for only the portion of awards that are expected to vest.

The weighted average grant date fair value of employee and director stock options granted for the nine months ended September 30, 2019 was $3.07 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, 2019
Stock price	$ 4.74
Exercise price	$ 4.74
Expected term	5.50
Expected volatility	76.92%
Risk-free interest rate	1.97%
Dividend rate	0.00%

Non-Employee Stock Options

The following table summarizes stock options outstanding and exercisable by consultants as of September 30, 2019:

Number of Stock Options Outstanding	Expiration Date	Stock Options Outstanding Remaining Contractual Life (In Years)	Exercise Price	Fair Value Post Modification [1]	Grant Date Fair Value	Number of Stock Options Exercisable
30,000	December 8, 2019	0.19	$ 12.72	$ 2.18	$ —	30,000
72,000	October 3, 2020	1.01	$ 5.15	$ 5.35	$ —	72,000
110,000	October 28, 2020	1.08	$ 3.18	$ 6.59	$ —	110,000
20,000	May 18, 2027	7.63	$ 7.35	$ 7.65	$ —	10,000
15,000	August 8, 2027	7.85	$ 10.38	$ 7.38	$ —	7,500
15,000	November 6, 2027	8.10	$ 16.20	$ 6.98	$ —	3,750
15,000	August 22, 2028	8.89	$ 10.23	$ —	$ 8.87	15,000
277,000						**248,250**

1. Reflects fair value of modified stock options as of August 8, 2018.

Restricted Stock Units

During the nine months ended September 30, 2019, the Company issued 964 shares of its common stock in settlement of vested RSUs. As of September 30, 2019, the Company had no RSUs outstanding.

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,	
	2019	2018	2019	2018
Research and development	$ 233	$ 208	$ 643	$ 745
Cost of sales	(6)	—	—	—
Selling, general and administrative	1,333	317	2,693	6,500
Total	**$ 1,560**	**$ 525**	**$ 3,336**	**$ 7,245**

5. ACCRUED EXPENSES

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

	As of	
	September 30, 2019	December 31, 2018
Employees benefits	$ 815	$ 876
Professional services	68	518
Due to HTC/Heuro	49	—
Legal fees	141	253
Royalty fees	52	—
Franchise fees	42	—
Rent	—	98
Severance	399	66
Other	20	1
Total	**$ 1,586**	**$ 1,812**

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, 2019, the Company recorded approximately $6,000 and $52,000, respectively, in royalty expenses in its condensed consolidated statement of operations.

(b) On October 30, 2017, HMI amended the Asset Purchase Agreement with A&B (HK) Company Ltd. ("A&B") which specified that if the Company fails to obtain FDA marketing authorization for commercialization of or otherwise fails to ensure that the PoNS device is available for purchase by the U.S. Government by December 31, 2021, the Company would be subject to a $2.0 million contract penalty payable to A&B, unless the Company receives an exemption for the requirement of FDA marketing authorization from the U.S. Army Medical Material Agency. In December 2018, the U.S. Army notified the Company that it was amending the Agreement such that the satisfaction of the obligation of the contract was changed from FDA marketing authorization of the PoNS device to submitting of an application for marketing authorization of the PoNS device with the FDA. As the Company submitted its application for marketing authorization of the PoNS device to the FDA on August 31, 2018, and with copies of the submission documents provided to the U.S. Army, the Company has met its obligation under the amended agreement. Based on this amendment the Company has determined that the possibility of a payment under this contractual penalty is remote.

(c) In November 2014, the Company signed a distribution agreement with Altair LLC to apply for the registration and distribution of the PoNS device in the territories of the former Soviet Union. Through March 31, 2019, the Company was entitled to receive a 7% royalty on sales of the devices within the territories. Altair terminated the distribution agreement effective May 20, 2019. The Company made no commercial sales in the territories pursuant to this distribution agreement.

(d) In March 2017, the Company entered into a lease for office space in Newtown, Pennsylvania. The initial term of the lease is from July 1, 2017 through December 31, 2022, with an option to extend until 2027. In July 2017, the Company amended the contract to commence the lease on July 17, 2017 through January 16, 2023, with an option to extend until January 2028. It is not reasonably certain at this point in time that the Company will elect to utilize the option to extend. Monthly rent plus utilities will be approximately $20,000 per month beginning in January 2019 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, 2019 (amounts in thousands).

For the Nine Months Ended September 30, 2019		
Operating lease cost	$	172
Operating lease - operating cash flows	$	185
Weighted average remaining lease term		3.30 years
Weighted average discount rate		15.1%
Future minimum lease payments under non-cancellable lease as of September 30, 2019 were as follows:		
For the Period Ending December 31,		
2019 (remaining three months)	$	62
2020		253
2021		260
2022		267
2023		10
Total future minimum lease payments		**852**
Less imputed interest		(177)
Total liability	**$**	**675**
Reported as of September 30, 2019		
Current operating lease liability		164
Non-current operating lease liability		511
Total	**$**	**675**

(e) On December 29, 2017, HMI (formerly known as NeuroHabilitation Corporation) entered into a Manufacturing and Supply Agreement ("MSA") with Key Tronic Corporation ("Key Tronic"), for the manufacture and supply of the Company's PoNS device based upon the Company's product specifications as set forth in the MSA. Per the agreement, the Company shall provide to Key Tronic a rolling forecast for the procurement of parts and material and within normal lead times based on estimated delivery dates for the manufacture of the PoNS device. The term of the agreement is for three years and will automatically renew for additional consecutive terms of one year, unless cancelled by either party upon 180-day written notice to the other party prior to the end of the then current term. As of September 30, 2019, the Company had approximately $0.3 million in commitments to Key Tronic to complete the Company's forecasts for the procurement of materials necessary for the delivery of PoNS devices.

(f) In September 2018, the Company entered into a strategic alliance agreement with HTC and Heuro to establish up to three founding clinics to treat patients and create a replicable model for future clinic expansion. Under the terms of the agreement, the parties developed a clinic system to facilitate the commercialization of the PoNS Treatment in Canada. Under the terms of the agreement, the parties contracted with the clinics and developed a model for the clinics to deliver clinical services, featuring the PoNS Treatment to manage neurological conditions. During the second quarter of 2019, the Company entered into the clinic expansion phase of this alliance with the addition of three new PoNS authorized clinics, bringing the total number of clinics authorized to treat patients with the PoNS device to five in Canada. As of September 30, 2019, the arrangement provided for HTC to pay the Company CAD$750,000 in three annual payments of CAD$250,000 beginning December 31, 2019, in consideration for the exclusivity right the Company granted to Heuro. The Company and HTC governed the agreement through a joint steering committee, and each funded up to 50% of Heuro's operating budget as agreed to by the joint steering committee and shared in the net profits and losses of Heuro on a 50/50 basis. For the three and nine months ended September 30, 2019, the Company recorded $0.1 million and $0.5 million, respectively, in expenses for its share of the estimated costs incurred by Heuro which was recorded as selling, general and administrative expenses. In addition, the Company recorded $5,000 and $0.1 million for the three and nine months ended September 30, 2019, respectively, in cost of sales for services rendered in the Company's condensed consolidated statements of operations and comprehensive loss. Further for the three and nine months ended September 30, 2019, the Company recognized $0 and $49,000, respectively, in fee revenue related to its arrangement with HTC and Heuro (see Note 2). On October 30, 2019, the Company entered into a Share Purchase Agreement with HTC to purchase Heuro. The receivable will be considered part of the consideration for acquisition and will be embedded in the purchase price allocation. See Note 9 for details of the transaction.

Legal Contingencies

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

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

On September 9, 2019, three Helius shareholders each filed motions in the *Caramahai* and *Evans* cases seeking to consolidate the two proceedings into a single putative class action. The individual motions also sought to have the movant appointed as Lead Plaintiff 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 motion filed by the third movant remains pending before the Court and unopposed.

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

7. VARIABLE INTEREST ENTITIES

A variable interest entity ("VIE") is an entity that either (i) has insufficient equity to permit the entity to finance its activities without additional subordinated financial support, or (ii) has equity investors who lack the characteristics of a controlling financial interest. Under ASC 810, an entity that holds a variable interest in a VIE and meets certain requirements would be considered to be the primary beneficiary of the VIE and is required to consolidate the VIE in its condensed consolidated financial statements. In order to be considered the primary beneficiary of a VIE, an entity must hold a variable interest in the VIE and have both:

- the power to direct the activities that most significantly impact the economic performance of the VIE; and
- the right to receive benefits from, or the obligation to absorb losses of the VIE that could be potentially significant to the VIE.

