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

FORM 10-Q

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

For the quarterly period ended June 30, 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 August 6, 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)

	June 30, 2019	December 31, 2018
ASSETS		
Current assets		
Cash	$ 14,311	$ 25,583
Accounts receivable	723	177
Other receivables	291	98
Inventory	902	392
Prepaid expenses	302	447
Other current assets	—	264
Total current assets	16,529	26,961
Property and equipment, net	711	554
Other assets		
Operating lease right-of-use asset, net	619	—
Non-current receivables	320	294
Other assets	18	18
Total other assets	957	312
TOTAL ASSETS	**$ 18,197**	**$ 27,827**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 3,047	$ 2,392
Accrued liabilities	1,376	1,812
Operating lease liability	156	—
Derivative financial instruments	282	13,769
Total current liabilities	4,861	17,973
Non-current liabilities		
Operating lease liability	554	—
TOTAL LIABILITIES	**5,415**	**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 June 30, 2019 and December 31, 2018	—	—
Class A common stock, $0.001 par value; 150,000,000 shares authorized; 25,903,544 and 25,827,860 shares issued and outstanding as of June 30, 2019 and December 31, 2018, respectively	26	26
Additional paid-in capital	107,437	105,411
Accumulated other comprehensive loss	(827)	(591)
Accumulated deficit	(93,854)	(94,992)
TOTAL STOCKHOLDERS’ EQUITY	**12,782**	**9,854**
TOTAL LIABILITIES AND STOCKHOLDERS’ EQUITY	**$ 18,197**	**$ 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 Income (Loss)
(Amounts in thousands except shares and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenue:				
Product sales, net	$ 469	$ —	$ 1,146	$ —
Fee revenue	49	—	49	—
Total operating revenue	**518**	**—**	**1,195**	**—**
Cost of sales:				
Cost of product sales	212	—	448	—
Gross profit	**306**	**—**	**747**	**—**
Operating expenses:				
Research and development	2,275	2,921	4,956	5,472
Selling, general and administrative	3,845	8,886	8,426	11,051
Total operating expenses	**6,120**	**11,807**	**13,382**	**16,523**
Operating loss	**(5,814)**	**(11,807)**	**(12,635)**	**(16,523)**
Other income (expense):				
Other income	13	1	24	59
Change in fair value of derivative financial instruments	5,548	(6,249)	13,837	(3,724)
Foreign exchange gain (loss)	67	229	(88)	1,197
Total other income (expense)	**5,628**	**(6,019)**	**13,773**	**(2,468)**
Net (loss) income	**(186)**	**(17,826)**	**1,138**	**(18,991)**
Other comprehensive (loss) income:				
Foreign currency translation adjustments	(124)	119	(236)	(834)
Comprehensive (loss) income	**$ (310)**	**$ (17,707)**	**$ 902**	**$ (19,825)**
Net (loss) income per share				
Basic	**$ (0.01)**	**$ (0.78)**	**$ 0.04**	**$ (0.88)**
Diluted	**$ (0.01)**	**$ (0.78)**	**$ 0.04**	**$ (0.90)**
Weighted average shares outstanding				
Basic	**25,870,600**	**22,918,692**	**25,851,501**	**21,633,948**
Diluted	**25,870,600**	**23,045,565**	**25,953,654**	**21,763,083**

(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 June 30, 2019 and 2018
(Except shares data, amounts in thousands)

	Common Stock, $0.001 par value		Common Stock, no par value		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount				
Balance as of March 31, 2018	**—**	**$ —**	**20,797,309**	**$ 59,229**	**$ 6,982**	**$ (906)**	**$ (67,534)**	**$ (2,229)**
Proceeds from exercise of stock options and warrants	—	—	116,997	883	—	—	—	883
Proceeds from the issuance of common stock and accompanying warrants in connection with 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			—	(1,272)	—	—	—	(1,272)
Reclassification of liability-classified warrants upon exercise	—	—	—	502	—	—	—	502
Reclassification of exercised compensation options and warrants from additional paid-in capital	—	—	—	110	(110)	—	—	—
Reclassification from stock-based compensation liability to common stock as a result of exercise of stock options	—	—	—	32	—	—	—	32
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)
Foreign currency translation adjustments	—	—	—	—	—	119	—	119
Net loss	—	—	—	—	—	—	(17,826)	(17,826)
Balance as of June 30, 2018	**—**	**$ —**	**23,377,491**	**$ 70,512**	**$ 3,582**	**$ (787)**	**$ (85,360)**	**$ (12,053)**