The Company regularly assesses its relationships with contractual third party and other entities for potential VIE's. In making this assessment, the Company considers the potential that its contracts or other arrangements provide subordinated financial support, absorb losses or rights to residual

returns of the entity and the ability to directly or indirectly make decisions about the entity's activities. If the Company determines that it is the primary beneficiary of a VIE, the Company consolidates the statements of operations and financial condition of the VIE into its condensed consolidated financial statements.

Unconsolidated Variable Interest Entity

The Company utilized the consolidation guidance under ASC 810 to determine whether Heuro was a VIE, and if so, whether the Company was the primary beneficiary of Heuro (see Note 6(f)). As of September 30, 2019, the Company had concluded that Heuro was a VIE based on the fact that the equity investment at risk in Heuro was not sufficient. The Company's variable interests in Heuro arise from a profit-sharing arrangement with Heuro. In determining whether the Company is the primary beneficiary and whether the Company has the right to receive benefits and the obligation to absorb losses that could potentially be significant to the VIE, the Company evaluated its economic interest in Heuro.

This evaluation considered all relevant factors of Heuro's structure, including its capital structure, contractual rights to earnings (losses) as well as other contractual arrangements that have the potential to be economically significant. Following the guidance in ASC 810, although the Company has the obligation to absorb losses as of September 30, 2019, the Company concluded that it is not the primary beneficiary, as it does not have the power to direct the activities that most significantly affect the economic performance of Heuro. The significant economic activities identified were financing activities, research and development activities, commercialization activities, supply and distribution activities, business strategy activities and clinic expansion activities. The evaluation of each of these factors in reaching a conclusion about the potential significance of the Company's economic interests and control was a matter that required the exercise of professional judgement.

Accordingly, as of September 30, 2019, the Company did not consolidate Heuro in its condensed consolidated financial statements. In addition, as of September 30, 2019, the Company had no carrying amounts for assets and approximately $0.1 million in liabilities relating to the variable interest in the VIE. The Company believes that its maximum exposure to loss as a result of its involvement with the VIE is limited to CAD$0.1 million.

On October 30, 2019, the Company entered into a Share Purchase Agreement with HTC to purchase Heuro. See Note 9 for details of the transaction

8. RELATED PARTY TRANSACTIONS

During the three months ended September 30, 2019 and 2018, the Company paid approximately $2,000 and $25,000 respectively, in consulting fees to a director of the Company. During the nine months ended September 30, 2019 and 2018, the Company paid approximately $25,000 and $34,000, respectively, in consulting fees to a director of the Company. As of September 30, 2019, the Company owed $2,000 in consulting fees to a director of the Company.

In April 2016, the Company entered into a consulting agreement with Montel Media, Inc. ("Montel Media"), pursuant to which Montel Media provides consulting services for the promotion of the Company's clinical trials and ongoing media and marketing strategies. Montel Media is owned by Montel Williams, who beneficially owns greater than 5% of the Company's common stock. Under the agreement, Montel Media received $15,000 per month. During the first quarter of 2018, the Company terminated its agreement with Montel Media. The Company paid Montel Media $0 and $45,000, respectively, during the three and nine months ended September 30, 2018.

For the three months ended September 30, 2018, a benefit of $17,000, which included a foreign exchange gain of $5,000 was included in the change in fair value of derivative financial instruments as the fair value of stock-based compensation attributed to the options granted to a director for consulting services rendered with respect to the design and development of the PoNS device. For the nine months ended September 30, 2018, a benefit of $0.3 million, which included a foreign exchange gain of $18,000 was included in the change in fair value of derivative financial instruments as the fair value of stock-based compensation attributed to the options granted to a director for consulting services rendered with respect to the design and development of the PoNS device. With the adoption of ASC 2018-07 during the third quarter of 2018, all non-employee stock-based compensation are no longer recorded as derivative financial instruments.

The Company's Chief Medical Officer was a founding member of Clinvue LLC. ("Clinvue"), a company that provided regulatory advisory services to the Company until it ceased operations during the fourth quarter of 2018. For the three and nine months ended September 30, 2018, the Company paid $0 and $0.1 million, respectively to Clinvue for consulting services. The Company made no payment to Clinvue for the three and nine months ended September 30, 2019.

9. SUBSEQUENT EVENTS

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 $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 the Company 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, 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 PoNS Treatment and the NeuroCatch™ device throughout Canada. This co-promotion arrangement terminates upon the earlier of the collection of data from 200 patients in Canada and December 31, 2020. Also, subject to certain terms and conditions, 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.

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, 2018, 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, 2018 filed with the Securities and Exchange Commission, or the SEC, on March 14, 2019, or our 2018 Annual Report. All financial information is stated in U.S. dollars unless otherwise specified. Our condensed consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States, or U.S. GAAP.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties, including statements regarding our market, strategy, competition, capital needs, business plans and expectations. Such forward-looking statements involve risks and uncertainties regarding the success of our business plan, availability of funds, our ability to maintain and enforce our intellectual property rights, government regulations, operating costs, and our ability to achieve significant revenues and other factors. Forward-looking statements are made, without limitation, in relation to operating plans, availability of funds and operating costs. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "may", "will", "should", "expect", "plan", "intend", "anticipate", "believe", "estimate", "predict", "potential" or "continue", the negative of such terms or other comparable terminology. Actual events or results may differ materially. In evaluating these statements, you should consider various factors, including the risks outlined in the "Risk Factors" sections of our 2018 Annual Report and this report. These factors may cause our actual results to differ materially from any forward-looking statements. While these forward-looking statements, and any assumptions upon which they are based, are made in good faith, based on information available to us as of the date hereof, and reflect our current judgment regarding our business plans, our actual results will almost always vary, sometimes materially, from any estimates, predictions, projections, assumptions or other future performance suggested herein. We do not intend to update any of the forward-looking statements to conform these statements to actual results, except as required by applicable law, including the securities laws of the United States. The forward-looking statements are subject to a number of risks and uncertainties which are discussed in the section entitled "Item 1A. Risk Factors" in this Quarterly Report on Form 10-Q and in our 2018 Annual Report and those described from time to time in our future reports filed with the SEC. Although we believe that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee future results, events, levels of activity, performance or achievement. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

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

Overview

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

Our first product, known as the Portable Neuromodulation Stimulator, or PoNS™, is an active, therapeutic, class II medical device authorized for sale in Canada intended as a short term treatment (14 weeks) of chronic balance deficit due to mild-to-moderate traumatic brain injury, or mmTBI, and is to be used in conjunction with therapeutic activities, or PoNS Treatment™. The PoNS™ device is an investigational medical device in the United States, the European Union, or EU, and Australia, or AUS, and it is currently under review for clearance by the AUS Therapeutic Goods Administration, or TGA. PoNS Treatment™ is not currently commercially available in the United States, the European Union or Australia. The PoNS device, when combined with targeted therapeutic activities and/or cognitive therapy, or PoNS Treatment™, is the first and only treatment that combines neurostimulation of cranial nerves via the tongue to restore lost function. In April 2019, we announced that the U.S. Food and Drug Administration, or FDA, had completed its review and denied our request for de novo classification of the PoNS device in the United States. A new FDA submission with additional supporting clinical data will be required for clearance in the United States. We are working with the FDA to define the scope of this ongoing clinical work. We have withdrawn our application from the EU marketing process due to uncertainty in Europe due to the switch from the Medical Device Directive, or MDD, to the Medical Device Regulation, or MDR, and the withdrawal of Lloyd's Register Quality Assurance, our notified body, from the notified body business. We will reconsider submitting to the EU when conditions stabilize.

Business Update

Regulatory

In April 2019, we announced that the FDA had completed its review of, and denied our request for de novo classification of the PoNS device. In reaching its conclusion, the FDA noted that it did not have sufficient information to discern the relative independent contributions of the PoNS device and physical therapy to establish sufficient evidence of effectiveness of our PoNS device based on the data in our clinical trials. The FDA

has indicated that we need additional clinical data to support a marketing clearance in the United States. Based on this feedback, we have revised our strategy for marketing authorization in the United States.

Given the change in our United States regulatory timeline, we have prioritized our resources to support our resubmission to the FDA and commercialization efforts in Canada. As a result, we reduced our workforce by over 30% to scale back the staff that was hired to prepare for our commercial launch in the United States while maintaining the necessary distribution, regulatory and quality system infrastructure to support our commercial launch in Canada. In addition, we placed our clinical experience programs on hold, given that we are now able to gather anonymized outcomes and compliance data from patients treated in Canada to support our reimbursement strategy. Finally, we identified and added external resources with specialized clinical and regulatory expertise to inform our revised U.S. regulatory strategy and help us navigate the resubmission process.

In May 2019, we initiated our application process to the TGA for marketing authorization of our PoNS device in Australia. TGA's active review of our file commenced in September 2019 and we have provided responses to all questions received thus far. In addition, 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 a CE mark.

In June 2019, we provided an update on our strategy to resubmit an application for de novo clearance of our PoNS device with the FDA. As part of the strategy, members of our management team participated in an informational discussion with FDA in June 2019 regarding the issues the FDA raised in its April response letter. We have concluded that, while we will not finalize our resubmission protocol until after we engage with the FDA in a pre-submission meeting, such a protocol will, at a minimum, need to include new data evaluating the effect of physical therapy alone, without use of the PoNS device. Additional data or analyses may also be required, subject to further input from the FDA.

Based on the FDA's clarifications, we submitted a request to the FDA for a pre-submission meeting focused on discussing our resubmission strategy. The pre-submission meeting with FDA was held in October 2019. The discussion during the course of the meeting focused on supporting FDA's request for a study that demonstrates the benefit of PoNS Treatment compared to physical therapy alone in a way that can be generalized to the intended population of patients with balance deficits following mmTBI. The FDA indicated that additional data is required to support the new de novo submission. Study design, endpoints, eligible patient population and the duration of the investigation were discussed. Two analysis methods were proposed and will be implemented to maximize the information gained in the study while allowing for efficient enrollment and study execution. Overall, the meeting provided the information needed to help finalize the design of the new study in accordance with FDA's current recommendations. We have already incorporated the FDA's new feedback in our plans and we estimate that we will be able to submit a new request for de novo classification based on the results of our new study in the third quarter of 2020.

We are now engaged in continuing to drive our regulatory strategy in Canada. In-market experience reinforces our prior market assessment indicating Multiple Sclerosis, or MS, is an unmet clinical need in Canada. We are therefore preparing label expansion plans in Canada. A pre-submission communication is planned first for Health Canada.

Canada Commercialization Efforts

During the third quarter of 2019, additional patients completed the 14-week treatment protocol at the two founding clinic locations in Montreal, Quebec and Surrey, British Columbia. These clinics were opened pursuant to our arrangement with Health Tech Connex Inc., or HTC, and Heuro Canada, Inc., or Heuro. The initial high-level results about 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. In addition, the majority of patients have shown improvement in comfortable gait speed, a measure of their ability to walk, with a meaningful clinical difference at the end of their treatment, while also demonstrating a mean patient adherence to treatment of over 90%, which is also consistent with what we experienced in our clinical trials. We believe the consistency of the patient results from our initial commercial experience supports our plans to build the infrastructure to expand access to our novel PoNS Treatment in Canada.

During the second quarter of 2019, we also announced the expansion of the clinic development plan with HTC and Heuro into three new markets, Toronto, Calgary and Ottawa, with the authorization of one clinic in each of these markets. As these three new clinics have no prior experience when it comes to implementing our PoNS Treatment and integrating it into their clinic operations, we are taking a measured approach during our site training and authorization process to ensure that they are equipped with the know-how to achieve positive outcomes similar to the Surrey and Montreal clinics. These new clinics in turn, are also focused on integrating the PoNS Treatment into their practices. We expect it will take additional time for them to become fully operational and able to attract a significant population of interested patients. Our financial results for the third quarter of 2019 include the results of all five markets.

In June 2019, we launched a digital marketing campaign with the objective of increasing awareness of the PoNS Treatment and authorized clinics among targeted patients and their caregivers and providing contact information on authorized PoNS clinics. Our sales effort is focused on raising awareness of the PoNS Treatment among physiatrists and physical therapists, and in generating referrals to authorized PoNS clinics. Our Medical Affairs team continue their efforts in building awareness through development of key opinion leaders across Canada. We expanded our sales and marketing to Toronto, Calgary and Ottawa during the third quarter of 2019.

During the third quarter of 2019, as we recognized the need to streamline our decision process and react to evolving market factors which are a part of launching a novel technology like the PoNS, we began moving away from the franchise model to an authorized clinic model to work with

the physical therapy centers. In addition, we decided to build a more traditional medical device infrastructure and hired a VP and General Manager, based in Canada with a history of leadership roles in medical device companies to lead the commercialization activities across Canada. We have further expanded the team to include commercial strategy, operations and reimbursement expertise.

While the vast majority of our initial sales of the PoNS device were to self-pay patients, we have initiated a process for the collection and review of real-world evidence to support current and future payer efforts to seek reimbursement. During the third quarter, we received full reimbursement for the PoNS Treatment for two patients and focused activities to use these two successful reimbursement applications into a structured templated program for the authorized clinics to submit for further reimbursement applications. These efforts will be primarily deployed in the auto accident insurance and workers compensation markets. Lastly, we continue to focus on identifying, engaging and training new neuroplasticity clinics in Canada to become PoNS Treatment centers in order to expand patient access to care and are focusing on expanding the capacity and through-put of the clinics we have engaged. This initial commercialization experience will help us learn how to accelerate Canadian deployment as well as give us valuable information to potentially deploy in other markets around the world if we gain additional regulatory clearances.

Share Purchase Agreement and Co-Promotion Agreement

During the third quarter of 2019, we engaged with HTC through the joint steering committee in discussions regarding the future development of the commercialization of the PoNS device and PoNS Treatment in Canada. As we worked with Heuro to expand the commercial infrastructure, the complexity and feasibility of using a franchise model to build a market for PoNS including the physical therapy component became challenging. By acquiring Heuro, as noted below, we were able to streamline the decision-making process and increase our ability to react to evolving market factors as the market for the PoNS Treatment is being developed.

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

In connection with the Share Purchase Agreement, on October 30, 2019, we entered into a Clinical Research and Co-Promotion Agreement with HTC, or the Co-Promotion Agreement, whereby each company will promote the sales of the PoNS Treatment and the NeuroCatch™ device throughout Canada. This co-promotion arrangement terminates upon the earlier of the collection of data from 200 patients in Canada and December 31, 2020. Also, subject to certain terms and conditions, we granted to HTC the exclusive right to provide the PoNS Treatment in the Fraser Valley and Vancouver metro regions of British Columbia, where HTC has operated a PoNS authorized clinic since February 2019. HTC will purchase the PoNS devices for use in these regions exclusively from us and on terms no less favorable than the then-current standard terms and conditions. This exclusivity right has an initial term of ten (10) years, renewable by HTC for one additional ten (10) year term upon sixty (60) days' written notice to us.

Results of Operations

Three Months Ended September 30, 2019 compared to the Three Months Ended September 30, 2018

The following table summarizes our results of operations for the three months ended September 30, 2019 and 2018 (amounts in thousands):

	Three Months Ended September 30,		
	2019	2018	Change
Revenue:			
Product sales, net	$ 150	$ —	$ 150
Fee revenue	—	—	—
Total operating revenue	**150**	**—**	**150**
Cost of sales:			
Cost of product sales	89	—	89
Gross profit	**61**	**—**	**61**
Operating expenses:			
Research and development	1,506	2,309	(803)
Selling, general and administrative	4,291	2,581	1,710
Total operating expenses	**5,797**	**4,890**	**907**
Operating loss	**(5,736)**	**(4,890)**	**(846)**
Other income (expense):			
Other income	11	4	7
Change in fair value of derivative financial instruments	196	368	(172)
Foreign exchange (loss) gain	(59)	1	(60)
Total other income (expense)	**148**	**373**	**(225)**
Net loss	**$ (5,588)**	**$ (4,517)**	**$ (1,071)**

Revenue

Revenue for the three months ended September 30, 2019 was $0.2 million. This was generated through product sales of our PoNS device in Canada pursuant to our executed supply agreements with neuroplasticity clinics in Canada. We generated no revenue for the three months ended September 30, 2018.

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. It also includes certain support services provided by Heuro on our behalf. For the three months ended September 30, 2019, we incurred $0.1 million in our cost of sales. We had no cost of sales for the three months ended September 30, 2018.