	Common Stock, $0.001 par value		Common Stock, no par value		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount				
Balance as of March 31, 2019	**25,844,180**	**$ 26**	**—**	**$ -**	**$ 106,363**	**$ (703)**	**$ (93,668)**	**$ 12,018**
Proceeds from exercise of stock options and warrants	58,400	—	—	—	123	—	—	123
Settlement of restricted stock units	964	—	—	—	—	—	—	—
Reclassification of derivative financial instruments from exercise of stock options and warrants	—	—	—	—	10	—	—	10
Stock-based compensation			—	—	941	—	—	941
Foreign currency translation adjustments	—	—	—	—	—	(124)	—	(124)
Net loss	—	—	—	—	—	—	(186)	(186)
Balance as of June 30, 2019	**25,903,544**	**$ 26**	**—**	**$ —**	**$ 107,437**	**$ (827)**	**$ (93,854)**	**$ 12,782**

(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 Six Months Ended June 30, 2019 and 2018
(Except shares data, amounts in thousands)

	Common Stock, $0.001 par value		Common Stock, no par value		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Loss	Deficit	Total
Balance as of December 31, 2017	**—**	**$ —**	**20,178,226**	**$ 52,230**	**$ 6,602**	**$ 47**	**$ (66,369)**	**$ (7,490)**
Proceeds from the exercise of stock options and warrants			736,080	4,636	—	—	—	4,636
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	—	—	—	(1,272)	—	—	—	(1,272)
Stock-based compensation expense	—	—	—	—	380	—	—	380
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)
Foreign currency translation adjustments	—	—	—	—	—	(834)	—	(834)
Net loss	—	—	—	—	—	—	(18,991)	(18,991)
Balance as of June 30, 2018	**—**	**$ —**	**23,377,491**	**$ 70,512**	**$ 3,582**	**$ (787)**	**$ (85,360)**	**$ (12,053)**

	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	—	—	—	—	1,776	—	—	1,776
Foreign currency translation adjustments	—	—	—	—	—	(236)	—	(236)
Net income	—	—	—	—	—	—	1,138	1,138
Balance as of June 30, 2019	**25,903,544**	**$ 26**	**—**	**$ —**	**$ 107,437**	**$ (827)**	**$ (93,854)**	**$ 12,782**

(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)

	Six Months Ended June 30,	
	2019	**2018**
Cash flows from operating activities:		
Net income (loss)	$ 1,138	$ (18,991)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Change in fair value of derivative financial instruments	(13,837)	3,724
Stock-based compensation expense	1,776	6,720
Unrealized foreign exchange loss (gain)	153	(1,285)
Depreciation expense	47	22
Changes in operating assets and liabilities:		
Accounts receivable	(546)	—
Other receivables	(207)	174
Inventory	(510)	—
Prepaid expenses	145	152
Other assets	264	—
Operating lease liability	(7)	—
Accounts payable	655	(1,938)
Accrued liabilities	(285)	294
Net cash used in operating activities	**(11,214)**	**(11,128)**
Cash flows from investing activities:		
Purchase of property and equipment	(204)	(199)
Net cash used in investing activities	**(204)**	**(199)**
Cash flows from financing activities:		
Proceeds from the issuance of common stock and accompanying warrants	—	18,400
Share issuance costs	(52)	(1,324)
Proceeds from the exercise of stock options and warrants	215	4,636
Net cash provided by financing activities	**163**	**21,712**
Effect of foreign exchange rate changes on cash	(17)	40
Net (decrease) increase in cash	(11,272)	10,425
Cash at beginning of period	25,583	5,562
Cash at end of period	**$ 14,311**	**$ 15,987**

(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 authorized medical device in Canada for the treatment of chronic balance deficit associated with a mild to moderate traumatic brain injury ("mmTBI"), and is an investigational, non-invasive, medical device for which the Company has submitted an application for a CE mark for marketing authorization in the European Union and to the Therapeutic Goods Administration for marketing authorization in Australia, to improve balance in patients following a mmTBI. The Company's PoNS device, when combined with targeted physical and/or cognitive therapy, ("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.