Research and Development Expense

Research and development, or R&D, expenses were $1.5 million for the three months ended September 30, 2019 compared to $2.3 million for the three months ended September 30, 2018, a decrease of $0.8 million. The decrease was primarily driven by a $0.6 million reduction in product development costs due to the completion of the PoNS device development, the transfer to scale manufacturing and a $0.3 million decrease in consulting fees. These were partially offset by a $0.2 million increase in medical affairs expenses related to our clinical and scientific data and clinical education to key opinion leaders, professional societies and practitioners to help enhance our PoNS Treatment at home and in the clinic as well as feedback that can be incorporated in our PoNS device and training materials. Wages and salaries also increased by $0.1 million due to increased regulatory and quality management headcount to support our Canadian launch.

Selling, General and Administrative Expense

Selling, general and administrative, or SG&A, expenses were $4.3 million for the three months ended September 30, 2019 compared to $2.6 million for the three months ended September 30, 2018, an increase of approximately $1.7 million. The increase was primarily due to a $1.0 million increase in stock-based compensation expense as well as $0.6 million increase due to higher severance expense combined with a higher headcount to support our commercial launch in Canada.

Change in Fair Value of Derivative Financial Instruments

The change in fair value of derivative financial instruments was a gain of $0.2 million for the three months ended September 30, 2019 compared to a gain of $0.4 million for the three months ended September 30, 2018.

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.

Nine Months Ended September 30, 2019 compared to the Nine Months Ended September 30, 2018

The following table summarizes our results of operations for the nine months ended September 30, 2019 and 2018 (amounts in thousands):

	Nine Months Ended September 30,		
	2019	2018	Change
Revenue:			
Product sales, net	$ 1,295	$ —	$ 1,295
Fee revenue	49	—	49
Total operating revenue	1,344	—	1,344
Cost of sales:			
Cost of product sales	538	—	538
Gross profit	**806**	**—**	**806**
Operating expenses:			
Research and development	6,462	7,781	(1,319)
Selling, general and administrative	12,715	13,632	(917)
Total operating expenses	**19,177**	**21,413**	**(2,236)**
Operating loss	**(18,371)**	**(21,413)**	**3,042**
Other income (expense):			
Other income	35	63	(28)
Change in fair value of derivative financial instruments	14,033	(3,356)	17,389
Foreign exchange (loss) gain	(147)	1,198	(1,345)
Total other income (expense)	13,921	(2,095)	16,016
Net loss	**$ (4,450)**	**$ (23,508)**	**$ 19,058**

Revenue

Revenue for the nine months ended September 30, 2019 was $1.3 million. This was primarily generated through product sales of our PoNS device in Canada pursuant to our executed supply agreements with neuroplasticity clinics in Canada. In addition, we generated $49,000 in fee revenue from franchise agreements Heuro executed with neuroplasticity clinics engaging in providing the PoNS Treatment. We generated no revenue for the nine months ended September 30, 2018.

Cost of Sales

For the nine months ended September 30, 2019, we incurred $0.5 million in our cost of sales. This included the costs 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. It also includes certain support services provided by Heuro on our behalf. We had no cost of sales for the nine months ended September 30, 2018.

Research and Development Expense

R&D expenses were $6.5 million for the nine months ended September 30, 2019 compared to $7.8 million for the nine months ended September 30, 2018, a decrease of $1.3 million. The decrease was primarily attributable to a $2.9 million reduction in product development costs due to the completion of the PoNS device development and transfer to the scale manufacturer, which was partially offset by a $1.2 million increase in medical affairs expenses related to our medical science liaison's efforts in the delivery of our clinical and scientific data and clinical education to key opinion leaders, professional societies and practitioners to help enhance our PoNS Treatment at home and in the clinic as well as feedback that can be incorporated in our PoNS device and training materials. Wages and salaries also increased by $0.6 million due to increased regulatory and quality management headcount to support our Canadian launch.

Selling, General and Administrative Expense

SG&A expenses were $12.7 million for the nine months ended September 30, 2019 compared to $13.6 million for the nine months ended September 30, 2018. The decrease was primarily due to lower stock-based compensation expense of $3.8 million, which was mainly the result of the change in our functional currency. During the second quarter of 2018, all of our outstanding stock options were revalued due to the liability classification of our stock options as a result of a change in our functional currency in April 2018 as the exercise price of our stock options were

denominated in a currency other than our functional currency. Legal fees also decreased $0.6 million which was primarily attributable to our reduction of financing activities in 2019. This was partially offset by higher commercial operations expenses of $2.5 million as we invested in reimbursement, marketing and distribution capabilities in support of our US launch prior to receiving the denial for clearance from the FDA, as well as additional wages and salaries of $0.6 million to support our Canadian launch. Wages and salaries, including benefits and payroll taxes, also increased by $2.0 million due to an increase in severance expense combined with a higher headcount which was partially offset by a $1.0 million decrease in consulting expenses.

Change in Fair Value of Derivative Financial Instruments

The change in fair value of derivative financial instruments was a gain of $14.0 million for the nine months ended September 30, 2019 compared to a loss of $3.4 million for the nine months ended September 30, 2018.

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) Gain

Foreign exchange loss was $0.1 million for the nine months ended September 30, 2019 compared to a gain of $1.2 million for the nine months ended September 30, 2018. This was primarily due to the timing and volume of transactions in Canadian dollars.

Statement of Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2019 and 2018 (amounts in thousands):

	Nine Months Ended September 30,		
	2019	2018	Change
Net cash used in operating activities	$ (16,460)	$ (14,476)	$ (1,984)
Net cash used in investing activities	(260)	(425)	165
Net cash provided by financing activities	163	21,692	(21,529)
Effect of exchange rate changes on cash	(7)	44	(51)
Net (decrease) increase in cash	$ (16,564)	$ 6,835	$ (23,399)

Net Cash Used in Operating Activities

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 used in operating activities during the nine months ended September 30, 2018 was $14.5 million. This was comprised of a net loss of $23.5 million and net cash used in changes in operating assets and liabilities of $0.4 million, adjusted for non-cash items including the change in fair value of derivative financial instruments of $3.4 million, and stock-based compensation expense of $7.2 million, which amounts were partially offset by unrealized foreign exchange gains of $1.3 million.

Net Cash Used in Investing Activities

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 used in investing activities during the nine months ended September 30, 2018 was $0.4 million, which was primarily related to the purchase of furniture and fixtures for our office as well as laser marking equipment.

Net Cash Provided by Financing Activities

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

Net cash provided by financing activities during the nine months ended September 30, 2018 was $21.7 million, which was comprised of $18.4 million received from the sale of 2,463,185 shares of our common stock and accompanying warrants in our April 2018 public offering. In addition, we received $4.6 million in proceeds from the exercise of stock options and warrants. These amounts were partially offset by $1.3 million in share issuance costs incurred primarily in connection with the April 2018 public offering.

Liquidity and Capital Resources

Our condensed consolidated financial statements have been prepared assuming that we will continue as a going concern and, accordingly, do not include adjustments relating to the recoverability and realization of assets and classification of liabilities that might be necessary should we be

unable to continue in operation. Our major sources of cash have been proceeds from various public and private offerings of our common stock and exercises of stock options and warrants. From June 2014 through September 30, 2019, we raised approximately $94.2 million in gross proceeds from various public and private offerings of our common stock as well as the exercise of stock options and warrants.

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, 2019 and December 31, 2018 (amounts in thousands):

	September 30, 2019	December 31, 2018
Cash	$ 9,019	$ 25,583
Working capital	$ 7,764	$ 22,757

We currently have limited working capital and liquid assets. Our cash as of September 30, 2019 was approximately $9.0 million. While we have started generating revenue from the commercial sale of our PoNS device in Canada, we expect to incur significant losses until such time as our revenue exceeds our expenses and during this time, we will require additional funding to fund our ongoing activities. We believe that our existing capital resources will be sufficient to fund our operations into the first quarter of 2020. There can be no assurance that we will be successful in raising additional capital or that such capital, if available, will be on terms that are acceptable to us. If we are unable to raise sufficient additional capital, we may be compelled to reduce the scope of our operations and planned capital expenditure or sell certain assets, including intellectual property, and we may be forced to cease or wind down operations, seek protection under the provisions of the U.S. Bankruptcy Code, or liquidate and dissolve our company.

Contractual Commitments and Obligations

The disclosure of our contractual obligations and commitments was reported in our 2018 Annual Report. There have been no material changes from the contractual commitments and obligations previously disclosed in our 2018 Annual Report, other than the changes described in Note 6, “Commitments and Contingencies” to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Off-Balance Sheet Arrangements

In September 2018, we entered into an exclusive strategic alliance agreement with HTC and Heuro. Under the terms of the agreement, the parties developed a clinic system to facilitate the commercialization of the PoNS Treatment in Canada. The arrangement also provided for HTC to pay us CAD$750,000 in three annual payments of CAD$250,000 beginning December 31, 2019, in consideration for the exclusivity right we granted to Heuro. We and HTC governed the arrangement through a joint steering committee, and each funded up to 50% of the Heuro’s operating budget as agreed to by the joint steering committee, but not to exceed 50% of the operating budget associated with this arrangement and shared in the net profits and losses of Heuro on a 50/50 basis. For the three and nine months ended September 30, 2019, we recorded $0.1 million and $0.5 million, respectively, in expenses for our share of the estimated costs incurred by Heuro which amounts were recorded as selling, general and administrative expenses in our consolidated statement of operations and comprehensive loss. We believe that the maximum exposure to loss as a result of our involvement with Heuro was CAD$0.1 million as of September 30, 2019, which represented our potential remaining obligation to fund Heuro’s operating budget of up to CAD$1.0 million. On October 30, 2019, the Company entered into a Share Purchase Agreement with HTC to purchase Heuro. The CAD$750,000 receivable from the strategic alliance agreement entered into in September 2018 will be included as part of the consideration for acquisition and will be embedded in the purchase price allocation. See “Business Update – *Share Purchase Agreement and Co-Promotion Agreement*” for details of the transaction.

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 other than that described above and in Note 7 to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

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 2018 Annual Report. There have been no changes in critical accounting policies in the current year from those described in our 2018 Annual Report, except for the adoption of ASU No. 2016-02, *Leases*, using the modified retrospective method.

We elected the package of practical expedients permitted under the transition guidance within the new standard which allowed us to carry forward the historical lease classification. Adoption of this standard resulted in the recording of an operating lease right-of-use asset and corresponding operating lease liability of $0.7 million.

Recently Issued Accounting Pronouncements

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

JOBS Act

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

ITEM 3. Quantitative and Qualitative Disclosures about Market Risk

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

ITEM 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(b) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, under the direction of the Chief Executive Officer and the Chief Financial Officer, we have evaluated our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures were not effective as of the end of the period covered by this report due to the material weakness in our internal controls over financial reporting related to our verification process concerning wire transfer payments to vendors as discussed further below. Notwithstanding this material weakness, our management has concluded that the financial statements included elsewhere in this Quarterly Report present fairly, in all material respects, our financial position, results of operations and cash flows in conformity with generally accepted accounting principles.

In October 2019, we became aware that we had been a victim of a criminal fraud that law enforcement authorities refer to as business email compromise fraud, which involved impersonation of our vendor and fraudulent demands for wire transfers that targeted our finance department. We immediately responded to the criminal fraud. Despite our response, the fraud resulted in a transfer of approximately $0.1 million. To date, no funds have been recovered. The Company’s investigation into this matter continues as further discussed in Item 1A.

Remediation

During the fourth quarter of 2019, enhancements were made to our controls relating to electronic payments, including by wire transfer of funds. These enhancements include additional verification and documentation procedures to be followed prior to the initiation or approval of electronic payments by or for us. We believe these enhancements increase the ability of our personnel to identify and block attempts by third parties to fraudulently initiate electronic payments from us. Our management believes that the foregoing actions will help improve our internal controls over financial reporting. We are actively working to implement effective internal control over financial reporting, which includes remediation of these material weaknesses. However, such compliance is not guaranteed, and we cannot provide any assurance that our internal control over financial reporting will be effective as a result of these efforts.

Changes in Internal Control over Financial Reporting

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

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

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

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

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

On September 9, 2019, three Helius shareholders each filed motions in the *Caramahai* and *Evans* cases seeking to consolidate the two proceedings into a single putative class action. The individual motions also sought to have the movant appointed as Lead Plaintiff 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 motion filed by the third movant remains pending before the Court and unopposed.

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

Item 1A. Risk Factors

Our business is subject to risks and events that, if they occur, could adversely affect our financial condition and results of operations and the trading price of our securities. Except for the updated risk factors set forth immediately below, our risk factors have not changed materially from those risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2018. You should carefully consider the risk factors discussed in Part I, "Item 1A. Risk Factors" in our 2018 Annual Report. The risks described below and in our 2018 Annual Report are not the only risks facing us. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially and adversely affect our business, financial condition and/or operating results.

We have been the victim of a cyber-related crime and our controls may not be successful in avoiding further cyber-related crimes in the future.

In October 2019, we were the victim of a business email compromise, fraud which resulted in our incurring a loss of approximately $0.1 million. We are working with law enforcement authorities and the banks involved in the wire transfer to pursue recovery of the $0.1 million, but at this time we do not know whether we will be able to recover any of the funds, and we have been advised that it may take several months before we are better able to evaluate our recovery prospects. Enhancements have been made to our controls relating to electronic payments by or for us that we believe will reduce our risk of becoming a victim of future frauds related to our payments, including by wire transfers. However, cyber-related criminal activities continue to evolve and increase in sophistication, frequency and severity. As a result, the control enhancements that have been made, and any additional enhancements that may be made in the future, to our controls may not be successful in avoiding our becoming a victim to further cyber-related crimes.

Risks Related to Our Financial Position and Need for Capital

We will require additional financing to carry out our plan of operations and if we are unable to obtain such financing, our business may fail.

We currently have limited working capital and liquid assets. We had cash of $9.0 million at September 30, 2019. To date we have not generated significant revenue from the commercial sale of products or services. There are a number of conditions that we must satisfy before we will be able to generate significant revenue, including but not limited to FDA marketing authorization of the PoNS device for mmTBI, manufacturing of a commercially-viable version of the PoNS device, obtaining favorable reimbursement from third party payers, and demonstration of effectiveness sufficient to generate commercial orders by customers for our product. We do not currently have sufficient resources to accomplish all of these conditions necessary for us to generate significant revenue, and we believe our existing capital resources will be insufficient to fund our operations beyond the first quarter of 2020. We will therefore require substantial additional funds in order to continue to conduct the research and development and regulatory authorization activities necessary to bring our product to market, to establish effective marketing and sales capabilities and to develop other product candidates. We may never succeed in achieving regulatory authorization for our current product candidate in the United States, Europe or Australia. We may be unable to raise the additional funding to finance our business on commercially reasonable terms, or at all. If we are unable to obtain additional financing as needed, we may be forced to reduce the scope of our operations and

planned capital expenditures 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, which would have a material adverse effect on the value of our common stock.

Raising additional capital by issuing securities or through debt financings or licensing arrangements may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidate on terms unfavorable to us.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of such securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through strategic partnerships with third parties, we may have to relinquish valuable rights to our technologies or product candidate, future revenue streams, research programs or product candidate, or otherwise grant licenses on terms that are not favorable to us. If we are unable to raise additional capital when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts for our product candidate or our preclinical product candidates, or grant rights to develop and market potential future product candidates that we would otherwise prefer to develop and market ourselves. Any of these events could adversely affect our ability to achieve our product development and commercialization goals and have a material adverse effect on our business, financial condition and results of operations.

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

In connection with our management's assessment, our report from our independent registered public accounting firm for the fiscal year ended December 31, 2018 includes an explanatory paragraph stating that our recurring losses from operations and net capital deficiency raise substantial doubt about our ability to continue as a going concern. If we are unable to obtain sufficient funding, our business, prospects, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. For example, we believe our existing capital resources will be insufficient to fund our operations beyond the first quarter of 2020. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our consolidated financial statements, and investors will likely lose all or a part of their investment. Future reports from our independent registered public accounting firm may also contain statements expressing substantial doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all.

Risks Related to the Development and Commercialization of our Product Candidate

We currently only have one product candidate, which is still in development, and we have not obtained authorization from the FDA to commercially distribute the device in the United States, a CE Mark for commercial distribution in Europe or from the Therapeutic Goods Administration for commercial distribution in Australia, and we may never obtain such authorizations.

We currently have no products authorized for commercial distribution in either the United States, Europe or Australia. We are developing the PoNS device for use in the neuromodulation market, but we cannot begin marketing and selling the device in the United States, Europe or Australia until we obtain applicable authorizations from the FDA, European Union (Notified Body) or Therapeutic Goods Administration in Australia, respectively. While we have submitted applications for regulatory marketing authorization in these jurisdictions, the process of obtaining regulatory authorization is expensive and time-consuming and can vary substantially based upon, among other things, the type, complexity and novelty of a product. Changes in regulatory policy, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application may cause delays in the authorization of a product candidate or rejection of a regulatory application altogether.