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 as well as a rehabilitation clinic that will provide the PoNS Treatment to patients with balance and gait disorder upon receipt of marketing authorization from the FDA. The Company's wholly owned subsidiaries are comprised of HMI, Helius Medical Technologies (Canada), Inc. ("HMC") 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 June 30, 2019, the Company had cash of $14.3 million. For the six months ended June 30, 2019, the Company had an operating loss of $12.6 million and as of June 30, 2019, its accumulated deficit was $93.9 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 raise substantial doubt about the Company's ability to continue as a going concern. 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 June 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 Health Tech Connex Inc. ("HTC") and Heuro Canada, Inc. ("Heuro"), of which $0.3 million was classified as a non-current receivable. As of June 30, 2019, accounts receivable included revenue from product sales and fee revenue of approximately $0.5 million.

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 six months ended June 30, 2019.

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

	As of June 30, 2019	As of December 31, 2018
Raw materials	$ 701	$ 392
Work-in-process	73	—
Finished goods	128	—
Total	**$ 902**	**$ 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 June 30, 2019 and December 31, 2018, property and equipment consisted of the following (amounts in thousands):

	As of June 30, 2019	As of December 31, 2018
Leasehold improvement	$ 182	$ 182
Furniture and fixtures	248	185
Equipment	219	219
Computer software and hardware	185	44
Property and equipment	**834**	**630**
Less accumulated depreciation	(123)	(76)
Property and equipment, net	**$ 711**	**$ 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 June 30, 2019, the Company had only one operating lease, which was for its headquarters office in Newtown, Pennsylvania upon the adoption date. As of June 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 June 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 income (loss) as foreign exchange gain (loss).

The functional currency of HMC, the Company's Canadian subsidiary, 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 income (loss) for the reporting period, but rather are accumulated and gains and losses are recorded in foreign exchange gain (loss), as a component of comprehensive income (loss), within the condensed consolidated statements of operations and comprehensive income (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

Product sales are 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 brain vital signs of patients participating in the PoNS Treatment at neuroplasticity clinics in Canada. The Company acts in an agency capacity for services performed using the NeuroCatch device and remits 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 is met when it delivers the PoNS device to the clinic's facility and the clinic takes title of the PoNS device upon acceptance. Further, according to the Company's arrangement with HTC and Heuro, the Company shares 50/50 with Heuro in fees from support services excluding the CAD$600 payment for an assessment using the NeuroCatch device. For the three and six months ended June 30, 2019, the Company recorded $0.5 million and $1.2 million, respectively, in product sales net of $2,250 and $11,100, respectively, for HTC's portion related to assessments using the NeuroCatch device.

Fee Revenue

The Company's agreement with HTC and Heuro also entitles the Company to 50% of franchise fees collected by Heuro from each franchise agreement Heuro executes with neuroplasticity clinics engaged in providing the PoNS Treatment as a result of the Company's 50% share in Heuro profit/loss. For each of the three and six months ended June 30, 2019, the Company recognized $49,000 as its 50% portion of the franchise fee.

As of June 30, 2019, the Company had recorded $0.5 million in current receivables and had no contract assets or liabilities on its condensed consolidated balance sheet related to these supply agreements. As of June 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 income (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 income (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 income (loss). As of June 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 June 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 June 30, 2019 and December 31, 2018 (amounts in thousands):

	Fair Value	Level 1	Level 2	Level 3
June 30, 2019				
Liabilities:				
Derivative financial instruments	$ 282	—	—	$ 282
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 Income (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 income (loss) per share for the periods noted below is as follows (amounts in thousands except shares and per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Basic				
Numerator				
Net (loss) income	$ (186)	$ (17,826)	$ 1,138	$ (18,991)
Denominator				
Weighted average common shares outstanding	25,870,600	22,918,692	25,851,501	21,633,948
Basic net (loss) income per share	**$ (0.01)**	**$ (0.78)**	**$ 0.04**	**$ (0.88)**
Diluted				
Numerator:				
Net (loss) income, basic	$ (186)	$ (17,826)	$ 1,138	$ (18,991)
Effect of dilutive securities: warrants	—	(107)	—	(532)
Net (loss) income, diluted	$ (186)	$ (17,933)	$ 1,138	$ (19,523)
Denominator:				
Weighted average common shares outstanding - basic	25,870,600	22,918,692	25,851,501	21,633,948
Potential common share issuances:				
Incremental dilutive shares from equity instruments (treasury stock method)	—	126,873	102,153	129,135
Weighted average common shares outstanding	25,870,600	23,045,565	25,953,654	21,763,083
Diluted net (loss) income per share	**$ (0.01)**	**$ (0.78)**	**$ 0.04**	**$ (0.90)**

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 six months ended June 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 June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Stock options outstanding	3,281,499	2,561,146	2,909,499	2,561,146
Warrants outstanding	3,043,605	4,016,930	3,043,605	4,016,930
Restricted stock units	—	963	—	963
Total	**6,325,104**	**6,579,039**	**5,953,104**	**6,579,039**

Recent Accounting Pronouncements

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 June 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 second quarter of 2019, 22,031 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 income (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 June 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 June 30, 2019.

	June 30, 2019	April 24, 2018	April 13, 2018
Stock price	CAD $2.89	CAD $10.76	CAD $9.85
Exercise price	CAD $12.25	CAD $12.25	CAD $12.25
Warrant term	1.78 years	3.00 years	3.00 years
Expected volatility	71.25%	64.49%	64.20%
Risk-free interest rate	1.59%	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 six months ended June 30, 2019 and 2018 (amounts in thousands):

	Six Months Ended June 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 (gains) losses	385	(390)
Change in fair value of warrants during the period	(13,837)	889
Fair value of warrants at end of period	**$ 282**	**$ 14,371**

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 income (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 June 30, 2019 and December 31, 2018 were estimated using the Black-Scholes option pricing model with the following weighted average assumptions:

	June 30, 2019	December 31, 2018
Stock price	CAD$ 2.89	CAD$ 12.80
Exercise price	CAD$ 12.25	CAD$ 10.89
Warrant term	1.78 years	1.71 years
Expected volatility	71.25%	75.31%
Risk-free interest rate	1.59%	1.80%
Dividend rate	0.00%	0.00%

The following is a summary of the Company's warrant activity during the six months ended June 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	—	—	0.00	—
Cancelled/Expired	(922,348)	—	7.50	—
Exercised	(38,351)	—	7.50	—
Outstanding as of June 30, 2019	**2,392,285**	**651,320**	**$ 12.25**	**$ 12.24**

The Company's warrants outstanding and exercisable as of June 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 predecessor incentive plan (the "2016 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 June 30, 2019, there was an aggregate of 4,282,261 shares of common stock remaining available for grant under the Company's 2018 Plan.

For the six months ended June 30, 2019, the Company issued 640,158 stock options to employees and directors. The Company issued no stock options to consultants and non-employees during the six months ended Juned 30, 2019.

The following is a summary of the Company's stock option activity during the six months ended June 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	640,158	6.93	—
Forfeited/Cancelled	(146,708)	9.73	—
Exercised [1]	(520,000)	2.77	108
Outstanding as of June 30, 2019	**3,281,499**	**$ 7.67**	**$ —**
Exercisable as of June 30, 2019	**1,658,773**	**$ 3.46**	**$ —**