In April 2019, the FDA declined our request for de novo classification of the PoNS device for use to improve balance in patients with mmTBI. In reaching its conclusion, the FDA noted that it did not have sufficient information to discern the relative independent contributions of the PoNS device and physical therapy to establish sufficient evidence of effectiveness based on our clinical trials. We intend to generate additional data to address the FDA's concerns and resubmit our request for de novo classification. However, the FDA has substantial discretion in the de novo review process and may refuse to accept our application or may decide that our new data are insufficient to grant the de novo request and require additional pre-clinical, clinical, or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit, or prevent marketing authorization from the FDA or other regulatory authorities. Any marketing authorization from the FDA we ultimately obtain may be limited or subject to restrictions or post-market commitments that render the product candidate not commercially viable. If our attempts to obtain marketing authorization are unsuccessful, we may be unable to generate sufficient revenue to sustain and grow our business, and our business, financial condition, and results of operations will be materially adversely affected.

If we are able to complete development of the PoNS device and obtain marketing authorization of the PoNS device for the treatment of chronic balance deficit in patients with mmTBI in the United States, Europe or Australia, we plan to develop the PoNS device for other indications, or symptoms caused by neurological disorders. We would be required to commit our own resources to fund development of any other indications and each would require separate FDA clearance or other marketing authorization. The costs of such development efforts and FDA clearance or

other marketing authorization could be substantial and would likely require additional funding, and each such indication would be subject to the same foregoing risks and uncertainties for FDA clearance/authorization.

Risks Related to Government Regulation

Before we can market and sell our products outside of Canada, we will be required to obtain marketing authorization from the FDA and foreign regulatory authorities. These authorizations will take significant time and require significant research, development, and clinical study expenditures, and ultimately may not succeed.

Before we begin to label and market the PoNS Treatment for use in the United States, we are required to obtain marketing authorization via a *de novo* reclassification request for our product or approval of pre-market approval application from the FDA, unless an exemption from pre-market review applies. We will also be required to comply with costly and more often time-consuming regulatory requirements by foreign regulatory authorities, including Europe and Australia, if we want to sell our products outside of the United States. The process of obtaining regulatory authorizations or approvals, including completion of the *de novo* classification process, to market a medical device can be costly and time consuming, and we may not be able to successfully obtain pre-market reviews on a timely basis, if at all.

In August 2018, we submitted a request to the FDA for *de novo* classification of the PoNS device because there is currently no predicate cleared or approved by the FDA for commercial distribution and no existing classification decision by the FDA for such a device. In April 2019, the FDA denied our request for *de novo* classification. In reaching its conclusion, the FDA noted that it did not have sufficient information to discern the relative independent contributions of the PoNS device and physical therapy to establish sufficient evidence of effectiveness based on our clinical trials. We intend to generate additional data to address the FDA's concerns and resubmit our request for *de novo* classification. Because the FDA has required us to go through a lengthier, more rigorous examination for the PoNS device for mmTBI, introducing the product will be delayed until we can generate sufficient additional data, which will cause our launch in the United States to be delayed or, in the event that the FDA does not find our additional data sufficient to support *de novo* classification, we may be required to abandon our pursuit of approval to commercialize the PoNS device in the United States altogether. In addition, the FDA may determine that the PoNS device requires more extensive clinical investigation than currently planned or that it must undergo the more costly, lengthy and uncertain pre-market approval process. For example, if the FDA disagrees with our determination that the *de novo* classification procedures are the appropriate path to obtain marketing authorization for the PoNS device, the FDA may require us to submit a PMA application, which is generally more costly and more burdensome and can take several years from the time the application is submitted to the FDA until an approval is obtained, if ever. The FDA may also determine that input from outside experts is needed, which may require a public advisory panel meeting. This may also increase the time and cost to obtain approval or result in disapproval.

Once we have a marketing authorization, any modification to a device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design, or manufacture, requires a new submission, such as a 510(k) or, possibly, another *de novo* classification petition or a PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review such determinations. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. If the FDA disagrees with any of our regulatory determinations and requires us to submit new 510(k) notices, de novo submissions, or PMAs for modifications to our previously cleared products for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified products until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties.

Moreover, we are currently developing the PoNS device for other potential indications. At this time, we do not know what pathways the FDA or other regulatory authorities will require us to utilize for these additional indications. We may be required to pursue marketing authorization via more rigorous pathways, such as a PMA application in the United States, which may require more development work than we are currently planning. This would delay the potential marketing authorization for such indications, potentially make marketing authorization more difficult to obtain, and increase our costs.

We may be required to conduct a clinical trial to support a Premarket Approval application for the PoNS device and we expect to be required to conduct clinical trials to support regulatory marketing authorization of some of our potential future product candidates. Clinical trials are complex, expensive and may proceed more slowly than anticipated, and we cannot be certain that our product candidate will be shown to be safe and effective for human use.

In order to commercialize our product candidate in the United States, we may be required by the FDA to submit an application for premarket approval, or PMA, for review and approval by the FDA. A PMA application must be submitted to the FDA if our device cannot be cleared through the 510(k) clearance process, down classified via the *de novo* process, or is not exempt from premarket review by the FDA. In April 2019, the FDA declined our request for *de novo* classification. However, we intend to generate additional data, including additional clinical data, to address the FDA's concerns and resubmit our request for *de novo* classification. We could also be required to submit a PMA application for other potential future product candidates. If we are required by the FDA to submit a PMA application, the FDA will also require us to conduct clinical trials. We will receive marketing authorization from the FDA to commercialize products requiring a clinical trial only if we can demonstrate to the

satisfaction of the FDA, through well designed and properly conducted clinical trials, that our product candidate is safe, effective, and otherwise meet the appropriate standards required for marketing authorization for specified indications.

Clinical trials are complex, expensive, time consuming, uncertain and are subject to substantial and unanticipated delays. Before we may begin clinical trials, if a clinical trial is determined to present a significant risk, we may be required to submit and obtain approval for an investigational device exemption, or IDE, that describes, among other things, the manufacture of, and controls for, the device and a complete investigational plan. Clinical trials generally involve a substantial number of patients in a multi-year study. Because we do not have the infrastructure necessary to conduct clinical trials, we will have to hire one or more contract research organizations, or CROs, to conduct trials on our behalf. CRO contract negotiations may be costly and time consuming and we will rely heavily on the CRO to ensure that our trials are conducted in accordance with regulatory and industry standards. We may encounter problems with our clinical trials and any of those problems could cause us or the FDA to suspend those trials or delay the analysis of the data derived from them. Moreover, any failure to abide by the applicable regulatory requirements by us, our CROs, and/or clinical trial sites may result in regulatory enforcement action against such third parties or us.

Even after marketing authorization for our product is obtained, we are subject to extensive post-market regulation by the FDA and equivalent foreign competent authorities. Our failure to meet strict regulatory requirements could require us to pay fines, incur other costs or even close our facilities.

Even after we have obtained the proper regulatory clearance or approval to market a product, the FDA has the power to require us to conduct post-market studies. These studies can be very expensive and time-consuming to conduct. Failure to complete such studies in a timely manner could result in the revocation of clearance or approval and the recall or withdrawal of the product, which could prevent us from generating sales from that product in the United States.

The FDA has broad enforcement powers, and any regulatory enforcement actions or inquiries, or other increased scrutiny on us, could dissuade some healthcare professionals from using our products and adversely affect our reputation and the perceived safety and efficacy of our products.

We are also required to comply with the FDA's Quality System Regulation, or QSR, which covers the methods used in, and the facilities and controls used for, the design, manufacture, quality assurance, labeling, packaging, sterilization, storage, shipping, installation and servicing of our marketed products.

The FDA enforces these requirements via periodic announced and unannounced inspections of manufacturing facilities. In addition, in the future, regulatory authorities and/or customers may require specific packaging of sterile products, which could increase our costs and the price of our products.

Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the product from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

After commercialization, a recall of our products, either voluntarily or at the direction of a governmental authority, or a foreign competent authority, or the discovery of serious safety issues with our products, could have a significant adverse impact on us.

The FDA and similar foreign governmental authorities such as the competent authorities of the European Economic Area countries or Health Canada have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture or in the event that a product poses an unacceptable risk to health. Manufacturers may, under their own initiative, recall a product if any material deficiencies in our products are found. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues.

The FDA requires that certain classifications of voluntary recalls of devices be reported to the FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. Any recalls of any of our products would divert managerial and financial resources and could have an adverse effect on our reputation, results of operations and financial condition, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and our ability to generate profits.