1. For the six months ended June 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 June 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	0.44	$ 12.72	$ 2.18	$ —	20,000
80,000	December 8, 2019	0.44	$ 12.72	$ 2.18	$ —	80,000
20,000	March 16, 2020	0.71	$ 12.52	$ 2.43	$ —	20,000
150,000	October 21, 2020	1.31	$ 3.20	$ 6.57	$ —	150,000
20,000	December 31, 2020	1.50	$ 4.48	$ 5.86	$ —	20,000
595,000	July 13, 2020	1.04	$ 5.35	$ 5.18	$ —	595,000
20,000	August 8, 2020	1.11	$ 4.98	$ 5.42	$ —	20,000
617,000	April 17, 2027	7.79	$ 8.13	$ 7.54	$ —	308,500
6,146	May 18, 2027	7.88	$ 7.35	$ 4.75	$ —	6,146
10,000	May 18, 2027	7.88	$ 7.35	$ 7.65	$ —	5,000
30,000	August 8, 2027	8.10	$ 10.38	$ 7.38	$ —	7,500
20,000	April 9, 2028	8.77	$ 9.03	$ 8.01	$ —	5,000
337,500	May 15, 2028	8.87	$ 10.99	$ 7.89	$ —	151,563
150,000	July 9, 2028	9.02	$ 9.69	$ —	$ 6.83	—
71,795	August 22, 2028	9.14	$ 10.23	$ —	$ 7.21	—
11,500	September 4, 2028	9.18	$ 10.19	$ —	$ 7.19	—
50,000	September 10, 2028	9.19	$ 10.34	$ —	$ 7.30	—
50,000	September 24, 2028	9.23	$ 9.71	$ —	$ 6.79	—
75,000	October 15, 2028	9.29	$ 8.75	$ —	$ 6.19	—
10,000	October 29, 2028	9.33	$ 9.71	$ —	$ 6.87	—
20,000	November 19, 2028	9.38	$ 8.00	$ —	$ 5.66	—
15,000	December 17, 2028	9.46	$ 9.42	$ —	$ 6.66	—
50,000	January 14, 2029	9.54	$ 8.19	$ —	$ 5.67	—
7,500	January 22, 2029	9.56	$ 7.65	$ —	$ 5.30	—
7,500	February 4, 2029	9.60	$ 7.26	$ —	$ 5.03	—
560,558	March 28, 2029	9.74	$ 6.76	$ —	$ 4.62	25,565
3,004,499						**1,414,273**

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

As of June 30, 2019, the unrecognized compensation cost related to non-vested stock options outstanding for employees and directors, was $8.7 million which will be recognized over a weighted-average remaining vesting period of approximately 2.9 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 six months ended June 30, 2019 was $4.71 per option and the grant date fair values of these stock options were estimated using the Black-Scholes option pricing model using the following weighted average assumptions:

	Six Months Ended June 30, 2019
Stock price	$ 6.93
Exercise price	$ 6.93
Expected term	6.09 years
Expected volatility	76.90%
Risk-free interest rate	2.28%
Dividend rate	0.00%

Non-Employee Stock Options

The following table summarizes stock options outstanding and exercisable by consultants as of June 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	0.44	$ 12.72	$ 2.18		30,000
72,000	October 3, 2020	1.26	$ 5.15	$ 5.35		72,000
110,000	October 28, 2020	1.33	$ 3.18	$ 6.59		110,000
20,000	May 18, 2027	7.88	$ 7.35	$ 7.65		10,000
15,000	August 8, 2027	8.10	$ 10.38	$ 7.38		3,750
15,000	November 6, 2027	8.35	$ 16.20	$ 6.98		3,750
15,000	August 22, 2028	9.14	$ 10.23		$ 8.87	15,000
277,000						**244,500**

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

Restricted Stock Units

During the six months ended June 30, 2019, the Company issued 964 shares of its common stock in settlement of vested RSUs. As of June 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 income (loss) as follows (amounts in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Research and development	$ 215	$ 438	$ 410	$ 537
Cost of sales	2	—	5	—
Selling, general and administrative	724	5,895	1,361	6,183
Total	**$ 941**	**$ 6,333**	**$ 1,776**	**$ 6,720**

5. ACCRUED EXPENSES

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

	As of	
	June 30, 2019	December 31, 2018
Employees benefits	$ 734	$ 876
Professional services	196	518
Due to HTC/Heuro	189	—
Legal fees	156	253
Royalty fees	46	—
Franchise fees	28	—
Rent	—	98
Severance	26	66
Other	1	1
Total	**$ 1,376**	**$ 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 six months ended June 30, 2019, the Company recorded approximately $19,000 and $46,000, 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. 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 June 30, 2019 (amounts in thousands).

For the Six Months Ended June 30, 2019		
Operating lease cost	$	116
Operating lease - operating cash flows	$	123
Weighted average remaining lease term		3.54 years
Weighted average discount rate		15.1%
Future minimum lease payments under non-cancellable lease as of June 30, 2019 were as follows:		
For the Period Ending December 31,		
2019 (remaining six months)	$	123
2020		253
2021		260
2022		267
2023		10
Total future minimum lease payments		**913**
Less imputed interest		(203)
Total liability	**$**	**710**
Reported as of June 30, 2019		
Current operating lease liability		156
Non-current operating lease liability		554
Total	**$**	**710**

(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 June 30, 2019, the Company had approximately $0.5 million in obligations 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. The parties will contract with the clinics and develop 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. The arrangement currently provides 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 continue to govern the agreement through a joint steering committee, and are each funding up to 50% of Heuro's operating budget as agreed to by the joint steering committee and are sharing in the net profits and losses of Heuro on a 50/50 basis. For the three and six months ended June 30, 2019, the Company recorded $0.2 million and $0.4 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 $33,000 and $0.1 million for the three and six months ended June 30, 2019, respectively, in cost of sales for services rendered in the Company's condensed consolidated statements of operations and comprehensive income (loss). Further for the three and six months ended June 30, 2019, the Company recognized $49,000 in fee revenue related to its arrangement with HTC and Heuro (see Note 1).

Legal Contingencies

On or about July 9, 2019, a putative shareholder class action lawsuit, *Caramihai 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.

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 June 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 June 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 June 30, 2019, the Company did not consolidate Heuro in its condensed consolidated financial statements. In addition, as of June 30, 2019, the Company had no carrying amounts for assets and approximately $0.2 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$0.4 million.

8. RELATED PARTY TRANSACTIONS

During the three months ended June 30, 2019 and 2018, the Company paid approximately $13,000 and $6,000 respectively, in consulting fees to a director of the Company. During the six months ended June 30, 2019 and 2018, the Company paid approximately $23,000 and $9,000, respectively, in consulting fees to a director of the Company. As of June 30, 2019, the Company owed $1,000 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 $45,000 during the three and six months ended June 30, 2018.

For the three months ended June 30, 2018, a benefit of $37,000, which included a foreign exchange gain of $13,000 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 six months ended June 30, 2018, a benefit of $0.2 million, which included a foreign exchange gain of $13,000 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 six months ended June 30, 2018, the Company paid $10,000 and $0.1 million, respectively to Clinvue for consulting services. The Company made no payment to Clinvue for the three and six months ended June 30, 2019.

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. 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 authorized medical device in Canada for the treatment of chronic balance deficit associated with a mild to moderate traumatic brain injury, or mmTBI, and is an investigational, non-invasive, medical device for which we have submitted an application for a CE mark for marketing authorization in the European Union and to the Therapeutic Goods Administration for marketing authorization in Australia, to improve balance in patients following a mmTBI. Our PoNS device, when combined with targeted physical 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.

Business Update

Regulatory

In April 2019, we announced that the U.S. Food and Drug Administration, or the FDA, had completed its review of, and denied our request for de novo classification of the Portable Neuromodulation Stimulator (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 authorization 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 submitted our application to the Therapeutic Goods Administration for marketing authorization of our PoNS device in Australia. 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 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 to augment our registrational clinical trial protocol, which is intended to support the resubmission of our application for de novo clearance of the PoNS device. We intend to finalize our resubmission protocol after we engage with the FDA in the pre-submission meeting. We have also begun a data collection program to address questions regarding the relative contribution of physical therapy to the positive therapeutic outcomes of PoNS treatment in our clinical trials. This strategy has been developed with the guidance of regulatory counsel with wide experience in de novo applications to the neuromodulation division at the FDA, a statistician who worked in a senior position at the FDA for many years and a number of additional, prominent clinical advisors.

Canada Commercialization Efforts

During the second quarter of 2019, the first 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 first 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 experiencing a mean patient compliance of over 90%, which is also consistent with what we experienced in our clinical trials.

During the second quarter of 2019, we concentrated our sales and marketing activities in the Montreal and Surrey markets. Our key focus of the early commercialization of the PoNS device in Canada has been on positive clinical outcomes over speed of deployment.

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 intend to expand our sales and marketing to Toronto, Calgary and Ottawa during the third quarter of 2019.

While to date our initial sales of the PoNS device have been 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. Lastly, we continue to focus on identifying, engaging and training new neuroplasticity clinics to become PoNS Treatment centers in order to expand patient access to care. 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.