Any future failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in any of the following enforcement actions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications or repair, replacement, refund, recall, detention or seizure of our products;

- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance, *de novo* clearance, PMA approval, NDA, or BLA of new products or modified products;
- withdrawing clearances or approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

Any of these sanctions could have a material adverse effect on our reputation, business, results of operations and financial condition. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements, which could result in our failure to produce our products on a timely basis and in the required quantities, if at all.

U.S. legislative or FDA regulatory reforms may make it more difficult and costly for us to obtain regulatory approval of our product and to manufacture, market and distribute our products after marketing authorization is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of future products. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

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

None.

Item 3. Defaults upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

Exhibit No.	Description of Exhibit
3.1	Certificate of Conversion filed with the Delaware Secretary of State on July 18, 2018 (incorporated by reference to Exhibit 3.1 to the Form 10-Q filed August 9, 2018)
3.2	Certificate of Incorporation, as corrected (incorporated by reference to Exhibit 3.1 to the Form 8-K filed October 30, 2018)
3.3	Bylaws as amended and restated (incorporated by reference to Exhibit 3.3 to the Form 10-Q filed August 9, 2018)
10.1#	Separation Agreement between Helius Medical, Inc and Jennifer Laux, dated September 15, 2019
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.

SIGNATURES

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

HELIUS MEDICAL TECHNOLOGIES, INC.

Dated: November 12, 2019

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

Dated: November 12, 2019

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

Helius
MEDICAL

August 29, 2019

Ms. Jennifer Laux
741 Meadowcreek Circle Lower Gwynedd,
PA 19002

Re: Separation Agreement Dear Jen:
This letter sets forth the substance of the separation agreement (the "Agreement") which Helius Medical, Inc, (the "Company") is offering to you to aid in your employment transition. For purposes of this Agreement, references to the "Company" shall include affiliates of the Company.

I. **Separation.** Due to position elimination, your last day of work with the Company and your employment termination date will be Friday, August 30, 2019 (the "Separation Date"). The Company will not contest any claim that you might make for unemployment compensation benefits after that time.

2. **Severance Payment.** If you execute this Agreement, and fully comply with your obligations hereunder, the Company will make twenty-four severance payments to you in the bi-monthly, gross amount of $15,066.67 for twelve months following the Separation Date. These payments will be subject to standard payroll deductions and withholdings and will be made on the Company's ordinary payroll dates, beginning with the first such date which occurs at least eight (8) business days following the Company's receipt of your executed Agreement. The Company is offering severance to you in reliance on Treasury Regulation Section 1.409A l(b)(9) and the short-term deferral exemption in Treasury Regulation Section l.409A-l(b)(4). Any payments made in reliance on Treasury Regulation Section l.409A-l(b)(4) will be made not later than November 15, 2020. For purposes of Code Section 409A, your right to receive any installment payments under this letter (whether severance payments, reimbursements or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment.

3. **Benefit Plans.** If you are currently participating in the Company's group health insurance plans, your participation in the plan will end on August 31, 2019. Thereafter, you may continue participation in Helius' group medical and dental plans in accordance with the provisions offered under the Consolidated Omnibus Budget Reconciliation Act **(COBRA).** Notification of COBRA continuation and the ability to elect for such coverage has been provided under separate cover. Notwithstanding the above, your participation in Helius' group life insurance and long-term disability insurance will cease as of August 31, 2019.

4. **401(k) Retirement Plan.** If you participate in the Company's 401(k) retirement plan, deductions for the 401(k) Plan will end with your last regular paycheck on August 30, 2019. You will receive information by mail concerning 40l(k) plan rollover procedures should you be a participant in this program.

5. **Stock Options.** The 150,000 options granted to you under the 2018 Omnibus Stock Incentive Plan will fully vest as of your Separation Date. You will have 90 days from your Separation Date to exercise your vested options.

6. **Other Compensation or Benefits.** You acknowledge that, except as expressly provided in this Agreement, you will not receive any additional compensation, severance, incentive pay, vacation pay, or any other benefits after the Separation Date.

7. **Expense Reimbursements.** You agree that, within ten (10) days of the Separation Date, you will submit your final documented expense reimbursement statement reflecting all business expenses you incurred through the Separation Date, if any, for which you seek reimbursement. The Company will reimburse you for reasonable business expenses pursuant to its regular business practice.

8. **Return of Company Property.** By September 5, 2019, you agree to return to the Company all Company documents (and all copies thereof) and other Company property that you have had in your possession at any time, including, but not limited to, Company files, notes, drawings, records, business plans and forecasts, financial information, specifications, computer-recorded information, tangible property (including, but not limited to, computers), credit cards, entry cards, identification badges and keys; and, any materials of any kind that contain or embody any proprietary or confidential information of the Company (and all reproductions thereof). Please coordinate return of Company property with Human Resources. Receipt of the severance benefits described in Section 3 of this Agreement is expressly conditioned upon return of all Company Property.

9. **Proprietary Information and Post-Termination Obligations.** Both during and after your employment you will refrain from any unauthorized use or disclosure of the Company's proprietary or confidential information or materials. Confidential information that is also a "trade secret," as defined by law, may be disclosed (A) if it is made (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. In addition, in the event that you file a lawsuit for retaliation by the Company for reporting a suspected violation of law, you may disclose the trade secret to your attorney and use the trade secret information in the court proceeding, if you: (A) file any document containing the trade secret under seal; and (B) do not disclose the trade secret, except pursuant to court order.

10. **Confidentiality.** The provisions of this Agreement will be held in strictest confidence by you and will not be publicized or disclosed in any manner whatsoever; *provided, however,* that: (a) you may disclose this Agreement to your immediate family; (b) you may disclose this Agreement in confidence to your attorney, accountant, auditor, tax preparer, and financial advisor; and (c) you may disclose this Agreement insofar as such disclosure may be required by law , so long as you first provide Company ,with written notice of your intent to make such disclosure at least five business days prior to such disclosure, to the extent not prohibited by law. Notwithstanding the foregoing, nothing in this Agreement shall limit your right to voluntarily communicate, without prior notice to the Company, with the Equal Employment Opportunity Commission, United States Department of Labor, the National Labor Relations Board, the Securities and Exchange Commission, other federal government agency or similar state or local agency or to discuss the terms and conditions of yow- employment with others to the extent expressly permitted by Section 7 of the National Labor Relations Act.

11. **Non-Disparagement.** You agree not to disparage the Company, and the Company's attorneys, officers, directors, managers, partners, employees, agents and affiliates, in any manner likely to be harmful to them or their business,

business reputation or personal reputation; provided that you may respond accurately and fully to any question, inquiry or request for information when required by legal process. Notwithstanding the foregoing, nothing in this Agreement shall limit your right to voluntarily communicate with the Equal Employment Opportunity Commission , United States Department of Labor, the National Labor Relations Board, the Securities and Exchange Commission, other federal government agency or similar state or local agency or to discuss the terms and conditions of your employment with others to the extent expressly permitted by Section 7 of the National Labor Relations Act Similarly, the Company will instruct the current Officers of the Company, Philippe Deschamps, Jonathan Sackier, and Joyce LaViscount not to make any statements which are intended or reasonably likely to disparage you in any manner likely to be harmful to you or your business, business reputation or personal reputation.

12. Cooperation after Termination. During the time that you are receiving payments under this Agreement, you agree to cooperate fully with the Company in all matters relating to the transition of your work and responsibilities on behalf of the Company , including, but not limited to, any present, prior or subsequent relationships and the orderly transfer of any such work and institutional knowledge to such other persons as may be designated by the Company, by making yourself reasonably available during regular business hours.

13. Covenant not to Voluntarily Participate in Claims Against the Company. Except as set forth in Section 14, you agree not to voluntarily assistor participate in any way in the filing, reporting or prosecution by you or any third party of a proceeding or Claim (as defined in Section 14) against the Company Parties (as defined in Section 14).