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 thus 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. Thus, our financial results for the second quarter of 2019, are almost exclusively derived from PoNS sales to the Montreal and Surrey clinics.

Results of Operations

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

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

	Three Months Ended June 30,		
	2019	2018	Change
Revenue:			
Product sales, net	$ 469	$ —	$ 469
Fee revenue	49	—	49
Total operating revenue	**518**	**—**	**518**
Cost of sales:			
Cost of product sales	212	—	212
Gross profit	**306**	**—**	**306**
Operating expenses:			
Research and development	2,275	2,921	(646)
Selling, general and administrative	3,845	8,886	(5,041)
Total operating expenses	**6,120**	**11,807**	**(5,687)**
Operating loss	**(5,814)**	**(11,807)**	**5,993**
Other income (expense):			
Other income	13	1	12
Change in fair value of derivative financial instruments	5,548	(6,249)	11,797
Foreign exchange gains	67	229	(162)
Total other income (expense)	**5,628**	**(6,019)**	**6,266**
Net loss	**$ (186)**	**$ (17,826)**	**$ 17,640**

Revenue

Revenue for the three months ended June 30, 2019 was $0.5 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 engaged in providing the PoNS Treatment. We generated no revenue for the three months ended June 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 June 30, 2019, we incurred $0.2 million in our cost of sales. We had no cost of sales for the three months ended June 30, 2018.

Research and Development Expense

Research and development, or R&D, expenses were $2.3 million for the three months ended June 30, 2019 compared to $2.9 million for the three months ended June 30, 2018, a decrease of $0.6 million. The decrease was primarily driven by a $1.3 million reduction in product development costs due to the completion of the PoNS device and a $0.2 million decrease in stock-based compensation expense. These were partially offset by a $0.8 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 $0.1 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 $3.8 million for the three months ended June 30, 2019 compared to $8.9 million for the three months ended June 30, 2018, a decrease of approximately $5.0 million. The decrease was primarily due to a $5.2 million reduction in stock-based compensation expense. 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. This was partially offset by $0.1 million in higher employee benefits due to 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 $5.5 million for the three months ended June 30, 2019 compared to a loss of $6.2 million for the three months ended June 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 Gains

Foreign exchange gains were approximately $0.1 million for the three months ended June 30, 2019 compared to a gain of $0.2 million for the three months ended June 30, 2018. This was primarily due to the timing and volume of transactions in Canadian dollars.

Six Months Ended June 30, 2019 compared to the Six Months Ended June 30, 2018

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

	Six Months Ended June 30,		
	2019	2018	Change
Revenue:			
Product sales, net	$ 1,146	$ —	$ 1,146
Fee revenue	49	—	49
Total operating revenue	1,195	—	1,195
Cost of sales:			
Cost of product sales	448	—	448
Gross profit	**747**	**—**	**747**
Operating expenses:			
Research and development	4,956	5,472	(516)
Selling, general and administrative	8,426	11,051	(2,625)
Total operating expenses	13,382	16,523	(3,141)
Operating loss	(12,635)	(16,523)	3,888
Other income (expense):			
Other income	24	59	(35)
Change in fair value of derivative financial instruments	13,837	(3,724)	17,561
Foreign exchange (loss) gains	(88)	1,197	(1,285)
Total other income (expense)	13,773	(2,468)	13,847
Net income (loss)	**$ 1,138**	**$ (18,991)**	**$ 20,129**

Revenue

Revenue for the six months ended June 30, 2019 was $1.1 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 six months ended June 30, 2018.

Cost of Sales

For the six months ended June 30, 2019, we incurred $0.4 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 six months ended June 30, 2018.

Research and Development Expense

R&D expenses were $5.0 million for the six months ended June 30, 2019 compared to $5.5 million for the six months ended June 30, 2018, a decrease of $0.5 million. The decrease was primarily attributable to a $2.2 million reduction in product development costs related to our PoNS device, which was partially offset by a $1.0 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 and other employee expenses also increased by $0.7 million due to increased regulatory and quality management headcount to support our Canadian launch.

Selling, General and Administrative Expense

SG&A expenses were $8.4 million for the six months ended June 30, 2019 compared to $11.1 million for the six months ended June 30, 2018. The decrease was primarily due to lower stock-based compensation expense of $4.8 million in 2018, 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. This was partially offset by higher commercial operations expenses of $2.2 million, including wages and salaries of $0.6 million to support our Canadian launch.

Change in Fair Value of Derivative Financial Instruments

The change in fair value of derivative financial instruments was a gain of $13.8 million for the six months ended June 30, 2019 compared to a loss of $3.7 million for the six months ended June 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 Gains (Loss)

Foreign exchange loss was $0.1 million for the six months ended June 30, 2019 compared to a gain of $1.2 million for the six months ended June 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 six months ended June 30, 2019 and 2018 (amounts in thousands):

	Six Months Ended June 30,		
	2019	2018	Change
Net cash used in operating activities	$ (11,214)	$ (11,128)	$ (86)
Net cash used in investing activities	(204)	(199)	(5)
Net cash provided by financing activities	163	21,712	(21,549)
Effect of exchange rate changes on cash	(17)	40	(57)
Net (decrease) increase in cash	$ (11,272)	$ 10,425	$ (21,697)

Net Cash Used in Operating Activities

Net cash used in operating activities during the six months ended June 30, 2019 was $11.2 million. This was comprised of a loss from operations of $12.6 million and $0.5 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 $1.8 million and unrealized foreign exchange losses of $0.2 million.

Net cash used in operating activities during the six months ended June 30, 2018 was $11.1 million. This was comprised of a net loss of $19.0 million and net cash used in changes in operating assets and liabilities of $1.3 million, adjusted for non-cash items including the change in fair value of derivative financial instruments of $3.7 million, and stock-based compensation expense of $6.7 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 six months ended June 30, 2019 was $0.2 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 six months ended June 30, 2018 was $0.2 million, which was primarily related to the purchase of furniture and fixtures for our office.

Net Cash Provided by Financing Activities

Net cash provided by financing activities during the six months ended June 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 six months ended June 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 and $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 June 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 June 30, 2019 and December 31, 2018 (amounts in thousands):

	June 30, 2019	December 31, 2018
Cash	$ 14,311	$ 25,583
Working capital	$ 11,950	$ 22,757

We currently have limited working capital and liquid assets. Our cash as of June 30, 2019 was approximately $14.3 million. While we have started generating revenue from the commercial sale of our PoNS device in Canada, we expect to incur significant losses until such time as our revenue exceeds our expenses and during this time, we will require additional funding to fund our ongoing activities. We believe that our existing capital resources will be sufficient to fund our operations through the end of the fourth quarter of 2019. 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 provides 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 continue to govern the arrangement through a joint steering committee, and we and HTC each fund 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 share in the net profits and losses of Heuro on a 50/50 basis. For the three and six months ended June 30, 2019, we recorded $0.2 million and $0.4 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 income (loss). We believe that the maximum exposure to loss as a result of our involvement with Heuro was CAD$0.4 million as of June 30, 2019, which represents our potential remaining obligation to fund Heuro’s operating budget of up to CAD$1.0 million. Our relationship with HTC and Heuro is currently evolving as we work to advance the clinic expansion plan.

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

In August 2018, the Financial Accounting Standards Board, or 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. We are evaluating the effect that ASU 2018-13 will have on our 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. We are in the process of evaluating the impact the standard will have on our condensed consolidated financial statements.

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, we have concluded that our disclosure controls and procedures were effective as of the end of the period covered by this report.

Changes in Internal Control over Financial Reporting

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

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

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

On or about July 9, 2019, a putative shareholder class action lawsuit, *Caramihai 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.

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.

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. 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, 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.

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, 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 surgeons 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, PMA approval, NDA, or BLA of new products or modified products;
- withdrawing 510(k) clearances 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)
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: August 8, 2019

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

Dated: August 8, 2019

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

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) I am 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 my supervision, to ensure that material information relating to the registrant is made known to me 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 my 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 my 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) I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions);

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

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

Date: August 8, 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) I am 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 my supervision, to ensure that material information relating to the registrant is made known to me 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 my 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 my 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) I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions);

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

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

Date: August 8, 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 JUNE 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 June 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: August 8, 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 JUNE 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 June 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: August 8, 2019

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