14. Release. In exchange for the payments and other consideration under this Agreement, to which you would not otherwise be entitled, and except as otherwise set forth in this Agreement, you, on behalf of yourself and, to the extent permitted by law, on behalf of your spouse, heirs, executors, administrators, assigns, insurers, attorneys and other persons or entities, acting or purporting to act on your behalf (collectively, the "Employee Parties"), hereby generally and completely release, acquit and forever discharge the Company, its parents and subsidiaries, and its and their officers, directors, managers, partners, agents, representatives, employees, attorneys, shareholders, predecessors, successors, assigns, insurers and affiliates (the "Company Parties") of and from any and all claims, liabilities, demands , contentions, actions, causes of action, suits, costs, expenses, attorneys' fees, damages, indemnities, debts, judgments, levies, executions and obligations of every kind and nature, in law, equity, or otherwise, both known and unknown, suspected and unsuspected, disclosed and undisclosed, arising out of or in any way related to agreements, events, acts or conduct at any time prior to and including the execution date of this Agreement, including but not limited to: all such claims and demands directly or indirectly arising out of or in any way connected with your employment with the Company or the termination of that employment; claims or demands related to salary, bonuses, commissions, stock, stock options, or any other ownership interests in the Company, vacation pay, fringe benefits, expense reimbursements, severance pay, or any other form of compensation; claims pursuant to any federal, state or local law, statute, or cause of action; tort law; or contract law (individually a "Claim" and collectively "Claims") . The Claims you are releasing and waiving in this Agreement include, but are not limited to, any and all Claims that any of the Company Parties:

- has violated its personnel policies, handbooks, contracts of employment, or covenants of good faith and fair dealing;
- has discriminated against you on the basis of age, race, color, sex (including sexual harassment), national origin, ancestry, disability, religion, sexual orientation, marital status, parental status, source of income, entitlement to benefits, any union activities or other protected category in

violation of any local, state or federal law, constitution, ordinance, or regulation, including but not limited to: Title VII of the Civil Rights Act of 1964, as amended; the Civil Rights Act of 1991; 42 U S.C. § 1981, as amended; the Equal Pay Act; the Americans With Disabilities Act; the Genetic Information Nondiscrimination Act; the Family and Medical Leave Act; the Pennsylvania Human Relations Act; the Pennsylvania Equal Pay Law; the Pennsylvania Wage Payment and Collection Law; the Pennsylvania Whistleblower Law; the Employee Retirement Income Security Act; the Employee Polygraph Protection Act; the Worker Adjustment and Retraining Notification Act; the Older Workers Benefit Protection Act; the anti retaliation provisions of the Sarbanes-Oxley Act, or any other federal or state law regarding whistleblower retaliation; the Lilly Ledbetter Fair Pay Act; the Uniformed Services Employment and Reemployment Rights Act; the Fair Credit Reporting Act; and the National Labor Relations Act; has violated any statute, public policy or common law (including but not limited to Claims for retaliatory discharge; negligent hiring, retention or supervision; defamation; intentional or negligent infliction of emotional distress and/or mental anguish; intentional interference with contract; negligence; detrimental reliance; loss of consortium to you or any member of your family and/or promissory estoppel).

Notwithstanding the foregoing, other than events expressly contemplated by this Agreement you do not waive or release rights or Claims that may arise from events that occur after the date this waiver is executed. Also excluded from this Agreement are any Claims which cannot be waived by law, including, without limitation, any rights you may have under applicable workers' compensation laws and your right, if applicable, to file or participate in an investigative proceeding of any federal, state or local governmental agency. Nothing in this Agreement shall prevent you from filing, cooperating with, or participating in any proceeding or investigation before the Equal Employment Opportunity Commission, United States Department of Labor, the National Labor Relations Board, the Occupational Safety and Health Administration, the Securities and Exchange Commission or any other federal government agency, or similar state or local agency ("Government Agencies"), or exercising any rights pursuant to Section 7 of the National Labor Relations Act. You further understand this Agreement does not limit your ability to voluntarily communicate with any Government Agencies or otherwise participate in any investigation or proceeding that may be conducted by any Government Agency, including providing documents or other information, without notice to the Company. While this Agreement does not limit your right to receive an award for information provided to the Securities and Exchange Commission, you understand and agree that, you are othe1wise waiving, to the fullest extent permitted by law, any and all rights you may have to individual relief based on any Claims that you have released and any rights you have waived by signing this Agreement. If any Claim is not subject to release, to the extent permitted by law, you waive any right or ability to be a class or collective action representative or to otherwise participate in any putative or certified class, collective or multi-party action or proceeding based on such a Claim in which any of the Company Parties is a party. This Agreement does not abrogate your existing rights under any Company benefit plan or any plan or agreement related to equity ownership in the Company; however, it does waive, release and forever discharge Claims existing as of the date you execute this Agreement pursuant to any such plan or agreement.

15. Your Acknowledgments and Affirmations. You acknowledge and agree that (i) the consideration given to you in exchange for the waiver and release in this Agreement is in addition to anything of value to which you were already entitled; (ii) that you have been paid for all time worked, have received all the leave, leaves of absence and leave benefits and protections for which you are eligible, and have not suffered any on-the-job injury for which you have not already filed a Claim; (iii) you have been given 60 days from the date of this Agreement to read and consider the terms set forth in this Agreement and to consult an attorney or advisor of your choosing; and (iv) you are knowingly and voluntarily executing this Agreement waiving and releasing any Claims you may have as of the date you execute it. You affirm that all of

the decisions of the Company Parties regarding your pay and benefits through the date of your execution of this Agreement were not discriminatory based on age, disability, race, color, sex, religion, national origin or any other classification protected by law. You affirm that you have not filed or caused to be filed, and are not presently a party to, a Claim against any of the Company Parties. You further affirm that you have no known workplace injuries or occupational diseases. You acknowledge and affirm that you have not been retaliated against for reporting any allegation of corporate fraud or other wrongdoing by any of the Company Parties, or for exercising any rights protected by law, including any rights protected by the Fair Labor Standards Act, the Family Medical Leave Act, or any related statute or local leave or disability accommodation laws, or any applicable state workers' compensation law.

16. **No Admission.** This Agreement does not constitute an admission by the Company of any wrongful action or violation of any federal, state, or local statute, or common law rights, including those relating to the provisions of any law or statute concerning employment actions, or of any other possible or claimed violation of law or rights.

17. **Breach.** You agree that upon any breach of this Agreement you will repay all amounts paid and/or forfeit any remaining amounts owing to you under this Agreement. Further, you acknowledge that it may be impossible to assess the damages caused by your violation of the terms of Sections 9, 10, 11 and 13 of this Agreement and Section 7 of the Employment Agreement ("Employment Agreement") between you and the Company dated July 9, 2019 and further agree that any threatened or actual violation or breach of those Sections of this Agreement or Section 7 of the Employment Agreement will constitute immediate and irreparable injury to the Company. You therefore agree that any such breach of this Agreement or the Employment Agreement is a material breach of this Agreement, and, in addition to any and all other damages and remedies available to the Company upon your breach of this Agreement, the Company shall be entitled to an injunction to prevent you from violating or breaching this Agreement. You agree that if the Company is successful in whole or part in any legal or equitable action against you under this Agreement, you agree to pay all of the costs, including reasonable attorneys' fees, incurred by the Company in enforcing the terms of this Agreement.

18. **Miscellaneous.** This Agreement constitutes the complete, final and exclusive embodiment of the entire agreement between you and the Company withregard to this subject matter. It is entered without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes any other such promises, warranties or representations. This Agreement may not be modified or amended except in a writing signed by both you and a duly authorized officer of the Company. This Agreement will bind the heirs, personal representatives, successors and assigns of both you and the Company, and inure to the benefit of both you and the Company, their heirs, successors and assigns. If any provision of this Agreement is determined to be invalid or unenforceable, in whole or in part, this determination will not affect any other provision of this Agreement and the provision in question will be modified by the court so as to be rendered enforceable. This Agreement will be deemed to have been entered into and will be construed and enforced in accordance with the laws of the Commonwealth of Pennsylvania as applied to contracts made and to be performed entirely within Pennsylvania.

If this Agreement is acceptable to you, please sign below and return it to Ellyn Ito, VP Human Resources, on or before October 30, 2019. The Company's offer contained herein will automatically expire if we do not receive the fully signed Agreement within this timeframe.

I wish you good luck in your future endeavors.

Sincerely,
HELIUS MEDICAL, INC

By: /s/ Joyce LaViscount

AGREED AND ACCEPTED:

/s/ Jennifer Laux 9/15/19

EXHIBIT 31.1

CERTIFICATIONS

I, Phillippe Deschamps, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 12, 2019

/s/ Phillippe Deschamps
Phillippe Deschamps
Chief Executive Officer and Director

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, 2019

/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, 2019
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I am the Chief Executive Officer of Helius Medical Technologies, Inc., a Delaware corporation (the "Company"). I am delivering this certificate in connection with the Form 10-Q of the Company for the quarter ended September 30, 2019 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, 2019

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

EXHIBIT 32.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
HELIUS MEDICAL TECHNOLOGIES, INC.
FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2019
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, 2019 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, 2019

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